OBESITY CARE ADVOCACY NETWORK

September 6, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: CMS-1770-P: Medicare Program; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements

Dear Administrator Brooks-LaSure:

On behalf of the Obesity Care Advocacy Network (OCAN), we appreciate the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services (CMS) Medicare Physician Fee Schedule (MPFS) proposed rule for calendar year (CY) 2023 (CMS-1770-P).

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. We welcome the opportunity to work with CMS to address the needs of Medicare beneficiaries living with obesity and ask that you consider our comments on the proposed rule.

Valuation of Specific Codes (Section II.E.4)

(29) Caregiver Behavior Management Training (CPT codes 96X70 and 96X71)

OCAN appreciates CMS's interest and recognition of the important role that caregivers play in supporting the health and well-being of Medicare beneficiaries. We also support of the AMA/Specialty Society RVS Update Committee's (RUC) work in developing the Caregiver Behavior Management Training CPT codes 96X70 and 96X71 as the rationale behind these codes is to support the necessary services that many beneficiaries require to improve clinical outcomes related to the primary diagnosis and care plan.

OCAN echoes comments submitted by the American Psychological Association (APA) that this code family primarily benefits the patients as they are necessary to report the behavioral management/modification training provided to multiple-family groups of parent(s)/caregiver(s) (without the patient present) of a patient with a mental or physical health diagnosis. These codes allow for reporting the physician/QHP work and/or time associated with the parent/caregiver training which are

performed in tandem with the diagnostic and intervention services rendered directly to the "identified patient" that support the patient's optimal level of function.

We are troubled by CMS's interpretation of section 1862(a)(1)(A) of the Social Security Act. While we understand it is not typical for Medicare to reimburse for services furnished exclusively to parent(s)/caregiver(s) rather than to the individual Medicare beneficiary, it cannot be denied that the service provided by the physician or other qualified health professional requires a significant amount of provider work, pre-, intra-, and post-service provider time, and varying levels of service intensity and complexity.

Additionally, OCAN was disappointed that CMS chose not to review or provide comment on the RUC-recommended valuation of these codes. There are codes in CPT that describe services that do not include direct contact with the patient but are still considered integral to the patient's care. Further, when the RUC has provided valuation recommended for such services in the past, CMS has reviewed and provided comment during the rulemaking cycle.

We encourage the agency to acknowledge that there are scenarios where training, instruction or intervention is delivered to a beneficiary by way of caregiver who can adequately interpret and act upon the information in accordance with the clinical treatment plan. In the absence of such a caregiver, there is a risk that adherence to the treatment plan will be low, which will ultimately result in poor clinical outcomes.

The following vignettes provided by our members illustrate where care was delivered to a beneficiary by way of a caregiver:

An evidence-based pediatric weight management program operating in a community-based setting includes a mixture of child/parent joint education and parent-only sessions. The parent-only sessions focus on topics that would be inappropriate or even harmful for the children to be present for such challenges that the parents face with affording healthy foods or safety concerns they have about the playgrounds in their neighborhood.

A dietitian and a speech language pathologist working in a neurology practice offer group education classes for caregivers of people who have suffered a stroke that resulted in chewing/swallowing difficulties. The classes focus on creating meals that comply with the International Dysphagia Diet Standardisation Initiative Framework for modified texture diets/liquids while also meeting the patient's nutritional needs to promote stroke recovery and prevent future strokes.

There are ample scenarios and evidence supporting the efficacy and effectiveness of direct intervention with the caregiver(s) of children, adolescents and adults to improve symptoms, functioning, adherence to treatment, and/or general welfare related to the patient's primary clinical diagnoses. As such, **we urge CMS to consider implementing payment for these important services under the PFS for CY 2023 and accept the initial RUC recommendations of a work RVU of 0.43 for CPT code 96X70 and a work RVU of 0.12 for CPT code 96X71.**

