

118TH CONGRESS
1ST SESSION

S. 2129

To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 22, 2023

Mr. LANKFORD (for himself and Mr. MENENDEZ) 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 require PDP sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

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 “Ensuring Access to
5 Lower-Cost Medicines for Seniors Act”.

1 **SEC. 2. REQUIREMENTS FOR PDP SPONSORS OF PRESCRIP-**
2 **TION DRUG PLANS AND MEDICARE ADVAN-**
3 **TAGE ORGANIZATIONS OFFERING MA-PD**
4 **PLANS UNDER PART D OF THE MEDICARE**
5 **PROGRAM THAT USE FORMULARIES.**

6 (a) IN GENERAL.—Section 1860D–4(b)(3) of the So-
7 cial Security Act (42 U.S.C. 1395w–104(b)(3)) is amend-
8 ed by adding at the end the following new subparagraphs:

9 “(J) REQUIRED INCLUSION OF CERTAIN
10 GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL
11 PRODUCTS.—

12 “(i) IN GENERAL.—Subject to the
13 succeeding provisions of this subparagraph,
14 with respect to a plan year beginning on or
15 after January 1, 2025, the following rules
16 shall apply:

17 “(I) If the formulary includes a
18 part D reference drug, the formulary
19 shall include each part D generic drug
20 of such part D reference drug for
21 which the wholesale acquisition cost is
22 less than the wholesale acquisition
23 cost of such part D reference drug.

24 “(II) If the formulary includes a
25 part D reference biological product,
26 the formulary shall include at least

1 one part D biosimilar biological of
2 such part D reference biological prod-
3 uct for which the wholesale acquisition
4 cost is less than the wholesale acquisi-
5 tion cost of such part D reference bio-
6 logical product (if one or more such
7 part D biosimilar biologicals is avail-
8 able).

9 “(ii) DETERMINATIONS AND IMPLE-
10 MENTATION.—Determinations of part D
11 generic drugs and part D biosimilar bio-
12 logical products described in subclauses (I)
13 and (II) of clause (i) and implementation
14 of formulary requirements under clause (i)
15 shall be made by PDP sponsors offering
16 prescription drug plans in accordance with
17 uniform requirements established by the
18 Secretary (by program instruction or oth-
19 erwise), which shall provide for such deter-
20 minations to be made as of specified dates
21 (in the case of determinations during a
22 plan year, on a quarterly basis), and for
23 any associated formulary changes to be im-
24 plemented promptly thereafter (in accord-
25 ance with timeframes specified by the Sec-

1 retary). Such uniform requirements shall
2 also specify circumstances under which a
3 part D generic drug or part D biosimilar
4 biological product shall be deemed for pur-
5 poses of subclauses (I) and (II) of clause
6 (i) to have a lower wholesale acquisition
7 cost than its part D reference drug or part
8 D reference biological product (so as to re-
9 quire its inclusion on formularies), includ-
10 ing where no wholesale acquisition cost is
11 published for such part D reference drug
12 or part D reference biological product or
13 the part D reference drug or part D ref-
14 erence biological product is not available
15 for purchase by the PDP sponsor (or its
16 network pharmacies) from its manufac-
17 turer at the published wholesale acquisition
18 cost.

19 “(iii) PROHIBITION ON CERTAIN LIM-
20 ITS ON ACCESS.—The PDP sponsor offer-
21 ing the prescription drug plan may not im-
22 pose limits on access to a part D generic
23 drug required to be included on the for-
24 mulary under clause (i)(I) or a part D bio-
25 similar biological product required to be in-

1 cluded on the formulary under clause
2 (i)(II), including through prior authoriza-
3 tion, utilization management, or step ther-
4 apy, that are more restrictive than any
5 such limits imposed on access to the part
6 D reference drug of such part D generic
7 drug or part D reference biological product
8 of such part D biosimilar biological prod-
9 uct, respectively, or that otherwise have
10 the effect of giving preferred status to such
11 part D reference drug or part D reference
12 biological product over such part D generic
13 drug or part D biosimilar biological prod-
14 uct, respectively.

