AMENDMENT IN THE NATURE OF A SUBSTITUTE то H.R. 4818

OFFERED BY MR. SMITH OF MISSOURI

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the "Treat and Reduce Obe-3 sity Act of 2024". 4 SEC. 2. INCLUDING WEIGHT LOSS AGENTS AS COVERED 5 PART D DRUGS UNDER THE MEDICARE PRO-

GRAM IN CERTAIN CIRCUMSTANCES.

7 (a) IN GENERAL.—

(1) REMOVAL OF EXCLUSION.—Section 1860D– 8 9 2(e) of the Social Security Act (42 U.S.C. 1395w-10 102(e)) is amended—

11 (A) in paragraph (2)(A), in the first sen-12 tence---

(i) by striking "and other than" and 13 14 inserting "other than"; and

(ii) by inserting "and, with respect to 15 16 plan years beginning on or after January 17 1, 2027, other than subparagraph (A) of 18 such section if the drug is approved under

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1	section 505 of the Federal Food, Drug,
2	and Cosmetic Act or licensed under section
3	351 of Public Health Service Act for long-
4	term weight reduction in individuals with
5	obesity (as defined in section
6	1861(yy)(2)(C)) and is used for the treat-
7	ment of obesity for a specified individual,"
8	after "benzodiazepines),"; and
9	(B) by adding at the end the following new
10	paragraph:
11	"(5) Specified individual defined.—For
12	purposes of paragraph $(2)(A)$, the term 'specified in-
13	dividual' means an individual enrolled under a pre-
14	scription drug plan for a plan year who, during the
15	1-year period ending on the first day of such plan
16	year (or, in the case such individual enrolled in such
17	plan after the first day of such plan year, the 1-year
18	period ending on the first day that such individual
19	was enrolled under such plan), was continuously re-
20	ceiving an agent for weight loss (as described in sec-
21	tion $1927(d)(2)(A)$) for the treatment of obesity (as
22	defined in section $1861(yy)(2)(C)$) for which benefits
23	were provided to such individual under a Federal
24	health care program (as defined in section 1128B),
25	the program established under chapter 89 of title 5,

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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).".

5 (2) ENSURING ELIGIBILITY.—Section 1860D-4
6 of the Social Security Act (42 U.S.C. 1395w-104)
7 is amended by adding at the end the following new
8 subsection:

9 "(p) ENSURING ELIGIBILITY WITH RESPECT TO AC10 CESS TO WEIGHT LOSS AGENTS.—

11 "(1) IN GENERAL.—A PDP sponsor of a pre-12 scription drug plan may not make payment for a 13 drug for which coverage is available under such plan 14 only to specified individuals (as defined in section 15 1860D–2(e)) that is dispensed to an enrollee of such 16 plan unless such sponsor has determined that such 17 individual is a specified individual.

18 "(2) TIMING.—In the case of an individual en-19 rolled under a prescription drug plan who requests 20 coverage under such plan of a drug described in 21 paragraph (1), the PDP sponsor of such plan shall, 22 not later than 72 hours after receiving from such in-23 dividual documentation purporting to demonstrate 24 that such individual is a specified individual, deter4

mine whether such individual is in fact a specified
 individual.

3 "(3) REGULATIONS.—Not later than 1 year
4 after the date of the enactment of this subsection,
5 the Secretary shall through notice-and-comment
6 rulemaking establish requirements relating to a PDP
7 sponsor's determination of whether an individual is
8 a specified individual. Such requirements shall—

9 "(A) specify the documentation that such
10 sponsor must receive in order to make such a
11 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.

16 "(4) AVAILABILITY OF DOCUMENTATION RE17 LATING TO DETERMINATIONS.—A PDP sponsor
18 shall retain all documentation described in para19 graph (3)(A) received by such sponsor in deter20 mining whether an individual is a specified indi21 vidual and make such documentation available to the
22 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

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a review of prescription drug plans' and MA-PD plans'
 compliance with the amendments made by subsection (a).

3 (c) MEDPAC INFORMATION.—The Medicare Pay-4 ment Advisory Commission shall, to the extent practicable 5 and subject to data availability, as part of the part D status report chapter in the March 2026 report to Congress, 6 7 provide information on differences in commercial, indi-8 vidual, and Medicaid coverage of anti-obesity medications, 9 differences in formulary treatment by prescription drug 10 plans under Medicare of GLP-1 products, and how the amendments made by subsection (a) may be associated 11 12 with different use of such medications among Medicare 13 beneficiaries, including underserved communities.

14SEC. 3. REVIEWING COVERAGE FOR INTENSIVE BEHAV-15IORAL THERAPY FOR OBESITY UNDER THE16MEDICARE PROGRAM.

17 (a) IN GENERAL.—Not later than 1 year after the 18 date of the enactment of this Act, the Secretary of Health 19 and Human Services (in this section referred to as the 20 "Secretary") shall initiate a reconsideration of the na-21 tional coverage determination entitled "Intensive Behav-22 ioral Therapy for Obesity" (Publication Number 100–3). 23 (b) POTENTIAL REVISIONS TO NCD BASED ON CLIN-24 ICAL GUIDELINES.—As part of the reconsideration of the 25 determination described in subsection (a), the Secretary 1~ may, if determined appropriate by the Secretary after tak-

2 ing into account such clinical guidelines and scientific lit-

3 erature with respect to intensive behavioral therapy for

4 obesity as the Secretary finds appropriate, revise such de-

5 termination based on such guidelines and literature.

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