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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R.

To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug 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 HOUSE OF REPRESENTATIVES

Mr. MCKINLEY introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug 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 of 2021”.

1 **SEC. 2. REQUIREMENTS FOR PDP SPONSORS OF PRESCRIP-**
2 **TION DRUG PLANS UNDER PART D OF THE**
3 **MEDICARE PROGRAM THAT USE**
4 **FORMULARIES.**

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

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

11 “(i) IN GENERAL.—With respect to a
12 plan year beginning on or after January 1,
13 2022, the formulary shall include—

14 “(I) each covered generic drug
15 for which the wholesale acquisition
16 cost is less than the wholesale acquisi-
17 tion cost of the reference drug of such
18 covered generic drug; and

19 “(II) each covered biosimilar bio-
20 logical product for which the whole-
21 sale acquisition cost is less than the
22 wholesale acquisition cost of the ref-
23 erence biological product of such cov-
24 ered biosimilar biological product.

25 “(ii) PROHIBITION ON CERTAIN LIM-
26 ITS ON ACCESS.—The PDP sponsor offer-

1 ing the prescription drug plan may not im-
2 pose limits on access to a covered generic
3 drug required to be included on the for-
4 mulary under clause (i)(I) or a covered
5 biosimilar biological product required to be
6 included on the formulary under clause
7 (i)(II), including through prior authoriza-
8 tion, utilization management, or step ther-
9 apy, that are more restrictive than any
10 such limits imposed on access to the ref-
11 erence drug of such covered generic drug
12 or reference biological product of such cov-
13 ered biosimilar biological product, respec-
14 tively, or that otherwise have the effect of
15 giving preferred status to such reference
16 drug or reference biological product over
17 such covered generic drug or covered bio-
18 similar biological product, respectively.

19 “(iii) DEFINITIONS.—In this subpara-
20 graph and subparagraph (J):

21 “(I) COVERED BIOSIMILAR BIO-
22 LOGICAL PRODUCT.—The term ‘cov-
23 ered biosimilar biological product’
24 means a covered part D drug that is

1 a biosimilar biological product (as de-
2 fined in section 1847A(c)(6)(H)).

3 “(II) COVERED GENERIC
4 DRUG.—The term ‘covered generic
5 drug’ means a covered part D drug
6 that is a drug described in section
7 1860D–2(e)(1)(A) and approved
8 under section 505(j) of the Federal
9 Food, Drug, and Cosmetic Act.

10 “(III) REFERENCE BIOLOGICAL
11 PRODUCT.—The term ‘reference bio-
12 logical product’ has the meaning given
13 such term in section 1847A(c)(6)(I).

14 “(IV) REFERENCE DRUG.—The
15 term ‘reference drug’ means, with re-
16 spect to a covered generic drug, the
17 listed drug (as described in clause (i)
18 of section 505(j)(2)(A) of the Federal
19 Food, Drug, and Cosmetic Act) that
20 is referred to in the abbreviated appli-
21 cation for such covered generic drug
22 under such section.

23 “(V) WHOLESAL ACQUISITION
24 COST.—The term ‘wholesale acquisi-

1 tion cost’ has the meaning given such
2 term in section 1847A(c)(6)(B).

3 “(J) COST-SHARING TIERING REQUIRE-
4 MENTS WITH RESPECT TO COVERED GENERIC
5 DRUGS AND COVERED BIOSIMILAR BIOLOGICAL
6 PRODUCTS.—

7 “(i) GENERIC DRUG COST-SHARING
8 TIER.—With respect to a plan year begin-
9 ning on or after January 1, 2022, the
10 PDP sponsor offering the prescription
11 drug plan shall—

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

17 “(II) apply a cost-sharing re-
18 quirement with respect to each cost-
19 sharing tier described in subclause (I)
20 on the formulary that is meaningfully
21 lesser than the lowest cost-sharing re-
22 quirement applicable with respect to
23 any cost-sharing tier on such for-
24 mulary that includes a brand drug
25 (referred to in this subparagraph as

1 the ‘lowest brand drug cost-sharing
2 tier’).

