July 1, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

As the primary sponsors of S. 595, the Treat and Reduce Obesity Act (TROA), we write to urge you to update your regulations for coverage of obesity treatments, including Food & Drug Administration (FDA) approved anti-obesity agents (AOMs). and Intensive Behavioral Therapy (IBT). We are hopeful that CMS will recognize the tremendous impact that COVID-19 is having on the health outcomes of so many Americans affected by obesity and that the agency moves swiftly to update Medicare's coverage policies to support comprehensive treatment of obesity to better protect seniors from this deadly pandemic.

As our country continues to deal with the response and impact of COVID-19, we have learned that obesity is the second greatest risk factor, after older age, for hospitalization among COVID-19 patients. A report from the CDC reveals that 78 percent of COVID-19 patients requiring admission to an intensive-care unit (ICU) had at least one underlying health condition, many of which were obesity-related diseases.[1] Data from New York City indicate that people with both COVID-19 and obesity are two times more likely to be admitted to the hospital, and people with severe obesity are 3.6 times more likely to require critical care, such as mechanical ventilation.[2]

In addition, COVID-19 is having a disproportionate effect on racial and ethnic minorities, as well as lower to middle income families that have inadequate access to healthy foods and sufficient housing. While data are still being collected and analyzed, the CDC reports that 33 percent of hospitalized patients were black, suggesting this population may be disproportionately affected. This population also has the highest prevalence of obesity, at 39.1 percent. To combat COVID-19, it will be important to understand and address these disparities within our population.

Obesity is a serious chronic disease caused by multiple biological, genetic, and behavioral factors. We introduced TROA to address the growing burden of obesity on seniors by improving access to IBT and by clarifying Medicare Part D coverage of FDA-approved treatments. Clarification was necessary because current CMS guidance does not permit coverage for drugs that treat obesity under Part D -- on the grounds that such drugs are excluded under the Medicare statute as agents "used for anorexia, weight loss, or weight gain."[3]

In the time since CMS issued these regulations, we have improved our clinical and scientific understanding of the biological factors that contribute to obesity. We now know that effective treatment of obesity must address the biological processes that cause the disease as well as the behavioral contributors. More than 185 Republicans and Democrats are currently on record supporting the Treat and Reduce Obesity Act. This broad bipartisan support for this legislation is a strong signal that Congress did not intend for CMS to exclude obesity treatment from Part D coverage.

CMS has used its administrative authority in the past to allow coverage of treatments that impact patient weight when they are used for a medically accepted indication to address an underlying chronic disease. CMS did so when the agency allowed Medicare Part D coverage of Serostim®, which is indicated for the treatment of HIV patients with wasting or cachexia "to increase lean body mass and body weight and improve physical endurance." In fact, CMS notes that "[p]rescription drug products being used to treat AIDS wasting and cachexia ***are not considered agents used for weight gain***."[4]

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[1] Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 — United States, February 12–March 28, 2020. MMWR Morb Mortal Wkly Rep 2020;69:382–386. DOI: http://dx.doi.org/10.15585/mmwr.mm6913e2
[2] Rabin, Roni Caryn. "Obesity Linked to Severe Coronavirus Disease, Especially for Younger Patients." New York Times, 16 April 2020: https://www.nytimes.com/2020/04/16/health/coronavirus-obesity-higher-risk.html.
[3] *See* SSA § 1860D-2(e)(2); SSA§1927(d)(2).
[4] Medicare National Coverage Determinations Manual, ch. 1, pt. 2, § 100.1.

Coverage of FDA-approved obesity medications would be consistent with CMS approach for other chronic disease treatments, and current FDA guidance. FDA's guidance distinguishes drugs used for weight *management* from drugs used for weight *loss*, as weight maintenance includes the "goal of reduced morbidity and mortality through quantifiable improvements in biomarkers such as blood pressure, lipids, and HbA1c."[5] Further, the modern generation of AOMs have profiles that are safe and effective for long-term therapy compared to some of the older generation short-term therapies. Thus, CMS' current policy runs counter to FDA Guidance, as well as Congressional intent that focused on precluding coverage of cosmetic weight loss products.

We are also concerned about the narrow interpretation taken by CMS of the U.S. Preventive Services Task Force (USPSTF) recommendation related to adult obesity in developing its Intensive Behavioral Therapy for Obesity coverage determination.[6,7] Specifically, we question the decisions by CMS to continue to only cover services provided in a primary care setting and only allow primary care providers to bill for these services despite the fact the USPSTF does not recommend such restrictions on location and provider-type.

In its 2018 Grade B recommendation "Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions," USPSTF recommends that "clinicians offer or refer adults with a body mass index (BMI) of 30 or higher… to intensive, multicomponent behavioral interventions."[8] From 2003 through 2012, USPSTF recommended that primary care providers "offer" these interventions.[9] Since 2012, the USPSTF recommendation has explicitly included language to "refer" for these services in addition to "offering" them; the subsequent 2018 update maintains this language.[10] Given the consistent findings of the USPSTF that referrals out of the primary care setting for behavioral interventions for obesity are evidence-based, we urge CMS to revisit its 2011 Intensive Behavioral Therapy for Obesity coverage determination, particularly as it relates to the location and provider-type restrictions.

In summary, we applaud CMS for taking a number of actions during this pandemic to ensure that patients continue to have access to care. We believe updating Medicare's coverage policies surrounding the aforementioned obesity treatment avenues is critical to our response to COVID 19 and future public health emergencies. Thank you.

Sincerely,

Bill Cassidy, M.D.
Member of Congress

Thomas R. Carper
Member of Congres

[5] FDA, *Draft Guidance for Industry: Developing Products for Weight Management*, February 2007, at 1.
[6] Centers for Medicare and Medicaid Services. November 29, 2011. National Coverage Determination (NCD) for Intensive Behavioral Therapy for Obesity (210.12). Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353
[7] Centers for Medicare and Medicaid Services. November 29, 2011. Decision Memo for Intensive Behavioral Therapy for Obesity (CAG-00423N). Available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=253&NCDId=353&ncdver=1
[8] US Preventive Services Task Force. September 2018. *Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions*. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/obesity-in-adults-interventions1
[9] US Preventive Services Task Force. January 2003. *Obesity in Adults: Screening and Counseling, 2003*. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/obesity-in-adults-screening-and-counseling-2003
[10] US Preventive Services Task Force. June 2012. *Obesity in Adults: Screening and Management*. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/obesity-in-adults-screening-and-management-2012