Request for Information

(38) Medicare Potentially Underutilized Services

OCAN commends CMS's actions aimed at looking for ways to increase utilization for the many high-value but vastly under-utilized Medicare benefits that not only promote beneficiary health and wellbeing but are also cost-effective. As one OCAN member has stated in past comments,[1,2] a major barrier to many of these underutilized benefits is access. While lack of access is multi-factorial, benefit design is a common factor that appears to affect access. Antiquated benefit design (e.g., benefit design the relies on outdated recommendations or overly strict supervision requirements) that restricts qualified health care providers from delivering services and limits coverage to specific, finite settings interferes with a beneficiary's ability to access high-value services. In addition, team-based care is essential for delivering timely and effective person-centered health care and as such, it requires the expertise of a wide range of qualified physician and non-physician practitioners who are critical to achieve successful patient outcomes and control the progression of chronic disease. Practitioners, however, do not necessarily need to be located within the same physician office/suite to provide services as part of the patient-centered health care team**.**

The past two and a half years of the public health emergency have demonstrated that safe and effective care can be achieved by health care teams who are located outside of the same physician office setting, but also has allowed improved beneficiary access to much needed services, in particular for those beneficiaries whose access was limited because of challenges related to transportation, long commutes to physician offices, inflexible work schedules, and/or provider shortages. **OCAN remains concerned that coverage for services to prevent, manage, and/or treat chronic conditions such as diabetes, prediabetes, and obesity currently exists as a patchwork within CMS with persistent gaps and limitations related to the receipt of same-day service, referrals, coverage levels, payment, and sites of service.**

OCAN offers comment on the following services:

Intensive Behavioral Therapy for Obesity (IBT for Obesity)

The goal of the Medicare IBT for Obesity benefit is to treat beneficiaries with obesity and reduce the rates of its comorbidities among older adults. As CMS has indicated, this benefit is not being utilized to its full potential, thus falling short of the goal.[3] Obesity is the biggest driver of preventable health conditions and increased healthcare costs. As of 2019, only 2.16% of the more than 7.6 million Medicare FFS beneficiaries with obesity received IBT for obesity.[4] Unfortunately, the underutilization of IBT has resulted in health inequity, increased healthcare costs that could have been avoided, and lower quality of life. This barrier, along with the prohibition of new medications to treat obesity and chronic weight management under Medicare Part D, have placed severe limitations on Medicare beneficiary access to

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[1] HHS-OS-2019-0015, Solicitation for Public Comments on Questions from the National Clinical Care Commission. Academy Urges HHS to Reduce Barriers to Nutrition Services. https://www.eatrightpro.org/news-center/on-the-pulse-of-public-policy/regulatory-comments/academy-urges-hhs-to-reduce-barriers-to-nutrition-services. Accessed August 10, 2022.
[2] Academy comments https://www.eatrightpro.org/-/media/eatrightpro-files/news-center/on-the-pulse/regulatorycomments/feedback-to-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.pdf?la=en&hash=1C3F5C335061EC8AF9E209D766B760BE81908B4E. Accessed August 10, 2022
[3] Medicare Provider Utilization and Payment Data: Physician and Other Supplier PUF CY2017. Data.cms.gov. https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/fs4p-t5eq. Accessed July 30, 2020.
[4] Medicare Provider Utilization and Payment Data: Physician and Other Supplier PUF CY2019. Data.cms.gov. https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-geography-and-service/data. Accessed April 9, 2022.

obesity treatment and care. According to the CDC, more than two out of every three adults in the U.S. have obesity or overweight and are poised to develop a wide range of weight-related chronic diseases that disables our population and fuels our nation's health costs.[5,6] People with obesity have health costs that are 42% higher than those with healthy weight.[7]

OCAN believes that both the provider and location restrictions are barriers that prevent eligible beneficiaries from accessing the IBT for Obesity benefit. Under current rules, IBT for Obesity can only be covered if Medicare beneficiaries receive the service from—or under the supervision of—their physician or other primary care provider (PCP) in a primary care setting (such as a physician's office).[8] Other physician specialties, registered dietitians (RDs), clinical psychologists, and community-based lifestyle programs are limited in their ability to provide this service. For example, the service may be provided by RDs or other non-PCP professionals and billed incident-to the PCP, but only if the service is provided in the primary care setting and the PCP is on-site to provide supervision, if needed. In practice, requires that an RD or other professional either co-locate in a primary care provider's office or work out of that office certain times of the week to see these patients. Additionally, this limitation fully excludes community-based programs from the benefit that are inherently delivered outside of the primary care setting.

