Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1734–P,
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

October 5, 2020

RE: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Secretary Azar and Administrator Verma:

The Obesity Care Advocacy Network (OCAN) appreciates the actions CMS took to respond to the COVID-19 public health emergency and to ensure access to care for seniors, particularly those living with chronic disease. OCAN is a diverse group of organizations that have come together with the purpose of changing how we perceive and approach the obesity epidemic in this nation. As part of this effort, we strive to prevent disease progression, improve access to evidence-based treatments for obesity, improve standards of quality care in obesity management, eliminate weight bias, and foster innovation in future obesity treatments.

Our comments below reflect our support for additional flexibilities established to ensure access to the Medicare Diabetes Prevention Program (MDPP). Programs like the MDPP demonstrate success in reducing obesity and the risk of obesity-related diseases in individuals with prediabetes. However, MDPP is only part of the solution because it is only available to those patients who have pre-diabetes. Leading clinical guidelines recommend that patients with obesity have access to the full spectrum of treatment options, including intensive behavioral therapy, bariatric surgery, and pharmacotherapy.

Thus, we urge CMS to expand access to MDPP to patients with obesity through an 1135 waiver or an CMMI pilot. These policy changes would put CMS in alignment with the overall Health and Human Services national objectives to address the nation's most critical public health issues including overweight and obesity. It also provides beneficiaries access to critical treatments to both mitigate the risks associated with the COVID-19 pandemic and reduce the risk of developing obesity-related comorbidities.

From 2017 to 2018, the age-adjusted prevalence of obesity in adults was 42.4%, with no significant differences between men and women among all adults or by age group.[1] About 2 in 5 adults and 1 in 5 children and adolescents in the United States have obesity,[2] and many others have overweight. According to the Centers for Disease Control and Prevention (CDC), obesity is epidemic in the United States today and a major cause of death, attributable to heart disease, cancer and diabetes.[3]

Because obesity and overweight contribute to a broad range of chronic diseases, the increase in their prevalence across the nation has major implications for the health and well-being of the population. In 2016, chronic diseases driven by obesity and overweight accounted for $480.7 billion in direct health care costs in the U.S., with an additional $1.24 trillion in indirect costs due to lost economic productivity. The total cost of chronic diseases due to obesity and overweight was $1.72 trillion—equivalent to 9.3%of the U.S. gross domestic product. Obesity and its associated complications are by far the greatest contributor to the burden of chronic diseases in the U.S., accounting for 47.1% of the total cost of chronic diseases nationwide.[4]

Addressing obesity as a chronic disease requires a concerted effort by communities, policymakers, patients, and the health care system. OCAN is committed to working with CMS to address this epidemic, and it is now more urgent than ever that seniors have access to recommended treatments for obesity. After old age, obesity and obesity-related chronic diseases are leading risk factors for complications from COVID-19. **With evidence mounting that obesity makes patients more susceptible to COVID-19[5] and increases the severity of the infection,[6] it is now more critical that seniors have access to the full range of guideline-recommended treatment options for obesity. This would include expanding the providers that are eligible to offer intensive behavioral therapy and reversing outdated guidance that prevents coverage of FDA-approved pharmacotherapy in Part D.**

OCAN is pleased to provide comments on the CY 2021 Medicare Physician Fee Schedule Proposed Rule. Below, we offer comments on the MDPP expanded model emergency policy and flexibilities that should be continued after the current public health emergency (PHE) and expansion of the providers that are eligible to offer intensive behavioral therapy.

Outdated National Coverage Determinations

Intensive Behavioral Therapy

We understand that CMS is seeking comment on outdated National Coverage Determinations (NCDs) as part of this proposed rule. As such, CMS covers intensive behavioral therapy (IBT), under an NCD, for obesity, defined as a body mass index (BMI) ≥ 30 kg/m2, for the prevention or early detection of illness or disability. However, CMS only covers IBT for obesity if provided by a primary care practitioner.

