

119TH CONGRESS
1ST SESSION

S. 475

To amend title XVIII of the Social Security Act to ensure appropriate access to non-opioid pain management drugs under part D of the Medicare program.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 6 (legislative day, FEBRUARY 5), 2025

Mr. TILLIS (for himself, Mr. KELLY, Mrs. CAPITO, Mr. Kaine, Mrs. BRITT, Mrs. SHAHEEN, Mr. BUDD, Mr. COONS, Mr. CORNYN, Mr. BOOKER, Mr. MORAN, Mr. BENNET, Mr. BANKS, Mr. PADILLA, Mr. DAINES, Mr. WARNER, and Mrs. HYDE-SMITH) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to ensure appropriate access to non-opioid pain management drugs under part D of the Medicare program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Alternatives to Prevent
5 Addiction In the Nation Act” or the “Alternatives to
6 PAIN Act”.

1 **SEC. 2. APPROPRIATE COST-SHARING FOR QUALIFYING**
 2 **NON-OPIOID PAIN MANAGEMENT DRUGS**
 3 **UNDER MEDICARE PART D.**

4 (a) MEDICARE PART D.—Section 1860D–2 of the
 5 Social Security Act (42 U.S.C. 1395w–102) is amended—

6 (1) in subsection (b)—

7 (A) in paragraph (1)(A), in the matter
 8 preceding clause (i), by striking “paragraphs
 9 (8) and (9)” and inserting “paragraphs (8),
 10 (9), and (10)”;

11 (B) in paragraph (2)(A), in the matter
 12 preceding clause (i), by striking “paragraphs
 13 (8) and (9)” and inserting “paragraphs (8),
 14 (9), and (10)”;

15 (C) by adding at the end the following new
 16 paragraph:

17 “(10) TREATMENT OF COST-SHARING FOR
 18 QUALIFYING NON-OPIOID PAIN MANAGEMENT
 19 DRUGS.—

20 “(A) IN GENERAL.—For plan years begin-
 21 ning on or after January 1, 2026, with respect
 22 to a covered part D drug that is a qualifying
 23 non-opioid pain management drug (as defined
 24 in subparagraph (B))—

25 “(i) the deductible under paragraph
 26 (1) shall not apply; and

1 “(ii) such drug shall be placed on the
 2 lowest cost-sharing tier, if any, for pur-
 3 poses of determining the maximum co-in-
 4 surance or other cost-sharing for such
 5 drug.

6 “(B) QUALIFYING NON-OPIOID PAIN MAN-
 7 AGEMENT DRUGS.—In this paragraph, the term
 8 ‘qualifying non-opioid pain management drug’
 9 means a drug or biological product—

10 “(i) that has a label indication ap-
 11 proved by the Food and Drug Administra-
 12 tion to reduce postoperative pain or any
 13 other form of acute pain;

14 “(ii) that does not act upon the body’s
 15 opioid receptors;

16 “(iii) for which there is no other drug
 17 or product that is—

18 “(I) rated as therapeutically
 19 equivalent (under the Food and Drug
 20 Administration’s most recent publica-
 21 tion of ‘Approved Drug Products with
 22 Therapeutic Equivalence Evalua-
 23 tions’); and

24 “(II) sold or marketed in the
 25 United States; and

1 “(iv) for which the wholesale acquisi-
 2 tion cost (as defined in section
 3 1847A(c)(6)(B)), for a monthly supply
 4 does not exceed the monthly specialty-tier
 5 cost threshold as determined by the Sec-
 6 retary from time to time.”; and

7 (2) in subsection (c), by adding at the end the
 8 following new paragraph:

9 “(7) TREATMENT OF COST-SHARING FOR
 10 QUALIFYING NON-OPIOID PAIN MANAGEMENT
 11 DRUGS.—The coverage is provided in accordance
 12 with subsection (b)(10).”.

13 (b) CONFORMING AMENDMENTS TO COST-SHARING
 14 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
 15 of the Social Security Act (42 U.S.C. 1395w–114(a)) is
 16 amended—

17 (1) in paragraph (1)(D), in each of the clauses
 18 (ii) and (iii), by striking “Subject to paragraph (6)”
 19 and inserting “Subject to paragraphs (6) and (7)”;
 20 and

21 (2) by adding at the end the following new
 22 paragraph:

23 “(7) TREATMENT OF COST-SHARING OR DE-
 24 DUCTIBLE FOR QUALIFYING NON-OPIOID PAIN MAN-
 25 AGEMENT DRUGS.—For plan years beginning on or

1 after January 1, 2026, with respect to a covered
 2 part D drug that is a qualifying non-opioid pain
 3 management drug (as defined in section 1860D–
 4 2(b)(10)(B))—

5 “(A) the deductible under section 1860D–
 6 2(b)(1) shall not apply; and

7 “(B) such drug shall be placed on the low-
 8 est cost-sharing tier, if any, for purposes of de-
 9 termining the maximum co-insurance or other
 10 cost-sharing for such drug.”.

11 **SEC. 3. PROHIBITION ON THE USE OF STEP THERAPY AND**
 12 **PRIOR AUTHORIZATION FOR QUALIFYING**
 13 **NON-OPIOID PAIN MANAGEMENT DRUGS**
 14 **UNDER MEDICARE PART D.**

15 Section 1860D–4(c) of the Social Security Act (42
 16 U.S.C. 1395w–104) is amended—

17 (1) by redesignating paragraph (6), as added by
 18 section 50354 of division E of the Bipartisan Budg-
 19 et Act of 2018 (Public Law 115–123), as paragraph
 20 (7); and

21 (2) by adding at the end the following para-
 22 graph:

23 “(8) PROHIBITION ON USE OF STEP THERAPY
 24 AND PRIOR AUTHORIZATION FOR QUALIFYING NON-
 25 OPIOID PAIN MANAGEMENT DRUGS.—

“(A) IN GENERAL.—For plan years beginning on or after January 1, 2026, a prescription drug plan or an MA–PD plan may not, with respect to a qualifying non-opioid pain management drug (as defined in section 1860D–2(b)(10)(B)) for which coverage is provided under such plan, impose any—

“(i) step therapy requirement under which an individual enrolled under such plan is required to use an opioid prior to receiving such drug; or

“(ii) prior authorization requirement.

“(B) STEP THERAPY.—In this paragraph, the term ‘step therapy’ means a drug therapy utilization management protocol or program that requires use of an alternative, preferred prescription drug or drugs before the plan approves coverage for the non-preferred drug therapy prescribed.

“(C) PRIOR AUTHORIZATION.—In this paragraph, the term ‘prior authorization’ means any requirement to obtain approval from a plan prior to the furnishing of a drug.”.

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