

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.

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## 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

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## 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”.

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