118TH CONGRESS 2D SESSION	<b>5.</b>
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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

Mr. Tillis (for himself and Mr. Kelly) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

## 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".

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 begin-
ning on or after January 1, 2025, 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

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	(2) by adding at the end the following new
21	paragraph:
22	"(7) Treatment of cost-sharing or de-
23	DUCTIBLE FOR QUALIFYING NON-OPIOID PAIN MAN-
24	AGEMENT DRUGS.—For plan years beginning on or
25	after January 1, 2025, with respect to a covered

1	part D drug that is a qualifying non-opioid pain
2	management drug (as defined in section 1860D-
3	2(b)(10)(B))—
4	"(A) the deductible under section 1860D-
5	2(b)(1) shall not apply; and
6	"(B) such drug shall be placed on the low-
7	est cost-sharing tier, if any, for purposes of de-
8	termining the maximum co-insurance or other
9	cost-sharing for such drug.".
10	SEC. 3. PROHIBITION ON THE USE OF STEP THERAPY AND
11	PRIOR AUTHORIZATION FOR QUALIFYING
12	NON-OPIOID PAIN MANAGEMENT DRUGS
13	UNDER MEDICARE PART D.
13 14	UNDER MEDICARE PART D.  Section 1860D-4(c) of the Social Security Act (42)
14	Section 1860D-4(c) of the Social Security Act (42
14 15	Section 1860D-4(c) of the Social Security Act (42 U.S.C. 1395w-104) is amended—
<ul><li>14</li><li>15</li><li>16</li></ul>	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
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	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 Budg-
14 15 16 17 18	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
14 15 16 17 18 19	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
14 15 16 17 18 19 20	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 para-
14 15 16 17 18 19 20 21	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:

1	"(A) In General.—For plan years begin-
2	ning on or after January 1, 2025, a prescrip-
3	tion drug plan or an MA-PD plan may not
4	with respect to a qualifying non-opioid pair
5	management drug (as defined in section
6	1860D-2(b)(10)(B)) for which coverage is pro-
7	vided under such plan, impose any—
8	"(i) step therapy requirement under
9	which an individual enrolled under such
10	plan is required to use an opioid prior to
11	receiving such drug; or
12	"(ii) prior authorization requirement.
13	"(B) Step therapy.—In this paragraph
14	the term 'step therapy' means a drug therapy
15	utilization management protocol or program
16	that requires use of an alternative, preferred
17	prescription drug or drugs before the plan ap-
18	proves coverage for the non-preferred drug
19	therapy prescribed.
20	"(C) Prior authorization.—In this
21	paragraph, the term 'prior authorization' means
22	any requirement to obtain approval from a plan
23	prior to the furnishing of a drug.".