OBESITY CARE
ADVOCACY NETWORK

September 7, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS Request for Information on Severe and Disabling Chronic Conditions and Enrollment in Medicare Advantage Chronic Condition Special Needs Plans (C-SNPs)

Dear Administrator Verma:

The Obesity Care Advocacy Network (OCAN) appreciates the opportunity to provide comments related to the Centers for Medicare & Medicaid Services (CMS) Request for Information (RFI) on Severe and Disabling Chronic Conditions and Enrollment in Medicare Advantage Chronic Condition Special Needs Plans (C-SNPs). OCAN is a diverse group of organizations that have come together with the purpose of changing how we perceive and approach the problem of obesity 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.

Obesity is a Complex and Chronic Disease

We are hopeful that CMS will take this opportunity to recognize obesity as a chronic and complex disease to encourage broader Medicare beneficiary access to the full range of science-based treatment avenues across all possible Medicare programs. Obesity involves numerous pathophysiologic processes, including changes at cellular, hormonal, neurochemical and organ levels. For example, at a cellular level, adipose (fat) cells secrete a range of inflammatory mediators that have wide-ranging biological effects, such as increasing blood vessel reactivity and decreasing insulin sensitivity.[i] Obesity causes or contributes to altered production of numerous hormones, such as stress hormones and estrogenic hormones, which have pathologic effects across bodily systems and cause further adverse health effects, including estrogen-dependent cancers.[ii] Numerous organs are affected by obesity, often bi-directionally, such that obesity causes organ dysfunction and the same organ dysfunction further exacerbates the individual's obesity. For example, obesity is a central cause of non-alcoholic fatty liver disease, and liver disease in turn contributes to insulin resistance, which further drives weight gain and contributes to many obesity-related health conditions such as diabetes and cardiovascular disease.[iii] In the case of severe obesity, all these factors are further magnified.

According to the Centers for Disease Control and Prevention, about 41 percent of adults aged 60 and over had obesity in the period of 2015 through 2016, representing more than 27 million people. Obesity also increases the risk for other chronic diseases and conditions, including high blood pressure, heart disease, certain cancers, nonalcoholic steatohepatitis (NASH), arthritis, mental illness, lipid disorders, sleep apnea and type 2 diabetes. As a result, a Medicare beneficiary with obesity costs on average $2,018 (in 2019 dollars) more than a healthy-weight beneficiary.

Traditionally, obesity was viewed as simply a matter of personal responsibility or willpower. Evolving research in the field, especially throughout the past two decades, has shown that obesity is a chronic, relapsing, multifactorial condition consistent with a disease. This research led the American Medical Association (AMA), with support from well-respected and established medical associations, to pass landmark policy in 2013 that recognized "obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention." The AMA policy is consistent with conclusions throughout the medical community regarding the nature and impact of obesity. The AMA's declaration came on the heels of official statements to the same effect by dozens of other professional organizations, medical and public health entities, and governmental and nongovernmental agencies, including the World Health Organization and the National Institutes of Health (see Appendix).

Despite these facts, Medicare beneficiaries continue to face obstacles to care because of outdated CMS policies surrounding obesity and categorization of chronic disease states. Examples include the current Medicare Part D prohibition on coverage of obesity drugs and the absence of obesity in several CMS documents such as Medicare's Chronic Conditions Chartbook, recently-implemented Medicare payments for non-face to face chronic care management services and the current list of 15 SNP-specific chronic conditions that is the basis for this RFI.

Failure to include obesity as one of the chronic conditions enumerated in the Chartbook -- which highlights the prevalence of chronic conditions among Medicare beneficiaries and the impact of chronic conditions on Medicare service utilization and spending – was especially glaring given that 13 of the15 conditions listed (high blood pressure, high cholesterol, ischemic heart disease, arthritis, diabetes, heart failure, chronic kidney disease, depression, COPD, atrial fibrillation, certain cancers, asthma, and stroke) are commonly associated with obesity and/or are exacerbated by obesity.

Obesity clearly meets the criteria CMS outlines in the final regulations as the rational for selecting the 15 conditions eligible for Medicare payment policies surrounding chronic care management. Specifically, (1) obesity is highly prevalent among the Medicare population; (2) obesity is chronic; i.e., typically lasts for more than 12 months; (3) obesity poses increased risk for death, acute exacerbation/decompensation, or functional decline; (4) obesity results in increased use of health care services; and (5) successful care management of obesity can improve outcomes/reduce costs.

In the case of Medicare Advantage Chronic Condition Special Needs Plans, OCAN would encourage CMS to add severe obesity to the current list of SNP-specific chronic conditions. As is the case for those conditions in the Chartbook, obesity has been linked to virtually all of the conditions put forth by the SNP Chronic Condition Panel in the fall of 2008.

