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Supplemental Background on the Treat and Reduce Obesity Act and other Patient Access to Care Issues

The Obesity Care Advocacy Network (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.

Throughout the last 10 years, OCAN and five of its founding members, which established the Obesity Care Continuum (OCC) in 2011, have made tremendous progress in educating federal and state policymakers about the need to recognize obesity as a complex and chronic disease and that patients deserve access to, and coverage of, the full continuum of evidence-based obesity treatment avenues.

Efforts Supporting Passage of TROA – Especially due to Obesity/COVID-19 Link

The obesity community has worked for a nearly a decade with Congress to pass S. 595/HR 1530, Treat and Reduce Obesity Act (TROA) to enhance Medicare beneficiaries' access to IBT and by allowing Medicare Part D to cover FDA-approved anti-obesity medications (AOMs). The genesis for TROA resulted partly from current regulations, which do not permit coverage for drugs that treat obesity under Part D -- on the grounds that such drugs are excluded under the Medicare statute as agents "used for anorexia, weight loss, or weight gain."[1]

Since the link between COVID-19 and obesity became evident, OCAN and its member groups have conducted significant outreach on both the federal and state levels. On the federal level, House and Senate TROA champions have been instrumental in organizing a group of 44 Members of Congress on a June 22nd letter to congressional leadership – urging them to include the provisions of TROA in any future pandemic relief legislation. OCAN groups echoed this message in its July 21st letter to leadership on this issue.

Senate TROA champions and OCAN have also urged CMS to use its administrative authority to implement TROA in separate letters to the agency on July 1st and July 7th, respectively. OCAN's July 7th letter to CMS resulted in a virtual meeting on August 17th between OCAN and key CMS staff within its Part B and Part D sections. While applauding CMS for many of the extraordinary steps in healthcare policy that the agency has taken to combat the COVID-19 pandemic, OCAN leaders urged CMS to do more — especially surrounding obesity given that it is the second greatest risk factor, after older age, for hospitalization among COVID-19 patients.

Following the August 17th meeting, OCAN shared with CMS our slide presentation as well as a number of resource documents that we had previously delivered to the agency as part of our continuing efforts to secure administrative action surrounding TROA. These included: the 2017 IHS Markit Budgetary Impact

[1] *See* SSA § 1860D-2(e)(2); SSA§1927(d)(2).

Analysis of Medicare Coverage for Anti-Obesity Interventions; the 2019 Avalere Health Study of the Estimated Federal Budget Impact of H.R.1953 – the Treat and Reduce Obesity Act of 2017; and the December, 2019 Obesity Care Advocacy Network memo, entitled "CMS Authority to Provide Coverage for Obesity Drugs Under Part D.

Finally, OCAN is extremely pleased that Congress has now clearly expressed its congressional intent through report language contained in the Consolidated Appropriations Act for 2021 where Congress "encourages CMS to work to ensure beneficiary access to the full continuum of care for obesity, including access to FDA-approved anti-obesity medications under Medicare Part D, if determined as clinically appropriate by the patient's physician, consistent with CMS' s approach to pharmacotherapy agents used for weight gain to treat AIDS wasting and cachexia. The agreement also encourages CMS to reexamine its Medicare Part B national coverage determination for intensive behavioral therapy for obesity considering current United States Preventive Services Task Force recommendations."

2018 United States Pharmacopeia Drug Classification Includes New Class for Anti-Obesity Agents

On February 28, 2018, the United States Pharmacopeia finalized its new Drug Classification (USP-DC) — an independent drug classification system, which is designed to address stakeholder needs emerging from the extended use of the USP Medicare Model Guidelines (USP MMG) beyond the Medicare Part D benefit. The final version of the USP-DC includes a new class for anti-obesity agents as well as recognition of new combination agents (Naltrexone/Bupropion and Phentermine/Topiramate). In discussions with the USP during the development of the drug classification, USP indicated that the Obesity Care Continuum's 2013 comment letter and subsequent 2016 OCAN comments regarding Medicare's Model Guidelines were the catalyst behind creation of the new anti-obesity agent class.

AMA Recognition of Obesity as a Chronic Disease and Support for TROA

OCAN has also secured the support of organized medicine for obesity-specific policies and passage of the Treat and Reduce Obesity Act through its work within the Obesity Caucus of the American Medical Association's (AMA) House of Delegates (HOD).

2013: AMA recognizes obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention.

2014: AMA, consistent with H-440.842, Recognition of Obesity as a Disease, will work with national specialty and state medical societies to advocate for patient access to and physician payment for the full continuum of evidence-based obesity treatment modalities (such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions).

2018: AMA will: (a) work with state and specialty societies to identify states in which physicians are restricted from providing the current standard of care with regards to obesity treatment; and (b) work with interested state medical societies and other stakeholders to remove out-of-date restrictions at the state and federal level prohibiting healthcare providers from providing the current standard of care to patients affected by obesity.

These efforts have resulted in formal AMA support for TROA since 2015.