Research has shown that PCPs report a variety of barriers when it comes to providing weight and related nutrition counselling including inadequate time, training, and office space.[9] Primary care providers' offices simply do not have the additional functional space for an entirely new practitioner to set up a separate room for individual or group nutrition and behavioral counseling. A recent study published in Family Practice reported that 64% of family medicine departments within large academic health care systems in the southeastern United States did not have an RD on site.[10] Moreover, because private practice RDs already have existing practices—of which Medicare beneficiaries may comprise merely a part—traveling back and forth from their own office to that of a primary care provider imposes incredible burdens and unnecessary expense. It also requires that the PCP office and the RD enter into a financial employer-employee relationship that may not be desired by either party. **Limiting the IBT for Obesity benefit to the primary care setting is a barrier that prevents PCPs from referring their patients to other providers who specialize in obesity treatment, because their services will not be covered.** Physician specialties, such as endocrinologists, RDs, nutrition professionals, and community-based lifestyle programs all have a role to play in obesity care and treatment. This limitation also fails to reflect how modern primary care functions—by fostering an environment of collaboration and coordination without co-location that eases the burden of providing care and improves access to care for patients.

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[5]] Centers for Disease Control and Prevention. FastStats: Obesity and This makes obesity and overweight the nation's major unaddressed medical condition driving health care costs and disability. Overweight. https://www.cdc.gov/nchs/fastats/obesity-overweight.htm May 3, 2017. Accessed November 20, 2017.

[6] Centers for Disease Control and Prevention. Adult Obesity Causes & Consequences. https://www.cdc.gov/obesity/adult/causes.html August 29, 2017. Accessed November 20, 2017

[7] Finkelstein EA, et.al. "Annual Medical Spending Attributable to Obesity: Payer-and Service-Specific Estimates." *Health Affairs*, 28(5): w822-831, 2009.

[8] Obesity Screening Coverage. Medicare.gov. https://www.medicare.gov/coverage/obesity-behavioral-therapy. Published 2020. Accessed July 23, 2020.

[9] Jacobs M, Harris J, Craven K, Sastre L. Sharing the 'weight' of obesity management in primary care: integration of registered dietitian nutritionists to provide intensive behavioural therapy for obesity for Medicare patients. *Fam Pract*. 2020. doi:10.1093/fampra/cmaa006

[10] Sastre LR and Van Horn LT. Family medicine physicians report strong support, barriers and preferences for Registered Dietitian Nutritionist care in the primary care setting. *Fam Pract* 2020 1-7 doi:10.1093/fampra/cmaa099.

OCAN's recommendation also aligns with the United States Preventive Services Taskforce (USPSTF) recommendation that IBT can produce effective, demonstrable results for patients with obesity, and that these services are more effective after referral to qualified healthcare professionals with proper training in obesity management.

Unfortunately, specialty physicians are limited in their ability to provide IBT. For example, endocrinologists provide care to patients with endocrine diseases and disorders including obesity. Endocrinologists provide significant contributions to the advancement of obesity prevention and treatment and have authored clinical practice guidelines on obesity care.[11] Despite their expertise in providing this care, endocrinologists are faced with the same limitations as other providers who are not providing this care in a primary care setting.

Community-based programs also have limitations in being able to provide IBT. In fact, the clinical evidence, and the evidence that supports the USPSTF recommendation, identifies digital and community programs delivered by those trained in behavior change science (health coaches, and others) as effective[12],[13],[14] and as primary care relevant ways to deliver the recommended service. Further NIH funded research demonstrated that health coach delivered community programs are more effective than primary care or health professional delivery of IBT[15]. The use of community-based programs and providers to deliver this service will provide primary care providers with the full network of evidence-based effective IBT to which they can refer and collaborate. Without such a network, physicians are left without tools and resources essential to achieving health.

Both beneficiary need and demand are high for obesity management services; to compound matters further, the US is still grappling with a PCP shortage. A 2020 study from the Association of American Medical Colleges predicted shortage of 21,400 to 55,200 primary care physicians by 2033.[16] The concept of RDs and other professionals providing IBT for obesity services to Medicare beneficiaries is not new

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[11] Obesity Management and Therapies, Clinical Practice Guidelines, Endocrine Society. Retrieved from: https://www.endocrine.org/clinical-practice-guidelines/obesity