15 “(iv) DEFINITIONS.—In this subpara-
16 graph and subparagraph (K):

17 “(I) PART D BIOSIMILAR BIO-
18 LOGICAL PRODUCT.—The term ‘part
19 D biosimilar biological product’ means
20 a covered part D drug that is a bio-
21 similar biological product (as defined
22 in section 1847A(c)(6)(H)).

23 “(II) PART D GENERIC DRUG.—
24 The term ‘part D generic drug’ means
25 a covered part D drug that is ap-

1 proved under section 505(j) of the
2 Federal Food, Drug, and Cosmetic
3 Act.

4 “(III) PART D REFERENCE BIO-
5 LOGICAL PRODUCT.—The term ‘part
6 D reference biological product’ means
7 a covered part D drug that is a ref-
8 erence biological product (as defined
9 in section 1847A(c)(6)(I)).

10 “(IV) PART D REFERENCE
11 DRUG.—The term ‘part D reference
12 drug’ means, with respect to a part D
13 generic drug, a covered part D drug
14 that is the listed drug (as described in
15 clause (i) of section 505(j)(2)(A) of
16 the Federal Food, Drug, and Cos-
17 metic Act) that is referred to in the
18 abbreviated application for such part
19 D generic drug under such section.

20 “(V) WHOLESALE ACQUISITION
21 COST.—The term ‘wholesale acquisi-
22 tion cost’ has the meaning given such
23 term in section 1847A(c)(6)(B).

24 “(K) COST-SHARING TIERING REQUIRE-
25 MENTS WITH RESPECT TO PART D GENERIC

1 DRUGS AND PART D BIOSIMILAR BIOLOGICAL
2 PRODUCTS.—

3 “(i) GENERIC DRUG AND BIOSIMILAR
4 BIOLOGICAL PRODUCT COST-SHARING
5 TIER.—With respect to a plan year begin-
6 ning on or after January 1, 2025, if the
7 PDP sponsor offering the prescription
8 drug plan applies tiered cost-sharing
9 (through copayment or coinsurance tiers)
10 to covered part D drugs on a formulary,
11 the PDP sponsor shall—

12 “(I) have at least one cost-shar-
13 ing tier on the formulary that only in-
14 cludes part D generic drugs and part
15 D biosimilar biological products; and

16 “(II) with respect to each cost-
17 sharing tier described in subclause (I)
18 on the formulary, either apply no
19 cost-sharing requirement or a copay-
20 ment that is—

21 “(aa) in the case where the
22 lowest branded drug tier of such
23 formulary bases cost-sharing on a
24 copayment amount, an amount at
25 least \$20 lower than the copay-

1 ment for such lowest branded
2 drug tier (but in no case may
3 such copayment amount be less
4 than zero); or

5 “(bb) in the case where the
6 lowest branded drug tier of such
7 formulary bases cost-sharing on a
8 coinsurance percentage, an
9 amount at least \$20 lower than
10 the actuarially expected average
11 cost-sharing amount payable for
12 the covered part D drugs in-
13 cluded on such lowest branded
14 drug tier, determined using proc-
15 esses and methods established
16 under section 1860D–11(c) (but
17 in no case may such copayment
18 amount be less than zero).

19 “(ii) SPECIALTY GENERIC DRUG AND
20 BIOSIMILAR BIOLOGICAL PRODUCT COST-
21 SHARING TIER.—With respect to a plan
22 year beginning on or after January 1,
23 2025, if the PDP sponsor offering the pre-
24 scription drug plan has a specialty tier, the
25 PDP sponsor shall—

1 “(I) have a second specialty tier
2 on such formulary that only includes
3 part D generic drugs and part D bio-
4 similar biological products—

5 “(aa) for which the cost (as
6 defined by the Secretary) is
7 greater than a cost threshold
8 specified by the Secretary; and

9 “(bb) with respect to which
10 the part D reference drug for
11 such a part D generic drug or
12 the part D reference biological
13 product for such a part D bio-
14 similar biological product is ei-
15 ther included on a cost-sharing
16 tier on such formulary with a
17 cost-sharing requirement that is
18 greater than the cost-sharing re-
19 quirement applied under sub-
20 clause (II), or excluded from
21 such formulary; and

22 “(II) apply a coinsurance cost-
23 sharing requirement with respect to
24 the cost-sharing tier required for the
25 formulary under subclause (I) that is

1 at least 5 percentage points lower
2 than the coinsurance percentage appli-
3 cable to any other specialty tier of the
4 formulary.