1. Chronic alcohol and other drug dependence;
2. Autoimmune disorders, limited to: Polyarteritis nodosa, Polymyalgia rheumatica, Polymyositis, Rheumatoid arthritis, and Systemic lupus erythematosus;
3. Cancer, excluding pre-cancer conditions or in-situ status;
4. Cardiovascular disorders, limited to: Cardiac arrhythmias, Coronary artery disease, Peripheral vascular disease, and Chronic venous thromboembolic disorder;
5. Chronic heart failure;
6. Dementia;
7. Diabetes mellitus;
8. End-stage liver disease;
9. End-stage renal disease (ESRD) requiring dialysis;
10. Severe hematologic disorders, limited to: Aplastic anemia, Hemophilia, Immune thrombocytopenic purpura, Myelodysplatic syndrome, Sickle-cell disease (excluding sickle-cell trait), and Chronic venous thromboembolic disorder;
11. HIV/AIDS;
12. Chronic lung disorders, limited to: Asthma, Chronic bronchitis, Emphysema, Pulmonary fibrosis, and Pulmonary hypertension;
13. Chronic and disabling mental health conditions, limited to: Bipolar disorders, Major depressive disorders, Paranoid disorder, Schizophrenia, and Schizoaffective disorder;
14. Neurologic disorders, limited to: Amyotrophic lateral sclerosis (ALS), Epilepsy, Extensive paralysis (i.e., hemiplegia, quadriplegia, paraplegia, monoplegia), Huntington's disease, Multiple sclerosis, Parkinson's disease, Polyneuropathy, Spinal stenosis, and Stroke-related neurologic deficit; and
15. Stroke.

In conclusion, we hope that CMS will instruct the SNP Chronic Condition Panel to include obesity in its discussions as the panel reevaluates the current list of chronic conditions for Special Needs Plans. OCAN looks forward to serving as a resource to the panel and agency as this process moves forward.

Should you have any questions or need additional information, please feel free to contact OCAN Coordinator Chris Gallagher via email at chris@potomaccurrents.com or telephone at 571-235-6475. Thank you.

Sincerely,

Jeanne Blankenship
Co-Chair, Obesity Care Advocacy Network

Meredith Dyer
Co-Chair, Obesity Care Advocacy Network

Joe Nadglowski
Co-Chair, Obesity Care Advocacy Network

APPENDIX

Federal and State Policymaker Recognition of Obesity as a Chronic Disease

Federal and state policies reflect the established medical consensus that obesity without any co-existing conditions is a disease. Like medical knowledge and understanding of obesity, policymakers' views have been evolving throughout the past two decades. In 1977, the federal view espoused in the Health Care Financing Administrations' Coverage Issues Manual was that "obesity is not an illness." But by 1998 that view shifted when NIH, as noted above, determined that "obesity is a complex multifactorial chronic disease."

Other agencies began following suit. In 2002, the Internal Revenue Service (IRS) considered whether an individual who was diagnosed with obesity—but no other conditions—could deduct the cost of a weight-loss program. After reviewing the medical consensus on the issue and noting a Food and Drug Administration 2000 statement that "obesity is a disease," the IRS concluded that the individual could deduct the costs as a medical-care expense because he had "a disease, obesity." Later that same year, the Social Security Administration (SSA) published a policy–which remains in effect today–recognizing obesity as "a complex, chronic disease characterized by excessive accumulation of body fat." In this policy, the SSA directs disability evaluators that "we may also find that obesity, by itself, is medically equivalent to a listed impairment."

In 2004, CMS revised its Coverage Issues Manual and removed the 1977 statement that "obesity is not an illness." Two years later, the agency issued a National Coverage Determination providing coverage for bariatric surgery through the Medicare program. This change in approach can only be explained by a reassessment of obesity as a medical condition. Even the Department of Defense has now acknowledged that treatment for obesity is warranted "even if it is the sole or major condition treated."

Similar paradigm shifts have occurred in the Food and Drug Administration's (FDA's) approval process. For 13 years, the FDA approved no new medications or devices designed to treat obesity and in fact rejected two new offerings in 2011, likely due in part to a general misunderstanding of obesity as a lifestyle choice rather than a physiologic condition. After discussions with the obesity community the FDA has approved four new medications and five new devices for obesity since 2012.

Legislators at the federal and state levels are also now recognizing obesity as a chronic, complex disease in its own right. For example, in 2017, the United States Senate passed by unanimous consent a resolution in support of "National Obesity Care Week." The resolution recognized "the disease of obesity" and encouraged "all people in the United States to create a foundation of open communication to break barriers of misunderstanding and stigma regarding obesity and to improve the lives of all individuals affected by obesity and their families

At the state level, the National Lieutenant Governors Association (NLGA) adopted formal policy in 2018 encouraging states to "eliminate the stigma of obesity that impedes treatment" and provide "comprehensive care to manage this chronic disease." In the policy's preamble, the NLGA noted that obesity "is recognized as a chronic disease by many leading medical professional and patient organizations" and that "experts and researchers agree obesity is a complex disease influenced by various psychological, environmental, and genetic factors."

[i] Margaret F. Gregor & Gökhan S. Hotamisligil, Inflammatory Mechanisms in Obesity, 29 Annual Rev. Immunology, 415-445 (2011).
[ii] Celine Gerard & Kristy A Brown, Obesity and Breast Cancer - Role of Estrogens and the Molecular Underpinnings of Aromatase Regulation in Breast Adipose Tissue, 46 Molecular and Cellular Endocrinology, 15-30 (2018).
[iii] Norbert Stefan, Konstantinos Kantartzis & Hans-Ulrich Haring, Causes and Metabolic Consequences of Fatty Liver, 7 Endocrine Rev. 939-960 (2008).