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[1] Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity and severe obesity among adults: United States, 2017–2018. NCHS Data Brief, no. 360. Hyattsville, MD: National Center for Health Statistics; 2020.
[2] Hales, C.M., Carroll, M.D., Fryar, C.D., & Ogden, C.L. (2017) Prevalence of Obesity Among Adults and Youth: United States, 2015-2016. National Center for Health Statistics Data Brief [PDF file]. Retrieved from https://www.cdc.gov/nchs/data/databriefs/db288.pdf
[3] The Obesity Epidemic – transcript. Centers for Disease Control and Prevention website. https://www.cdc.gov/cdctv/diseaseandconditions/lifestyle/obesity-epidemic-transcript.html. Updated December 4, 2017.
[4] Waters H, Graf M. America's Obesity Crisis: The Health and Economic Costs of Excess Weight. The Milken Institute; October 2018. https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB.pdf. Accessed September 5, 2020.
[5] Hernández-Garduño E. Obesity Is the Comorbidity More Strongly Associated for COVID-19 in Mexico. A Case-Control Study. Obesity Research and Clinical Practice. 2020. & Tamara A, Tahapary DL. Obesity as a Predictor for a Poor Prognosis of COVID-19: A Systematic Review. Diabetes and Metabolic Syndrome: Clinical Research and Reviews. 2020;14(4):655-659.
[6] Lighter, J, Phillips, M, Hochman, S, Sterling, Johnson, D, Francois, F, et al. Obesity in patients younger than 60 years is a risk factor for Covid-19 hospital admission. Clin Infect Dis [Internet]. 2020 Apr 9 [cited 2020 Apr 23]. DOI: https://doi.org/10.1093/cid/ciaa415

The CDC reported that "obesity rates in the U.S. have increased dramatically over the last 30 years, and obesity is now epidemic in the United States." In the Medicare population, more than 30% of men and women have obesity. Obesity is directly or indirectly associated with many chronic diseases including cardiovascular disease, musculoskeletal conditions and diabetes. **Thus, to ensure that all Medicare beneficiaries who require IBT are able to access this important service we urge CMS to revise the current NCD to expand the eligible providers that are able to offer IBT to patients with obesity.**

MDPP Expanded Model Emergency Policy

Inclusion of Virtual Only Suppliers

OCAN is a strong supporter of the MDPP program and its potential to completely transform the trajectory of diabetes and obesity among Medicare beneficiaries. However, we remain disappointed that CMS has yet to include virtual-only suppliers as an option for beneficiaries. The lack of inclusion of virtual does not align with the Center for Disease Control National Diabetes Prevention Program and goes against CMS' own commitment to innovation. The current COVID-19 PHE has highlighted the critical need for innovation in telehealth and other virtual capabilities within the health care system. We believe that the future of health care will continue to move toward more virtual-based care and allowing virtual-only suppliers to provide services to Medicare beneficiaries within the MDPP is a step in that direction. In addition, on August 3, 2020, President Donald Trump signed an Executive Order on transforming rural health and improving telehealth access. The inclusion of virtual-only suppliers in the MDPP would align with the President's Executive Order and bridge a gap that prevents people in rural areas from accessing the vital services provided by MDPP suppliers.

Including virtual only suppliers of the MDPP would increase access to underserved and high-risk individuals living in rural areas and those living in poverty. These individuals face a number of impediments in accessing care, particularly transportation challenges. CMS beneficiaries from rural or disadvantaged communities with limited resources may not have the ability to go to a location consistently to access in-person services, however, many have mobile devices. President Trump has recognized the unique health challenges facing rural communities when he stated that "Americans living in rural areas have worse health outcomes and higher rates of preventable diseases than the over 57 million Americans living in urban areas." **We urge CMS to allow virtual only suppliers to participate in the MDPP, giving Medicare beneficiaries from all localities and social-economic backgrounds the ability to access services needed to live healthier lifestyles.**

We appreciate the opportunity to comment on this proposed rule. OCAN looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments or need additional information, please contact OCAN Washington Coordinator Chris Gallagher at chris@potomaccurrents.com or via telephone at 571-235-6475. Thank you.

Sincerely,

OCAN Co-Chairs Joe Nadglowski and Jeff Hild