5 “(iii) PLACEMENT OF CERTAIN GE-
6 NERIC DRUGS AND BIOSIMILAR BIOLOGI-
7 CAL PRODUCTS.—Each part D generic
8 drug and each part D biosimilar biological
9 product required to be included on the for-
10 mulary under subparagraph (J)(i) shall be
11 included either on a cost-sharing tier de-
12 scribed in clause (i)(I) or, if applicable, the
13 cost-sharing tier required for the formulary
14 under clause (ii)(I).

15 “(iv) APPLICATION.—

16 “(I) IN GENERAL.—The require-
17 ments under clauses (i) through (iii)
18 shall, subject to the requirements
19 under section 1860D–14, apply after
20 the individual has satisfied any de-
21 ductible under subsections (a)(2)(A)(i)
22 or (b)(1) of section 1860D–2.

23 “(II) LIMITATION.—The Sec-
24 retary shall not approve any benefit
25 design for a prescription drug plan or

1 an MA–PD plan to which the require-
2 ments of this subparagraph apply if
3 such benefit design has any deductible
4 applicable to any part D generic drug
5 or part D biosimilar biological product
6 unless such deductible, or a greater
7 deductible, also applies to all other
8 covered part D drugs on the for-
9 mulary of such plan (subject to the
10 requirements under section 1860D–
11 14), except for lesser or zero
12 deductibles applicable only to par-
13 ticular types of covered part D drugs
14 which the Secretary determines war-
15 rant favorable cost-sharing when such
16 lesser or zero deductibles are also ap-
17 plicable to part D generic drugs and
18 part D biosimilar biological products
19 of the given type.

20 “(v) DEFINITIONS.—In this subpara-
21 graph:

22 “(I) BRAND DRUG.—The term
23 ‘brand drug’ means a covered part D
24 drug that is approved under section
25 505(c) of the Federal Food, Drug,

1 and Cosmetic Act or licensed under
2 section 351(a) of the Public Health
3 Service Act.

4 “(II) LOWEST BRANDED DRUG
5 TIER.—The term ‘lowest branded
6 drug tier’ means the cost-sharing tier
7 of a formulary which includes at least
8 1 brand drug and provides for the
9 lowest level of cost sharing applicable
10 to any such tier, as determined by the
11 Secretary.

12 “(III) SPECIALTY TIER.—The
13 term ‘specialty tier’ means a cost-
14 sharing tier consisting only of covered
15 part D drugs that have a cost (as de-
16 fined by the Secretary) which equals
17 or exceeds an applicable cost threshold
18 established by the Secretary for high-
19 cost covered part D drugs to be eligi-
20 ble for inclusion on such cost-sharing
21 tier.”.

22 (b) CONFORMING AMENDMENTS.—Section 1860D–2
23 of the Social Security Act (42 U.S.C. 1395w–102) is
24 amended—

25 (1) in subsection (b)(2)—

1 (A) in subparagraph (A), by striking “and
2 paragraphs (8) and (9)” and inserting “, para-
3 graphs (8) and (9), and section 1860D-
4 4(b)(3)(K)”; and

5 (B) in subparagraph (B), by inserting be-
6 fore the period the following: “and section
7 1860D-4(b)(3)(K)”; and

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

10 “(7) TREATMENT OF COST-SHARING FOR PART
11 D GENERIC DRUGS AND PART D BIOSIMILAR BIO-
12 LOGICAL PRODUCTS.—The coverage is provided in
13 accordance with section 1860D-4(b)(3)(K).”.

○