3 “(ii) SPECIALTY GENERIC DRUG COST-
4 SHARING TIER.—With respect to a plan
5 year beginning on or after January 1,
6 2022, if the PDP sponsor offering the pre-
7 scription drug plan has a cost-sharing tier
8 for specialty brand drugs on the formulary,
9 the PDP sponsor shall—

10 “(I) have a cost-sharing tier on
11 such formulary that only includes cov-
12 ered generic drugs and covered bio-
13 similar biological products—

14 “(aa) for which the whole-
15 sale acquisition cost is greater
16 than a threshold specified by the
17 Secretary; and

18 “(bb) with respect to which
19 the reference drug for such a
20 covered generic drug or the ref-
21 erence biological product for such
22 a covered biosimilar biological
23 product is either included on a
24 cost-sharing tier on such for-
25 mulary with a cost-sharing re-

1 requirement that is greater than
2 the cost-sharing requirement ap-
3 plied under subclause (II), or ex-
4 cluded from such formulary; and
5 “(II) apply a cost-sharing re-
6 quirement with respect to the cost-
7 sharing tier required for the for-
8 mulary under subclause (I) that is
9 meaningfully lesser than the cost-
10 sharing requirement applicable with
11 respect to the cost-sharing tier for
12 specialty brand drugs on such for-
13 mulary.

14 “(iii) PLACEMENT OF CERTAIN GE-
15 NERIC DRUGS AND BIOSIMILAR BIOLOGI-
16 CAL PRODUCTS.—Each covered generic
17 drug and each covered biosimilar biological
18 product required to be included on the for-
19 mulary under subparagraph (I)(i) shall be
20 included either on a cost-sharing tier de-
21 scribed in clause (i)(I) or, if applicable, the
22 cost-sharing tier required for the formulary
23 under clause (ii)(I).

24 “(iv) DEFINITIONS.—In this subpara-
25 graph:

1 “(I) BRAND DRUG.—The term
2 ‘brand drug’ means a covered part D
3 drug that is a drug described in sec-
4 tion 1860D–2(e)(1)(A) and approved
5 under section 505(c) of the Federal
6 Food, Drug, and Cosmetic Act.

7 “(II) MEANINGFULLY LESSER.—
8 The term ‘meaningfully lesser’
9 means—

10 “(aa) for purposes of sub-
11 clause (II) of clause (i), such a
12 lesser cost-sharing requirement
13 that the Secretary determines
14 will likely significantly incentivize
15 the utilization of covered generic
16 drugs and covered biosimilar bio-
17 logical products on a cost-sharing
18 tier described in subclause (I) of
19 such clause on a formulary over
20 covered part D drugs on the low-
21 est brand drug cost-sharing tier
22 on such formulary; and

23 “(bb) for purposes of sub-
24 clause (II) of clause (ii), such a
25 lesser cost-sharing requirement

1 that the Secretary determines
2 will likely significantly incentivize
3 the utilization of covered generic
4 drugs and covered biosimilar bio-
5 logical products on the cost-shar-
6 ing tier required for the for-
7 mulary under subclause (I) of
8 such clause over covered part D
9 drugs on the cost-sharing tier for
10 specialty brand drugs on such
11 formulary.

12 “(III) SPECIALTY BRAND
13 DRUG.—The term ‘specialty brand
14 drug’ means a brand drug for which
15 the wholesale acquisition cost is great-
16 er than a threshold specified by the
17 Secretary.”.

18 (b) CONFORMING AMENDMENT.—Section 1860D–
19 2(b)(2)(B) of the Social Security Act (42 U.S.C. 1395w–
20 102(b)(2)(B)) is amended by inserting before the period
21 the following: “and section 1860D–4(b)(3)(J)”.