Federal & State Guidance Supporting Coverage of Obesity Treatment

2014 Office of Personnel Management FEHBP Guidance on FDA-Approved Anti-Obesity Drugs

In March of 2014, the federal Office of Personnel Management (OPM) issued specific guidance to Federal Employee Health Benefit Program carriers regarding obesity treatment services – stating that the

agency will no longer tolerate plans excluding obesity treatment coverage on the basis that obesity is a "lifestyle" condition or that treatment is "cosmetic." In addition, OPM highlighted that "there is no prohibition for carriers to extend coverage to this class of prescription drugs, provided that appropriate safeguards are implemented concurrently to ensure safe and effective use."

Later in 2014, obesity advocates were able to secure the support of nearly 50 House Members on a congressional sign-on letter to then HHS Secretary Sylvia Burwell – urging the Department to follow OPM's lead and issue similar guidance on obesity treatment coverage to state health exchanges. HHS Secretary Burwell did respond to the Johnson/Blumenaur letter in early 2015 – stating that, "I agree that obesity in this country is a critical issue and that it is affecting the well-being of our nation. I also agree that consumers in the Marketplace should have access to a range of evidence-based obesity treatments. HHS has implemented several provisions of the ACA that address coverage of obesity-related treatments in the Marketplace and seeks to provide access to the full continuum of care for obesity to all Americans."

2015 Department of Labor FAQ regarding General Plan Exclusions for Weight Management Services

In 2015, the Department of Labor issued guidance (eliminated from the DOL website under the Trump Administration), which stated that non-grandfathered health plans are prohibited from including general exclusions for weight management services for adult obesity in their plan documents. Despite the clear implementing regulations of the preventive health care services section of the ACA and the 2015 guidance from the Department of Labor, health plans continue to employ discriminatory medical management techniques to limit patient access to obesity screening and counseling services.

2015 NCOIL Policy Statement Supporting Coverage of Obesity Treatment

In 2015, the National Council of Insurance Legislators (NCOIL), the organization that represents legislators who chair Insurance Committees in state legislatures across the country, adopted its first ever disease-specific policy statement – urging Medicaid, state employee and state health exchange plans to update their benefit structures "to improve access to, and coverage of treatments for obesity such as pharmacotherapy and bariatric surgery."

2018 NLGA Policy Regarding the Treatment and Prevention of Obesity

In 2018, the National Lieutenant Governors Association (NLGA) adopted formal policy supporting efforts to reduce obesity stigma; establish statewide obesity councils and taskforces; support additional training for current and future healthcare professionals; and support access to obesity treatment options for state employees and other publicly funded healthcare programs.

2020 NHCSL Policy on Health Disparities and Patient Access to Obesity Care

In 2020, the National Hispanic Caucus of State Legislators (NHCSL) adopted formal policy recognizing that health inequities in communities of color have led to a disproportionate impact of COVID-19 and that states must address the high rates of obesity to improve the health of racial minorities and prepare for the next public health epidemic; and that NHCSL calls on Congress to eliminate the barriers to coverage of FDA-approved anti-obesity medications in the Medicare Part-D program; and that the NHCSL encourages legislators to take steps to address obesity in their own states to encourage healthier lifestyles, raise awareness and ensure their constituents, including those using Medicaid, have access to the full continuum of treatment options for obesity, including FDA-approved anti-obesity medications.

2020 NBCSL Policy on Health Disparities and Patient Access to Obesity Care

In 2020, the National Black Caucus of State Legislators (NBCSL) adopted formal policy that: recognizes that health inequities in communities of color have led to a disproportionate impact of COVID-19 and that

states must address the high rates of obesity to improve the health of communities of color and prepare for the next public health epidemic; calls on Congress to eliminate the barriers to coverage of proven FDA approved anti-obesity medications in the Medicare Part D program; encourages legislators of NBCSL will work within their states to ensure that the full continuum of treatment options, that have been approved by FDA, are available through Medicaid programs and state employee health plans; further urges additional resources from federal, state, and local governments to support community programs that provide long-term support for lifestyle changes that can reduce obesity and help people maintain their weight loss; and that a copy of this resolution be transmitted to the President of the United States, the Vice President of the United States, members of the United States House of Representatives and the United States Senate, and other federal and state government officials and agencies as appropriate.

OCAN Priorities for Administrative Action by the Incoming Biden Administration:

1. HHS should use its discretion to implement the policy provisions of the Treat and Reduce Obesity Act by immediately removing the Medicare Part D prohibition on FDA-approved obesity drugs.
2. HHS should issue guidance recognizing obesity as a chronic disease to preclude state health exchange plans from excluding coverage for obesity treatment services such as IBT, pharmacotherapy and bariatric surgery. At a minimum, HHS should issue guidance that parallels OPM's policy for FEHBP carriers to prohibit state health exchange plans from excluding obesity treatment coverage on the basis that obesity is a "lifestyle" condition or that treatment is "cosmetic."
3. Reinstate the Department of Labor FAQ regarding general health plan exclusions for weight management services.

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