



November 1, 2019

ATTN: United States Pharmacopeia

RE: USP Medicare Model Guidelines Version 8.0

The Obesity Care Advocacy Network (OCAN) appreciates the opportunity to provide public comment regarding the structural content and organization of the United States Pharmacopeia's (USP) Medicare Model Guidelines (MMG) Version 8.0. We remain concerned over the Medicare programs' continuing failure to allow the USP to include categories and classes for anti-obesity agents.

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.

OCAN applauded the USP for establishing a new class for anti-obesity agents when USP released its new Drug Classification (USP-DC) System in 2018 -- an independent drug classification system, which was developed in response to stakeholder input that it would be helpful to have a classification system beyond the MMG to assist with formulary support outside of Medicare Part D. The goal of the USP-DC is to create a comprehensive classification system for use in drug formulary development or review in non-acute or outpatient care settings.

When Congress enacted Medicare Part D, there were no widely accepted FDA-approved obesity drugs on the market. This fact, combined with the outdated misperception by many on Capitol Hill at that time that obesity was a lifestyle condition, led Congress to exclude Medicare Part D from covering "weight loss drugs." Throughout this decade, significant medical advances have been made in the development of obesity drugs. These new medications and our country's current and growing obesity epidemic clearly make the Part D statute no longer reflective of current scientific guidelines or current FDA approvals.

For these reasons, OCAN continues to work with other healthcare professional and patient organizations, such as the American Medical Association, in working with Congress to pass the Treat and Reduce Obesity Act (TROA) to rectify the outdated Medicare regulations governing obesity medications. This legislation enjoys strong bipartisan support in both houses of Congress and will allow the Medicare program to provide coverage of prescription drugs under Part D for chronic weight management to individuals who are affected by obesity, or with overweight with one or more co-morbidities.

Given the tremendous progress that has been made by the FDA in approving new obesity medications, coupled with the growing support in Congress for improving access to these new drugs, we urge the USP to immediately modify the Medicare Model Guidelines to include new categories and classes for obesity medications should TROA pass Congress and be signed into law. By quickly adopting the anti-obesity

classes outlined in the new Drug Classification, USP will ensure that Medicare patients will have access to the expanding range of these new therapies that are becoming more widely available in commercial plans.

Again, OCAN appreciates the work that USP is undertaking regarding the drug classification process and we look forward to working with you in the future to improve patient access to anti-obesity agents. Should you have any questions or need additional information, please feel free to contact OCAN Washington Coordinator Christopher Gallagher at chris@potomaccurrents.com or via telephone at 571-235-6475. Thank you.

Sincerely,

Academy of Nutrition and Dietetics
American Academy of PAs
American Association of Clinical Endocrinologists
American Society for Metabolic and Bariatric Surgery
Black Women's Health Imperative
Endocrine Society
Global Liver Institute
Novo Nordisk, Inc.
Obesity Action Coalition
Obesity Medicine Association
Redstone Global Center for Prevention and Wellness
SECA
The Obesity Society