## Explanation of Changes Reflected in the Chairman's Amendment in the Nature of a Substitute to H.R. 4818, *Treat and Reduce Obesity Act*

June 27, 2024

The Chairman's amendment in the nature of a substitute includes the following changes to H.R. 4818 as introduced:

1. Pg. 1, Line 3: Strike all after the enacting clause and insert the following:

SECTION 1. Short title.

This Act may be cited as the "Treat and Reduce Obesity Act of 2024".

- SEC. 2. INCLUDING WEIGHT LOSS AGENTS AS COVERED PART D DRUGS UNDER THE MEDICARE PROGRAM IN CERTAIN CIRCUMSTANCES.
- (a) In general.—
- (1) REMOVAL OF EXCLUSION.—Section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)) is amended—
  - (A) in paragraph (2)(A), in the first sentence—
  - (i) by striking "and other than" and inserting "other than"; and
  - (ii) by inserting "and, with respect to plan years beginning on or after January 1, 2027, other than subparagraph (A) of such section if the drug is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of Public Health Service Act for long-term weight reduction in individuals with obesity (as defined in section 1861(yy)(2)(C)) and is used for the treatment of obesity for a specified individual," after "benzodiazepines),"; and
  - (B) by adding at the end the following new paragraph:
- "(5) SPECIFIED INDIVIDUAL DEFINED.—For purposes of paragraph (2)(A), the term 'specified individual' means an individual enrolled under a prescription drug plan for a plan year who, during the 1-year period ending on the first day of such plan year (or, in the case such individual enrolled in such plan after the first day of such plan year, the 1-year period ending on the first day that such individual was enrolled under such plan), was continuously receiving an agent for weight loss (as described in section 1927(d)(2)(A)) for the treatment of obesity (as defined in section 1861(yy)(2)(C)) for which benefits were

provided to such individual under a Federal health care program (as defined in section 1128B), the program established under chapter 89 of title 5, United States Code, or under a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act)."

- (2) ENSURING ELIGIBILITY.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended by adding at the end the following new subsection:
- "(p) Ensuring eligibility with respect to access to weight loss agents.—
- "(1) IN GENERAL.—A PDP sponsor of a prescription drug plan may not make payment for a drug for which coverage is available under such plan only to specified individuals (as defined in section 1860D–2(e)) that is dispensed to an enrollee of such plan unless such sponsor has determined that such individual is a specified individual.
  - "(2) TIMING.—In the case of an individual enrolled under a prescription drug plan who requests coverage under such plan of a drug described in paragraph (1), the PDP sponsor of such plan shall, not later than 72 hours after receiving from such individual documentation purporting to demonstrate that such individual is a specified individual, determine whether such individual is in fact a specified individual.
- "(3) REGULATIONS.—Not later than 1 year after the date of the enactment of this subsection, the Secretary shall through notice-and-comment rulemaking establish requirements relating to a PDP sponsor's determination of whether an individual is a specified individual. Such requirements shall—
  - "(A) specify the documentation that such sponsor must receive in order to make such a determination; and
  - "(B) provide that such sponsor may not determine an individual to be a specified individual based solely on the attestation of such individual.
- "(4) AVAILABILITY OF DOCUMENTATION RELATING TO DETERMINATIONS.—A PDP sponsor shall retain all documentation described in paragraph (3)(A) received by such sponsor in determining whether an individual is a specified individual and make such documentation available to the Secretary upon request.".
- (b) REVIEW.—Not later than 5 years after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall conduct a review of prescription drug plans' and MA–PD plans' compliance with the amendments made by subsection (a).
- (c) MEDPAC INFORMATION.—The Medicare Payment Advisory Commission shall, to the extent practicable and subject to data availability, as part of the part D status report chapter in the

March 2026 report to Congress, provide information on differences in commercial, individual, and Medicaid coverage of anti-obesity medications, differences in formulary treatment by prescription drug plans under Medicare of GLP-1 products, and how the amendments made by subsection (a) may be associated with different use of such medications among Medicare beneficiaries, including underserved communities.

## SEC. **3.** REVIEWING COVERAGE FOR INTENSIVE BEHAVIORAL THERAPY FOR OBESITY UNDER THE MEDICARE PROGRAM.

- (a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall initiate a reconsideration of the national coverage determination entitled "Intensive Behavioral Therapy for Obesity" (Publication Number 100–3).
  - (b) POTENTIAL REVISIONS TO NCD BASED ON CLINICAL GUIDELINES.—As part of the reconsideration of the determination described in subsection (a), the Secretary may, if determined appropriate by the Secretary after taking into account such clinical guidelines and scientific literature with respect to intensive behavioral therapy for obesity as the Secretary finds appropriate, revise such determination based on such guidelines and literature.