AMENDMENT

OFFERED BY MS. KUSTER OF NEW HAMPSHIRE

Add at the end of the bill the following (and update the table of contents accordingly):

TITLE VI—MISCELLANEOUS

SEC. 601. REQUIREMENTS FOR PDP SPONSORS OF PRESCRIPTION DRUG PLANS UNDER PART D OF THE MEDICARE PROGRAM THAT USE FORMULARIES.

(a) REQUIREMENT FOR FORMULARIES TO INCLUDE CERTAIN GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended—

(A) in subparagraph (C)(i), by striking ''subparagraph (G)'' and inserting ''subparagraphs (G) and (I)'';

(B) in subparagraph (G)(i)(I), by inserting after ''subclause (II)'' the following: ''and subparagraph (I)''; and

(C) 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 plan years 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 Secretary may not establish any exception that permits the PDP sponsor offering the prescription drug plan to 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:

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

''(J) PLACEMENT OF DRUGS ON TIERS.—

''(i) GENERIC DRUG COST-SHARING TIER.—

''(I) IN GENERAL.—With respect to plan years beginning on or after January 1, 2021, subject to subclause (II), the formulary shall—

''(aa) have at least one generic drug cost-sharing tier, with each such generic drug cost-sharing tier only including covered generic drugs and covered biosimilar biological products; and

''(bb) apply a cost-sharing requirement with respect to each such generic drug cost-sharing tier that is meaningfully lesser (as defined by the Secretary) than the cost-sharing requirement with respect to the lowest brand drug cost-sharing tier of such formulary.

''(II) EXCEPTION.—In the case of a covered generic drug or a covered biosimilar biological product for which the wholesale acquisition cost is equal to or greater than the wholesale acquisition cost for the reference drug

for such covered drug or the reference biological product for such covered biosimilar biological product, such covered generic drug or covered biosimilar biological product may be included on any cost-sharing tier of the formulary.

''(ii) SPECIALTY GENERIC DRUG COST-SHARING TIER.—If the formulary has a specialty brand drug cost-sharing tier, such formulary shall—

''(I) have a specialty generic drug cost-sharing tier that only includes, subject to clause (ii)(II), covered generic drugs and covered biosimilar biological products—

''(aa) for which the wholesale acquisition cost is greater than a specialty generic drug 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 of such formulary with a cost-sharing requirement that is greater than the cost-sharing requirement applicable to such specialty generic drug cost-sharing tier, or excluded from such formulary; and

''(II) apply a cost-sharing requirement with respect to such specialty generic drug cost-sharing tier that is meaningfully lesser (as defined by the Secretary) than the cost-sharing requirement with respect to such specialty brand drug cost-sharing tier of such formulary.

''(iii) 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) LOWEST BRAND DRUG COST-SHARING TIER.—The term 'lowest brand drug cost-sharing tier' means, with respect to a formulary, the brand drug cost-sharing tier of such formulary with a cost-sharing requirement for brand drugs that is lesser than that of all other cost-sharing tiers of such formulary that include a brand drug.

''(III) MEANINGFULLY LESSER.—The term 'meaningfully lesser' means, as applicable, such a decrease in a cost-sharing requirement that the Secretary determines will likely significantly incentivize—

''(aa) the utilization of covered generic drugs and covered biosimilar biological products on any generic drug cost-sharing tier of a formulary over covered part D drugs on the lowest brand drug cost-sharing tier; of such formulary; or

''(bb) the utilization of covered generic drugs and covered biosimilar biological products on a specialty generic drug cost-sharing tier of a formulary over covered part D drugs on the specialty brand drug cost-sharing tier of such formulary.

''(IV) SPECIALTY BRAND DRUG COST-SHARING TIER.—The term 'specialty brand drug cost-sharing tier' means, with respect to a formulary, a cost-sharing tier of such formulary that includes covered part D drugs (other than covered generic drugs and covered biosimilar biological products required to be included on a generic drug cost-sharing tier under clause (i)) for which the wholesale acquisition cost is greater than a specialty brand drug threshold specified by the Secretary.''.