

116TH CONGRESS
2D SESSION

S. 4134

To establish a demonstration project to increase access to biosimilar biological products under the Medicare program.

IN THE SENATE OF THE UNITED STATES

JULY 1, 2020

Mr. CORNYN (for himself and Mr. BENNET) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

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”.

6 **SEC. 2. DEMONSTRATION PROJECT TO INCREASE ACCESS**
7 **TO BIOSIMILAR BIOLOGICAL PRODUCTS**
8 **UNDER THE MEDICARE PROGRAM.**

9 (a) ESTABLISHMENT.—Beginning not later than 1
10 year after the date of enactment of this Act, the Secretary

1 shall establish and implement a 5-year nationwide dem-
2 onstration project under part B of title XVIII of the Social
3 Security Act (42 U.S.C. 1395j et seq.) to evaluate the ben-
4 efits of providing a shared savings payment for biosimilar
5 biological products furnished under such part. At the dis-
6 cretion of the Secretary, the demonstration project may
7 be extended for an additional 2 years past the initial 5-
8 year period.

9 (b) PARTICIPATION.—

10 (1) IN GENERAL.—Participation in the dem-
11 onstration project shall be voluntary and a partici-
12 pating provider may terminate participation at any
13 time and the Secretary may terminate the participa-
14 tion of such a provider at any time for failure to
15 comply with the requirements of the demonstration
16 project.

17 (2) APPLICATION AND SELECTION.—To partici-
18 pate in the demonstration project, an eligible pro-
19 vider shall submit to the Secretary an application in
20 such form and manner and containing such informa-
21 tion as specified by the Secretary. Each eligible pro-
22 vider who submits such an application shall be se-
23 lected by the Secretary for participation under the
24 demonstration project.

1 (3) PARTICIPATION IN INNOVATION CENTER
2 MODELS.—Participation in the demonstration
3 project shall not preclude an eligible provider from
4 also participating in any model authorized under
5 section 1115A of the Social Security Act (42 U.S.C.
6 1315a), including the Oncology Care Model and the
7 Oncology Care First Model, or impact metrics or ex-
8 penditures with respect to an eligible provider under
9 any model authorized under such section.

10 (c) COVERAGE.—Except as otherwise provided in this
11 section, payment may be made under the demonstration
12 project for a biosimilar biological product only if such
13 product is covered under part B of title XVIII of the So-
14 cial Security Act (42 U.S.C. 1395j et seq.) and such pay-
15 ment shall be made in the same manner as payment is
16 provided for such a product under such part.

17 (d) ADDITIONAL PAYMENT.—

18 (1) IN GENERAL.—Subject to paragraphs (2)
19 and (3), in addition to the amount of payment that
20 would otherwise be made under part B of title XVIII
21 of the Social Security Act (42 U.S.C. 1395j et seq.)
22 for a biosimilar biological product furnished or dis-
23 pensed by a participating provider to a Medicare
24 beneficiary under the demonstration project, there
25 shall be made an additional payment, in an amount

1 determined by the Secretary, that reflects a portion
2 of any difference between such amount of payment
3 under such part, as compared to the amount of pay-
4 ment that would have been made under such part if
5 the reference biological product had been furnished
6 or dispensed to the beneficiary.

7 (2) MEDICARE BENEFICIARY COINSURANCE LI-
8 ABILITY.—The additional payment provided under
9 paragraph (1) shall not be taken into account when
10 determining the amount of coinsurance under sec-
11 tion 1833(a)(1)(S) of the Social Security Act (42
12 U.S.C. 1395l(a)(1)(S)) for a biosimilar biological
13 product furnished or dispensed to a Medicare bene-
14 ficiary by a participating provider under the dem-
15 onstration project. The Secretary may use a portion
16 of the difference described in such paragraph to
17 waive or reduce the amount of coinsurance otherwise
18 applicable under such section for such a biosimilar
19 biological.

20 (3) EXCEPTION TO ADDITIONAL PAYMENT.—A
21 participating provider may only receive the addi-
22 tional payment described in paragraph (1) with re-
23 spect to a biosimilar biological product furnished or
24 dispensed by the participating provider to a Medi-
25 care beneficiary under the demonstration project, if

1 the amount of payment determined under section
2 1847A of the Social Security Act (42 U.S.C.
3 1395w–3a) for the biosimilar biologic product is less
4 than the amount of payment determined under such
5 section for the reference biological product.

6 (e) WAIVER AUTHORITY.—The Secretary may waive
7 such requirements of titles XI and XVIII of the Social
8 Security Act (42 U.S.C. 1301 et seq., 1395 et seq.) as
9 may be necessary to carry out the demonstration project.

10 (f) DATA COLLECTION.—

11 (1) IN GENERAL.—The Secretary shall collect
12 data on the sex, race, ethnicity, and geographic and
13 socioeconomic characteristics of Medicare bene-
14 ficiaries to whom a biosimilar biological product is
15 furnished or dispensed by a participating provider
16 under the demonstration project.

17 (2) CONSIDERATION.—The Secretary shall take
18 into account data collected under paragraph (1) in
19 evaluating the demonstration project in each of the
20 reports submitted under subsection (g).

21 (g) REPORTS.—

22 (1) INTERIM EVALUATION AND REPORT.—Not
23 later than 3 years after the date of enactment of
24 this Act, the Secretary shall submit to Congress a
25 report that contains an analysis of the appropriate-

ness of expanding or extending the demonstration project and, to the extent such analysis determines such an expansion or extension appropriate, recommendations for such expansion or extension, respectively.

(2) EVALUATION AND REPORT.—Not later than 1 year after the date of completion of the demonstration project, the Secretary shall submit to Congress a report that contains a final analysis of the project and recommendations described in paragraph (1).

(h) DEFINITIONS.—In this section:

(1) BIOSIMILAR BIOLOGICAL PRODUCT.—The term “biosimilar biological product” has the meaning given that term in section 1847A(c)(6)(H) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(H)).

(2) DEMONSTRATION PROJECT.—The term “demonstration project” means the demonstration project conducted under this section.

(3) ELIGIBLE PROVIDER.—The term “eligible provider” means a provider of services or supplier that is eligible to receive payment under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) for furnishing or dispensing a biosimilar biological product.

1 (4) MEDICARE BENEFICIARY.—The term
2 “Medicare beneficiary” means an individual who is
3 enrolled for benefits under such part.

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

9 (6) REFERENCE BIOLOGICAL PRODUCT.—The
10 term “reference biological product” has the meaning
11 given that term in section 1847A(c)(6)(I) of the So-
12 cial Security Act (42 U.S.C. 1395w-3a(c)(6)(I)).

13 (7) SECRETARY.—The term “Secretary” means
14 the Secretary of Health and Human Services.

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