

**AMENDMENT**

**OFFERED BY MS. KUSTER OF NEW HAMPSHIRE**

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

1       **TITLE VI—MISCELLANEOUS**

2       **SEC. 601. REQUIREMENTS FOR PDP SPONSORS OF PRE-**  
3                   **SCRIPTION DRUG PLANS UNDER PART D OF**  
4                   **THE MEDICARE PROGRAM THAT USE**  
5                   **FORMULARIES.**

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

9           (1) IN GENERAL.—Section 1860D–4(b)(3) of  
10 the Social Security Act (42 U.S.C. 1395w–  
11 104(b)(3)) is amended—

12           (A) in subparagraph (C)(i), by striking  
13 “subparagraph (G)” and inserting “subpara-  
14 graphs (G) and (I)”;

15           (B) in subparagraph (G)(i)(I), by inserting  
16 after “subclause (II)” the following: “and sub-  
17 paragraph (I)”;

18           (C) by adding at the end the following new  
19 subparagraphs:

1           “(I) REQUIRED INCLUSION OF CERTAIN  
2           GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL  
3           PRODUCTS.—

4                   “(i) IN GENERAL.—With respect to  
5           plan years beginning on or after January  
6           1, 2021, the formulary shall include—

7                           “(I) each covered generic drug  
8                           for which the wholesale acquisition  
9                           cost is less than the wholesale acquisi-  
10                          tion cost of the reference drug of such  
11                          covered generic drug; and

12                           “(II) each covered biosimilar bio-  
13                          logical product for which the whole-  
14                          sale acquisition cost is less than the  
15                          wholesale acquisition cost of the ref-  
16                          erence biological product of such cov-  
17                          ered biosimilar biological product.

18                          “(ii) PROHIBITION ON CERTAIN LIM-  
19                          ITS ON ACCESS.—The Secretary may not  
20                          establish any exception that permits the  
21                          PDP sponsor offering the prescription  
22                          drug plan to impose limits on access to a  
23                          covered generic drug required to be in-  
24                          cluded on the formulary under clause (i)(I)  
25                          or a covered biosimilar biological product

1 required to be included on the formulary  
2 under clause (i)(II), including through  
3 prior authorization, utilization manage-  
4 ment, or step therapy, that are more re-  
5 strictive than any such limits imposed on  
6 access to the reference drug of such cov-  
7 ered generic drug or reference biological  
8 product of such covered biosimilar biologi-  
9 cal product, respectively, or that otherwise  
10 have the effect of giving preferred status to  
11 such reference drug or reference biological  
12 product over such covered generic drug or  
13 covered biosimilar biological product, re-  
14 spectively.

15 “(iii) DEFINITIONS.—In this subpara-  
16 graph:

17 “(I) COVERED BIOSIMILAR BIO-  
18 LOGICAL PRODUCT.—The term ‘cov-  
19 ered biosimilar biological product’  
20 means a covered part D drug that is  
21 a biosimilar biological product (as de-  
22 fined in section 1847A(e)(6)(H)).

23 “(II) COVERED GENERIC  
24 DRUG.—The term ‘covered generic  
25 drug’ means a covered part D drug

1 that is a drug described in section  
2 1860D–2(e)(1)(A) and approved  
3 under section 505(j) of the Federal  
4 Food, Drug, and Cosmetic Act.

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

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

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

22 “(J) PLACEMENT OF DRUGS ON TIERS.—

23 “(i) GENERIC DRUG COST-SHARING  
24 TIER.—

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

5                   “(aa) have at least one ge-  
6 neric drug cost-sharing tier, with  
7 each such generic drug cost-shar-  
8 ing tier only including covered  
9 generic drugs and covered bio-  
10 similar biological products; and

11                   “(bb) apply a cost-sharing  
12 requirement with respect to each  
13 such generic drug cost-sharing  
14 tier that is meaningfully lesser  
15 (as defined by the Secretary)  
16 than the cost-sharing require-  
17 ment with respect to the lowest  
18 brand drug cost-sharing tier of  
19 such formulary.

20                   “(II) EXCEPTION.—In the case  
21 of a covered generic drug or a covered  
22 biosimilar biological product for which  
23 the wholesale acquisition cost is equal  
24 to or greater than the wholesale ac-  
25 quisition cost for the reference drug

1 for such covered drug or the reference  
2 biological product for such covered  
3 biosimilar biological product, such  
4 covered generic drug or covered bio-  
5 similar biological product may be in-  
6 cluded on any cost-sharing tier of the  
7 formulary.

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

12 “(I) have a specialty generic drug  
13 cost-sharing tier that only includes,  
14 subject to clause (ii)(II), covered ge-  
15 neric drugs and covered biosimilar bi-  
16 ological products—

17 “(aa) for which the whole-  
18 sale acquisition cost is greater  
19 than a specialty generic drug  
20 threshold specified by the Sec-  
21 retary; and

22 “(bb) with respect to which  
23 the reference drug for such a  
24 covered generic drug or the ref-  
25 erence biological product for such

1 a covered biosimilar biological  
2 product is either included on a  
3 cost-sharing tier of such for-  
4 mulary with a cost-sharing re-  
5 quirement that is greater than  
6 the cost-sharing requirement ap-  
7 plicable to such specialty generic  
8 drug cost-sharing tier, or ex-  
9 cluded from such formulary; and

10 “(II) apply a cost-sharing re-  
11 quirement with respect to such spe-  
12 cialty generic drug cost-sharing tier  
13 that is meaningfully lesser (as defined  
14 by the Secretary) than the cost-shar-  
15 ing requirement with respect to such  
16 specialty brand drug cost-sharing tier  
17 of such formulary.

18 “(iii) DEFINITIONS.—In this subpara-  
19 graph:

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

1                   “(II) LOWEST BRAND DRUG  
2 COST-SHARING TIER.—The term ‘low-  
3 est brand drug cost-sharing tier’  
4 means, with respect to a formulary,  
5 the brand drug cost-sharing tier of  
6 such formulary with a cost-sharing re-  
7 quirement for brand drugs that is  
8 lesser than that of all other cost-shar-  
9 ing tiers of such formulary that in-  
10 clude a brand drug.

11                   “(III) MEANINGFULLY LESS-  
12 ER.—The term ‘meaningfully lesser’  
13 means, as applicable, such a decrease  
14 in a cost-sharing requirement that the  
15 Secretary determines will likely sig-  
16 nificantly incentivize—

17                   “(aa) the utilization of cov-  
18 ered generic drugs and covered  
19 biosimilar biological products on  
20 any generic drug cost-sharing  
21 tier of a formulary over covered  
22 part D drugs on the lowest brand  
23 drug cost-sharing tier; of such  
24 formulary; or



1                   “(bb) the utilization of cov-  
2                   ered generic drugs and covered  
3                   biosimilar biological products on  
4                   a specialty generic drug cost-  
5                   sharing tier of a formulary over  
6                   covered part D drugs on the spe-  
7                   cialty brand drug cost-sharing  
8                   tier of such formulary.

9                   “(IV) SPECIALTY BRAND DRUG  
10                  COST-SHARING TIER.—The term ‘spe-  
11                  cialty brand drug cost-sharing tier’  
12                  means, with respect to a formulary, a  
13                  cost-sharing tier of such formulary  
14                  that includes covered part D drugs  
15                  (other than covered generic drugs and  
16                  covered biosimilar biological products  
17                  required to be included on a generic  
18                  drug cost-sharing tier under clause  
19                  (i)) for which the wholesale acquisi-  
20                  tion cost is greater than a specialty  
21                  brand drug threshold specified by the  
22                  Secretary.”.

