May 21, 2024

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201 Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 200 Independence Avenue S.W., Ste 314G Washington, D.C. 20201

Re: Provide Comprehensive Care for the Treatment of Obesity

Dear Secretary Becerra and Administrator Brooks-LaSure,

We, the undersigned organizations, who together represent patients, healthcare providers, caregivers, seniors, and underserved communities, write to thank the Biden Administration for its commitment to addressing the obesity epidemic and continuing to take steps to ensure access to comprehensive treatment and care for those impacted by obesity. In particular, we commend the Administration for expanding Medicare beneficiaries' access to nutrition and obesity counseling in the National Strategy on Hunger, Nutrition, and Health and its decision to cover an obesity medication to reduce cardiovascular disease in Medicare. We also appreciate the interest expressed in the CY2023 Medicare Physician Fee Schedule to "understand what existing services within current Medicare benefits may represent high value, potentially underutilized services" and the request for information about "obstacles to accessing these services and how specific potential policy, payment or procedural changes could reduce potential obstacles and facilitate better access to high-value health services."¹

As part of a continuing strategy to provide access to comprehensive obesity care, we urge the Biden Administration to add obesity into the category of complex, chronic disease states under the National Strategy on Hunger, Nutrition, and Health guidelines. We also urge the Biden Administration to provide Medicare Part D prescription drug coverage of obesity medications and expand the type of qualified healthcare and community providers and evidence-based community programs that can deliver intensive behavioral therapy (IBT) under Medicare Part B.

The Centers for Medicare & Medicaid Services (CMS) currently prohibits Medicare Part D coverage of obesity medications, citing an outdated federal statute that excludes "agents when used for anorexia, weight loss, or weight gain" from Part D coverage. In addition, the National Coverage Determination (NCD) for IBT for obesity is overly restrictive to the types of providers and settings of care. These outdated CMS positions stand in contrast to the significant scientific developments that have been made to treat and manage obesity. In fact, many federal agencies and states have joined the American Medical Association (AMA) in recognizing obesity as a complex disease and provide coverage for comprehensive obesity care and treatment.

Diseases associated with obesity, such as heart disease, stroke, type 2 diabetes and certain types of cancer, are the <u>leading causes of preventable death</u> in the U.S. By 2030, experts believe that <u>50%</u> of Americans will be living with obesity. Obesity disproportionately impacts vulnerable communities,

¹ Centers for Medicare and Medicaid Services, Health and Human Services. CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. July 29, 2022. Available at: <u>https://www.federalregister.gov/documents/2022/07/29/2022-14562/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other</u>

including seniors aged 65 and older, non-Hispanic Black adults and Hispanic adults. Nearly <u>30%</u> of Americans aged 65 and older are living with obesity today. Beyond the profound health impacts that obesity has, <u>evidence</u> shows a strong correlation between body mass index and U.S. health care expenditures, as well as the potential economic benefits of reducing the burden of obesity in America.

A strong focus on treating obesity as a preventative measure for other diseases and chronic conditions would improve, overall, the health status of Medicare patients and reduce inpatient stays in skilled nursing facilities, falls and injuries and ER visits – all things Medicare tries to avoid due to cost. Treating and effectively managing obesity in older Americans provides the opportunity to improve the health of Medicare beneficiaries to reduce other related health care costs across the board. A recent <u>publication</u> by the Veterans Health Administration (VA) showed over one year a \$1,893 total cost of medical care reduction for each individual treated with obesity medications and MOVE!, an intensive lifestyle modification program.

In recent years, we witnessed groundbreaking innovations in obesity treatment, demonstrating profound efficacy and safety profiles of new-generation obesity medications. These medications have been approved by the U.S. Food and Drug Administration (FDA) for long-term use for chronic weight management or to reduce excess body weight and maintain weight reduction, showing significant progress in treating obesity as a complex, multifactorial disease. In March 2024, the FDA approved one such medication to treat cardiovascular disease risks – heart attack, stroke and death – for adults with obesity and a history of cardiovascular disease, making it the first obesity medication to obtain such approval. Nearly all FDA-approved obesity medications have been shown to improve glycemia in people with type 2 diabetes and delay progression to type 2 diabetes in at-risk individuals.

