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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Alternatives to Prevent Addiction In the Nation Act'' or the ''Alternatives to PAIN Act''.

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

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

(1) in subsection (b)—

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

(B) in paragraph (2)(A), in the matter preceding clause (i), by striking ''paragraphs (8) and (9)'' and inserting ''paragraphs (8), (9), and (10)''; and

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

''(10) TREATMENT OF COST-SHARING FOR QUALIFYING NON-OPIOID PAIN MANAGEMENT DRUGS.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2026, with respect to a covered part D drug that is a qualifying non-opioid pain management drug (as defined in subparagraph (B))—

''(i) the deductible under paragraph (1) shall not apply; and

"(ii) such drug shall be placed on the lowest cost-sharing tier, if any, for purposes of determining the maximum co-insurance or other cost-sharing for such drug.

"(B) QUALIFYING NON-OPIOID PAIN MANAGEMENT DRUGS.—In this paragraph, the term 'qualifying non-opioid pain management drug' means a drug or biological product—

"(i) that has a label indication approved by the Food and Drug Administration to reduce postoperative pain or any other form of acute pain;

"(ii) that does not act upon the body's opioid receptors;

"(iii) for which there is no other drug or product that is—

"(I) rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'); and

"(II) sold or marketed in the United States; and

"(iv) for which the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)), for a monthly supply does not exceed the monthly specialty-tier cost threshold as determined by the Secretary from time to time."; and

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

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

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

(1) in paragraph (1)(D), in each of the clauses (ii) and (iii), by striking "Subject to paragraph (6)" and inserting "Subject to paragraphs (6) and (7)"; and

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

"(7) TREATMENT OF COST-SHARING OR DEDUCTIBLE FOR QUALIFYING NON-OPIOID PAIN MANAGEMENT DRUGS.—For plan years beginning on or

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

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

"(B) such drug shall be placed on the lowest cost-sharing tier, if any, for purposes of determining the maximum co-insurance or other cost-sharing for such drug.".

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

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

(1) by redesignating paragraph (6), as added by section 50354 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), as paragraph (7); and

(2) by adding at the end the following paragraph:

"(8) PROHIBITION ON USE OF STEP THERAPY AND PRIOR AUTHORIZATION FOR QUALIFYING NON-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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