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118TH CONGRESS
1ST SESSION

H. R. 5461

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

SEPTEMBER 14, 2023

Ms. KUSTER (for herself, Mrs. MILLER-MEEKS, Ms. MATSUI, and Mr. DUNN of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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.

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 ''Ensuring Access to Lower-Cost Medicines for Seniors Act of 2023''.

SEC. 2. REQUIREMENTS FOR PDP SPONSORS OF PRESCRIPTION DRUG PLANS UNDER PART D OF THE MEDICARE PROGRAM THAT USE FORMULARIES.

Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended by adding at the end the following new subparagraph:

''(J) REQUIRED INCLUSION OF CERTAIN GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(i) IN GENERAL.—With respect to a plan year beginning on or after January 1, 2024, the formulary shall include in a preferred position relative to the reference drug—

''(I) each covered generic drug for which the wholesale acquisition cost is less than the wholesale acquisition cost of the reference drug of such covered generic drug; and

''(II) at least two covered biosimilar biological products for which the wholesale acquisition cost is less than the wholesale acquisition cost of the reference biological product of

such covered biosimilar biological product.

''(ii) PROHIBITION ON CERTAIN LIMITS ON ACCESS.—The PDP sponsor offering the prescription drug plan may not impose limits on access to a covered generic drug required to be included on the formulary under clause (i)(I) or a covered biosimilar biological product required to be included on the formulary under clause (i)(II), including through utilization management techniques such as prior authorization, or step therapy, that are more restrictive than any such limits imposed on access to the reference drug of such covered generic drug or reference biological product of such covered biosimilar biological product, respectively, or that otherwise have the effect of limiting the availability to enrollees of such covered generic drug or covered biosimilar biological product relative to such reference drug or reference biological product over such covered generic drug or covered biosimilar biological product, respectively.

"(iii) DEFINITIONS.—In this subparagraph and subparagraph (J):

"(I) COVERED BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'covered biosimilar biological product' means a covered part D drug that is a biosimilar biological product (as defined in section 1847A(c)(6)(H)).

"(II) COVERED GENERIC DRUG.—The term 'covered generic drug' means a covered part D drug that is a drug described in section 1860D–2(e)(1)(A) and approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

"(III) PREFERRED POSITION.—The term 'preferred position' means a product is placed on a more favorable formulary tier and has lower patient out-of-pocket costs than the corresponding reference drug or reference biological product.

"(IV) REFERENCE BIOLOGICAL PRODUCT.—The term 'reference bio-

logical product' has the meaning given such term in section 1847A(c)(6)(I).

"(V) REFERENCE DRUG.—The term 'reference drug' means, with respect to a covered generic drug, the listed drug (as described in clause (i) of section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act) that is referred to in the abbreviated application for such covered generic drug under such section.

"(VI) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B).".

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