

116TH CONGRESS
2D SESSION

H. R. 6179

To require the Secretary of Health and Human Services to establish a demonstration project to increase access to biosimilar biological products under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 10, 2020

Mr. CÁRDENAS (for himself, Mr. HUDSON, Ms. CRAIG, and Mr. FITZPATRICK) 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 require the Secretary of Health and Human Services to establish a demonstration project to increase access to biosimilar biological products under the Medicare program.

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 “Increasing Access to
5 Biosimilars Act of 2020”.

1 **SEC. 2. DEMONSTRATION PROJECT TO INCREASE ACCESS**
2 **TO BIOSIMILAR BIOLOGICAL PRODUCTS**
3 **UNDER THE MEDICARE PROGRAM.**

4 (a) **ESTABLISHMENT.**—Beginning not later than 1
5 year after the date of the enactment of this Act, the Sec-
6 retary of Health and Human Services shall establish and
7 implement a 3-year nationwide demonstration project
8 under part B of title XVIII of the Social Security Act to
9 evaluate the benefits of providing a shared savings pay-
10 ment for biosimilar biological products furnished under
11 such part.

12 (b) **PARTICIPATION.**—

13 (1) **IN GENERAL.**—Participation under the
14 demonstration project shall be voluntary, and a par-
15 ticipating provider may terminate participation at
16 any time and the Secretary may terminate the par-
17 ticipation of such a provider at any time.

18 (2) **APPLICATION AND SELECTION.**—To partici-
19 pate under the demonstration project, an eligible
20 provider shall submit to the Secretary an application
21 in such form and manner and containing such infor-
22 mation as specified by the Secretary. Each eligible
23 provider who submits such an application shall be
24 selected by the Secretary for participation under the
25 demonstration project.

1 (3) CLARIFICATION.—Participation under the
2 demonstration project shall not preclude eligible pro-
3 viders from also participating in any model author-
4 ized under section 1115A of the Social Security Act
5 (42 U.S.C. 1315a), including the Oncology Care
6 Model and Oncology Care First Model, or impact eli-
7 gible providers metrics or expenditures within other
8 models authorized under such section.

9 (c) COVERAGE.—Except as otherwise provided in this
10 section, payment may be made under the demonstration
11 project for a biosimilar biological product only if such prod-
12 uct is covered under part B of title XVIII of the Social
13 Security Act and such payment shall be made in the same
14 manner as payment is provided for such a product under
15 such part.

16 (d) ADDITIONAL PAYMENT.—

17 (1) IN GENERAL.—Under the demonstration
18 project, subject to paragraph (3), in addition to the
19 payment that would otherwise be made under part
20 B of title XVIII of the Social Security Act for a bio-
21 similar biological product furnished or dispensed by
22 a participating provider to a Medicare beneficiary,
23 there shall be made an additional payment, in an
24 amount determined by the Secretary, that is based
25 on the difference, if any, (or portion of such dif-

1 ference) between the costs to the provider in fur-
2 nishing the biosimilar biological product and the
3 costs to the provider if the provider had furnished
4 the reference biological product.

5 (2) NO INCREASE TO MEDICARE COINSUR-
6 ANCE.—The additional payment described under
7 paragraph (1) shall not increase a Medicare bene-
8 ficiary’s cost-sharing liability, as described in section
9 1833 of the Social Security Act (42 U.S.C. 1395l).

10 (3) EXCEPTION.—An eligible provider may only
11 receive the additional payment described in para-
12 graph (1), with respect to a biosimilar biological
13 product, if the payment amount under section
14 1847A of the Social Security Act (42 U.S.C.
15 1395w–3a) for such product is less than the pay-
16 ment amount under part B of title XVIII of such
17 Act for the reference biological product.

18 (e) WAIVER AUTHORITY.—The Secretary may waive
19 such requirements of title XVIII of the Social Security Act
20 as may be necessary to carry out the demonstration
21 project, except the Secretary may not increase the cost-
22 sharing that would otherwise, without application of this
23 section, be applied to an individual under section 1833 of
24 the Social Security Act (42 U.S.C. 1395l).

25 (f) REPORTS.—

1 (1) INTERIM EVALUATION AND REPORT.—Not
2 later than 3 years after the date of enactment of
3 this Act, the Secretary shall submit to Congress a
4 report that contains an analysis of the appropriate-
5 ness of expanding or extending the demonstration
6 project and, to the extent such analysis determines
7 such an expansion or extension appropriate, rec-
8 ommendations for such expansion or extension, re-
9 spectively.

10 (2) FINAL EVALUATION AND REPORT.—Not
11 later than one year after the date of completion of
12 the demonstration project, the Secretary shall sub-
13 mit to Congress a report that contains a final anal-
14 ysis of the project and recommendations described in
15 paragraph (1).

16 (g) DEFINITIONS.—In this section:

17 (1) DEMONSTRATION PROJECT.—The term
18 “demonstration project” means the demonstration
19 project conducted under this Act.

20 (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
21 term “biosimilar biological product” means a biologi-
22 cal product approved under an abbreviated applica-
23 tion for a license of a biological product that relies
24 in part on data or information in an application for

1 another biological product licensed under section 351
2 of the Public Health Service Act (42 U.S.C. 262) .

3 (3) ELIGIBLE PROVIDER.—The term “eligible
4 provider” means a provider of services or supplier
5 that is eligible to receive payment under part B of
6 title XVIII of the Social Security Act for furnishing
7 or dispensing biosimilar biological products.

8 (4) MEDICARE BENEFICIARY.—The term
9 “Medicare beneficiary” means an individual who is
10 enrolled for benefits under part B of title XVIII of
11 the Social Security Act.

12 (5) PARTICIPATING PROVIDER.—The term
13 “participating provider” means an eligible provider
14 that has been selected for participation under the
15 project under subsection (b)(2) and with respect to
16 whom such participation has not been terminated.

17 (6) REFERENCE BIOLOGICAL PRODUCT.—The
18 term “reference biological product” means the bio-
19 logical product licensed under section 351 of the
20 Public Health Service Act (42 U.S.C. 262) that is
21 referred to in the application described in paragraph
22 (2) of the biosimilar biological product.

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