

AMENDMENT NO. 4

Calendar No. \_\_\_\_\_

Purpose: To amend title XVIII of the Social Security Act to provide incentives to encourage the use of generics and biosimilars under part D of the Medicare program.

**IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.**

**S. 1895**

To lower health care costs.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. PAUL

Viz:

1 At the appropriate place in title II, insert the fol-  
2 lowing:

3 **SEC. 2\_\_ . INCENTIVIZING THE USE OF GENERICS AND**  
4 **BIOSIMILARS UNDER MEDICARE PART D.**

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

8 “(I) GENERIC DRUGS ON FORMULARY.—

9 “(i) IN GENERAL.—For plan year  
10 2021, and subsequent plan years, the for-  
11 mulary shall include a generic drug that  
12 references a brand drug if the negotiated

1 price (as described in section 1860D–2(d))  
2 under the plan for the generic drug is less  
3 than the negotiated price for the brand  
4 drug.

5 “(ii) BRAND DRUG DEFINED.—In this  
6 subparagraph, the term ‘brand drug’  
7 means a covered part D drug that is mar-  
8 keted under a new drug application ap-  
9 proved under section 505(e) of the Federal  
10 Food, Drug, and Cosmetic Act or under a  
11 biological product license application ap-  
12 proved under section 351(a) of the Public  
13 Health Service Act.

14 “(iii) GENERIC DRUG DEFINED.—In  
15 this subparagraph, the term ‘generic drug’  
16 means any covered part D drug that is not  
17 a brand drug, including a biosimilar bio-  
18 logical product (as defined in section  
19 1847A(e)(6)(H)).

20 “(J) LABELING OF FORMULARY TIERS.—

21 “(i) SEPARATE TIERS FOR BRAND  
22 AND GENERIC DRUGS.—For plan year  
23 2021, and subsequent plan years:

24 “(I) IN GENERAL.—The for-  
25 mulary may use drug tiers with dif-

1 differential in cost-sharing or copay-  
2 ments between tiers. Formulary tiers  
3 may not include both brand drugs and  
4 generic drugs, but shall have separate  
5 designated drug tiers for brand drugs  
6 and generic drugs.

7 “(II) TIERS.—The formulary  
8 may include a separate tier for—

9 “(aa) preferred brand drugs  
10 and preferred generic drugs, but  
11 the cost-sharing or copayment as-  
12 sociated with the preferred ge-  
13 neric drug tier shall be lower  
14 than the cost-sharing or copay-  
15 ment associated with the pre-  
16 ferred brand drug tier;

17 “(bb) nonpreferred brand  
18 drugs and nonpreferred generic  
19 drugs, but the cost-sharing or co-  
20 payment associated with the non-  
21 preferred generic drug tier shall  
22 be lower than the cost-sharing or  
23 copayment associated with the  
24 nonpreferred brand drug tier;  
25 and

1                   “(cc) brand specialty drugs  
2                   and generic specialty drugs, but  
3                   the cost-sharing or copayment as-  
4                   sociated with the generic spe-  
5                   cialty drug tier shall be lower  
6                   than the cost-sharing or copay-  
7                   ment associated with the brand  
8                   specialty drug tier.

9                   “(ii) DEFINITIONS.—In this subpara-  
10                  graph:

11                  “(I) BRAND SPECIALTY DRUG.—  
12                  The term ‘brand specialty drug’  
13                  means brand drug (as defined in sub-  
14                  paragraph (I)(2)) that is a specialty  
15                  drug.

16                  “(II) GENERIC SPECIALTY  
17                  DRUG.—The term ‘generic specialty  
18                  drug’ means generic drug (as defined  
19                  in subparagraph (I)(3)) that is a spe-  
20                  cialty drug.

21                  “(III) SPECIALTY DRUG.—The  
22                  term ‘specialty drug’ means a covered  
23                  part D drug that exceeds a cost  
24                  threshold established by the Sec-  
25                  retary.”.