Despite scientific developments, CMS maintains a restrictive interpretation of an outdated federal statute, which excludes coverage for treatments aimed at anorexia, weight loss or weight gain (the Statutory Exclusion), thus barring Medicare Part D coverage of obesity medications for the treatment of obesity. The CMS positions are increasingly indefensible, given the broad recognition of obesity as an independent, complex disease state by numerous federal agencies, including the Social Security Administration (SSA), National Institutes of Health (NIH), Food and Drug Administration (FDA), Veterans Affairs (VA), Centers for Disease Control and Prevention (CDC), Office of Personnel Management (OPM) and the Internal Revenue Service (IRS).

In 2023, Manatt Health, in collaboration with the Obesity Action Coalition (OAC) and The Obesity Society (TOS), released a white paper underscoring the legal and health policy rationales for coverage of obesity medications in Medicare Part D. The white paper demonstrates that CMS has administrative authority to adopt an alternative interpretation of the Statutory Exclusion that would not preclude Medicare Part D coverage of obesity medications and align with prevailing clinical guidelines, CMS precedent, and current U.S. Department of Health & Human Services (HHS) priorities. Notably, this approach is consistent with actions taken by the Department of Defense (DOD), the Department of Veterans Affairs (VA), and more than 15 states that provide Medicaid coverage of obesity medications as the American Academy of Pediatrics, American Association of Clinical Endocrinology (AACE), American Diabetes Association, American Gastroenterological Association, and Endocrine Society.

As a coalition, we also request a reconsideration of the 2011 National Coverage Determination (NCD) for Intensive Behavioral Therapy for Obesity (210.12) (the "2011 NCD" or the "2011 NCD for Obesity") to modify the limitations that this service only be delivered by primary care providers (physicians, nurse

practitioners (NPs), physician associates (PAs)) in a primary care setting. We request that CMS allow other qualified healthcare and community providers (i.e., registered dietitians, clinical psychologists, specialty physicians and other NPs and PAs) to independently provide and bill for this service without limitation to the primary care setting. We also request that Medicare Diabetes Prevention Programs be eligible to provide and bill for this service and for billing mechanisms to be put into place for other evidence-based community programs to provide this service incident to other Medicare billable providers.

To align with the science, prevailing federal and state policies, and broader public health priorities, we request the Biden Administration add obesity as a complex, chronic disease state under the National Strategy for Hunger, Nutrition, and Health, provide Medicare Part D prescription drug coverage of obesity medications, and update the Medicare Part B NCD on IBT for obesity. By extending these coverage updates, CMS will not only be acting in accordance with the latest scientific research and federal health initiatives but also will ensure more appropriate, comprehensive and patient-centered treatment of obesity and related comorbidities for Americans suffering from this disease.

Thank you for your attention to this critical matter.

Sincerely,

Obesity Action Coalition (OAC) A. Philip Randolph Institute Academy of Nutrition and Dietetics African American Wellness Project Alliance for Aging Research Alliance for Patient Access Alliance for Women's Health and Prevention American Association of Clinical Endocrinology (AACE) American Diabetes Association (ADA) American Gastroenterological Association American Medical Women's Association (AMWA) American Society for Metabolic and Bariatric Surgery American Society for Nutrition American Society for Preventive Cardiology (ASPC) Association of Asian Pacific Community Health Organizations (AAPCHO) Association of Black Cardiologists Association of Diabetes Care & Education Specialists California Black Health Network California Chronic Care Coalition **Caregiver Action Network** Center for Patient Advocacy Leaders (CPALs) Choose Healthy Life **Chronic Care Policy Alliance Council on Black Health Diabetes Leadership Council Diabetes Patient Advocacy Coalition Fatty Liver Foundation** Gerontological Society of America

Global Healthy Living Foundation Global Liver Institute HealthyWomen International Cancer Advocacy Network (ICAN) Looms For Lupus Lupus and Allied Diseases Association, Inc. Lupus Foundation of America MANA, A National Latina Organization Mended Hearts, Inc. National Asian Pacific Center on Aging (NAPCA) National Association of Hispanic Nurses National Black Nurses Association, Inc National Consumers League National Council on Aging National Grange National Hispanic Health Foundation National Kidney Foundation National Minority Quality Forum Nevada Chronic Care Collaborative Obesity Care Advocacy Network (OCAN) **Obesity Medicine Association** Partnership to Advance Cardiovascular Health (PACH) **Patients Rising** Preventive Cardiovascular Nurses Association RetireSafe **STOP Obesity Alliance** The Obesity Society (TOS) WomenHeart: The National Coalition of Women with Heart Disease YMCA of the USA 60 Plus Association