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116TH CONGRESS
1ST SESSION

H. R. 4913

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

OCTOBER 30, 2019

Mr. MCKINLEY (for himself and Ms. KUSTER of New Hampshire) 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. REQUIREMENTS FOR PDP SPONSORS OF PRESCRIPTION DRUG PLANS UNDER PART D OF THE MEDICARE PROGRAM THAT USE FORMULARIES.

(a) IN GENERAL.—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 subparagraphs:

''(I) 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, 2021, the formulary shall include—

''(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) each covered biosimilar biological product 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 offer-

ing 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 prior authorization, utilization management, 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 giving preferred status 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) REFERENCE BIOLOGICAL PRODUCT.—The term 'reference biological product' has the meaning given such term in section 1847A(c)(6)(I).

''(IV) 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.

''(V) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisi-

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

''(J) COST-SHARING TIERING REQUIREMENTS WITH RESPECT TO COVERED GENERIC DRUGS AND COVERED BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(i) GENERIC DRUG COST-SHARING TIER.—With respect to a plan year beginning on or after January 1, 2021, the PDP sponsor offering the prescription drug plan shall—

''(I) have at least one cost-sharing tier on the formulary that only includes covered generic drugs and covered biosimilar biological products; and

''(II) apply a cost-sharing requirement with respect to each cost-sharing tier described in subclause (I) on the formulary that is meaningfully lesser than the lowest cost-sharing requirement applicable with respect to any cost-sharing tier on such formulary that includes a brand drug (referred to in this subparagraph as

the 'lowest brand drug cost-sharing tier').

''(ii) SPECIALTY GENERIC DRUG COST-SHARING TIER.—With respect to a plan year beginning on or after January 1, 2021, if the PDP sponsor offering the prescription drug plan has a cost-sharing tier for specialty brand drugs on the formulary, the PDP sponsor shall—

''(I) have a cost-sharing tier on such formulary that only includes covered generic drugs and covered biosimilar biological products—

''(aa) for which the wholesale acquisition cost is greater than a threshold specified by the Secretary; and

''(bb) with respect to which the reference drug for such a covered generic drug or the reference biological product for such a covered biosimilar biological product is either included on a cost-sharing tier on such formulary with a cost-sharing re-

quirement that is greater than the cost-sharing requirement applied under subclause (II), or excluded from such formulary; and

''(II) apply a cost-sharing requirement with respect to the cost-sharing tier required for the formulary under subclause (I) that is meaningfully lesser than the cost-sharing requirement applicable with respect to the cost-sharing tier for specialty brand drugs on such formulary.

''(iii) PLACEMENT OF CERTAIN GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.—Each covered generic drug and each covered biosimilar biological product required to be included on the formulary under subparagraph (I)(i) shall be included either on a cost-sharing tier described in clause (i)(I) or, if applicable, the cost-sharing tier required for the formulary under clause (ii)(I).

''(iv) DEFINITIONS.—In this subparagraph:

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

"(II) MEANINGFULLY LESSER.—The term 'meaningfully lesser' means—

"(aa) for purposes of subclause (II) of clause (i), such a lesser cost-sharing requirement that the Secretary determines will likely significantly incentivize the utilization of covered generic drugs and covered biosimilar biological products on a cost-sharing tier described in subclause (I) of such clause on a formulary over covered part D drugs on the lowest brand drug cost-sharing tier on such formulary; and

"(bb) for purposes of subclause (II) of clause (ii), such a lesser cost-sharing requirement

that the Secretary determines will likely significantly incentivize the utilization of covered generic drugs and covered biosimilar biological products on the cost-sharing tier required for the formulary under subclause (I) of such clause over covered part D drugs on the cost-sharing tier for specialty brand drugs on such formulary.

''(III) SPECIALTY BRAND DRUG.—The term 'specialty brand drug' means a brand drug for which the wholesale acquisition cost is greater than a threshold specified by the Secretary.''.

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

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