[12] USPSTF, "Final Recommendation Statement: Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions" September 18, 2018. Accessed at. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/obesity-in-adults-interventions. "Few interventions included a primary care clinician as the primary interventionist over 3 to 12 months of individual counseling. In the trials not involving a primary care clinician, the interventionists were highly diverse and included behavioral therapists, psychologists, registered dietitians, exercise physiologists, lifestyle coaches, and other staff." [Clinical Considerations section]

[13] USPSTF, "Final Recommendation Statement: Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions" September 18, 2018. Accessed at. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/obesity-in-adults-interventions. "Few interventions included a primary care clinician as the primary interventionist over 3 to 12 months of individual counseling. In the trials not involving a primary care clinician, the interventionists were highly diverse and included behavioral therapists, psychologists, registered dietitians, exercise physiologists, lifestyle coaches, and other staff." [Clinical Considerations section]

[14] Gudzune KA, Doshi RS, Mehta AK, Chaudhry ZW, Jacobs DK, Vakil RM, Lee CJ, Bleich SN, Clark JM. Efficacy of commercial weight-loss programs: an updated systematic review. Ann Intern Med. 2015 Apr 7;162(7):501-12. doi: 10.7326/M14-2238. Erratum in: Ann Intern Med. 2015 May 19;162(10):739-40. PMID: 25844997; PMCID: PMC4446719. Accessible at: https://pubmed.ncbi.nlm.nih.gov/25844997/

[15] Pinto AM, Fava JL, Hoffman DA, Wing RR. Combining behavioral weight loss treatment and a commercial program: a randomized clinical trial. Obesity (Silver Spring). 2013;21):673-680.

[16] IHS Markit. *The Complexities of Physician Supply and Demand: Projections From 2018 to 2033*. 2020. Washington, D.C.: Association of American Medical Colleges. Available at: https://www.aamc.org/system/files/2020-06/stratcomm-aamc-physician-workforce-projections-june-2020.pdf

and is currently happening through often cumbersome incident-to billing arrangements. There is consensus among surveyed physicians that RDs are qualified providers of IBT for obesity, and psychologists are also highly qualified providers.[17] Research conducted by the Academy of Nutrition and Dietetics in 2018 found that RDs who reported billing services "incident to" a physician were overwhelmingly billing for individual (75%) and group (19%) IBT for obesity incident to PCPs.[18] This same research reported that adult overweight/obesity was the second most common diagnosis for which RDs received reimbursement from third party payers, including payers outside of Medicare.[19]

Mandating that services can only be provided "incident to" under direct supervision presents a major barrier and is impracticable. This requirement creates an unnecessary administrative burden on the PCP and office staff because it requires meeting the supervision requirements for health care professionals who are regularly considered independent providers of such services by scope of practice and state licensure laws, and are considered by Medicare to be independent providers of similar services to beneficiaries with diabetes and renal disease.[20] It also often requires initiation and management of contractual agreements between PCPs and provider types that do not commonly work for PCP practices.

In summary, OCAN believes that CMS should allow other providers, including registered dietitians, psychologists, other physician specialties and community-based lifestyle programs, to serve as direct providers for the IBT for Obesity benefit and allow them the ability to see these patients outside of the primary care setting upon referral from a physician. The current policy does not align with the clinical science, professional standards for care, or USPSTF recommendations. OCAN believes that expanding the number of direct providers would greatly improve beneficiary access to this highly evidence-based service which ensures access to comprehensive obesity care that is essential to addressing our country's chronic disease crisis.

Thank you again for the opportunity to provide comments on this proposed rule. Should you have any questions or require additional information, please feel free to contact any of us.

Sincerely,

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[17] Bleich S, Bennett W, Gudzune K, Cooper L. National survey of US primary care physicians' perspectives about causes of obesity and solutions to improve care. BMJ Open. 2012;2(6):e001871. doi:10.1136/bmjopen-2012-001871

[18] Jortberg BT, Parrott JS, Schofield M, et al. Trends in Registered Dietitian Nutritionists' Knowledge and Patterns of Coding, Billing, and Payment. *J Acad Nutr Diet.* 2020;120(1):134-145.e133.

[19] Parrott JS, White JV, Schofield M, et. Al. Current coding practices and patterns of code use of registered dietitian nutritionists: The Academy of Nutrition and Dietetics 2013 coding survey. J Acad Nutr Diet. 2014;114:1619-1629.

[20] 42 CFR §410.26(b); 42 CFR §410.32(b)(3)(iii); 42 CFR §410.26(b)(5)