

116TH CONGRESS
1ST SESSION

H. R. 4455

To amend title XVIII of the Social Security Act to provide for a temporary payment increase under the Medicare program for certain biosimilar biological products to encourage the development and use of such products.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2019

Mr. SCHRADER (for himself and Mr. GLANFORTE) 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

A BILL

To amend title XVIII of the Social Security Act to provide for a temporary payment increase under the Medicare program for certain biosimilar biological products to encourage the development and use of such products.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Bolstering Innovative
5 Options to Save Immediately on Medicines Act” or the
6 “BIOSIM Act”.

1 **SEC. 2. TEMPORARY INCREASE IN MEDICARE PART B PAY-**
2 **MENT FOR CERTAIN BIOSIMILAR BIOLOGI-**
3 **CAL PRODUCTS.**

4 Section 1847A(b)(8) of the Social Security Act (42
5 U.S.C. 1395w-3a(b)(8)) is amended—

6 (1) by redesignating subparagraphs (A) and
7 (B) as clauses (i) and (ii), respectively, and moving
8 the margin of each such redesignated clause 2 ems
9 to the right;

10 (2) by striking “PRODUCT.—The amount” and
11 inserting the following: “PRODUCT.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), the amount”; and

14 (3) by adding at the end the following new sub-
15 paragraph:

16 “(B) TEMPORARY PAYMENT INCREASE.—

17 “(i) IN GENERAL.—In the case of a
18 qualifying biosimilar biological product
19 that is furnished during the applicable 5-
20 year period for such product, the amount
21 specified in this paragraph for such prod-
22 uct with respect to such period is the sum
23 determined under subparagraph (A), ex-
24 cept that clause (ii) of such subparagraph
25 shall be applied by substituting ‘8 percent’
26 for ‘6 percent’.

1 “(ii) APPLICABLE 5-YEAR PERIOD.—
2 For purposes of clause (i), the applicable
3 5-year period for a biosimilar biological
4 product is—

5 “(I) in the case of such a product
6 for which payment was made under
7 this paragraph as of December 31,
8 2019, the 5-year period beginning on
9 January 1, 2020; and

10 “(II) in the case of such a prod-
11 uct for which payment is first made
12 under this paragraph during a cal-
13 endar quarter during the period be-
14 ginning January 1, 2020, and ending
15 December 31, 2024, the 5-year period
16 beginning on the first day of such cal-
17 endar quarter during which such pay-
18 ment is first made.

19 “(iii) QUALIFYING BIOSIMILAR BIO-
20 LOGICAL PRODUCT DEFINED.—For pur-
21 poses of this subparagraph, the term
22 ‘qualifying biosimilar biological product’
23 means a biosimilar biological product de-
24 scribed in paragraph (1)(C) with respect to
25 which—

1 “(I) in the case of a product de-
2 scribed in clause (ii)(I), the average
3 sales price is not more than the aver-
4 age sales price for the reference bio-
5 logical product; and
6 “(II) in the case of a product de-
7 scribed in clause (ii)(II), the wholesale
8 acquisition cost is not more than the
9 wholesale acquisition cost for the ref-
10 erence biological product”.

○