118TH CONGRESS
2D SESSION

S. 3934

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 SENATE OF THE UNITED STATES

MARCH 14, 2024

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

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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 2023".

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

(a) ESTABLISHMENT.—Subject to subsection (f), beginning not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish and implement a 3-year nationwide demonstration project under part B of title XVIII of the Social Security Act to evaluate the benefits of providing a shared savings payment for biosimilar biological products furnished under such part.

(b) PARTICIPATION.—

(1) IN GENERAL.—Participation under the demonstration project shall be voluntary, and a participating provider may terminate participation at any time and the Secretary may terminate the participation of such a provider at any time.

(2) APPLICATION AND SELECTION.—To participate under the demonstration project, an eligible provider shall submit to the Secretary an application in such form and manner and containing such information as specified by the Secretary. Each eligible provider who submits such an application shall be selected by the Secretary for participation under the demonstration project.

3

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
12 product is covered under part B of title XVIII of the So-
13 cial Security Act and such payment shall be made in the
14 same manner as payment is provided for such a product
15 under 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).

1 (f) ENSURING NO INCREASE IN MEDICARE EXPEND-

2 ITURES.—The Secretary may not implement the dem-

3 onstration project described in subsection (a) unless the

4 Chief Actuary of the Centers for Medicare & Medicaid

5 Services certifies that implementation of such model will

6 not result in an increase in expenditures under title XVIII

7 of the Social Security Act (42 U.S.C. 1395 et seq.).

8 (g) REPORTS.—

9 (1) INTERIM EVALUATION AND REPORT.—Not

10 later than 3 years after the date of enactment of

11 this Act, the Secretary shall submit to Congress a

12 report that contains an analysis of the appropriate-

13 ness of expanding or extending the demonstration

14 project and, to the extent such analysis determines

15 such an expansion or extension appropriate, rec-

16 ommendations for such expansion or extension, re-

17 spectively.

18 (2) FINAL EVALUATION AND REPORT.—Not

19 later than one year after the date of completion of

20 the demonstration project, the Secretary shall sub-

21 mit to Congress a report that contains a final anal-

22 ysis of the project and recommendations described in

23 paragraph (1).

24 (h) DEFINITIONS.—In this section:

1 (1) DEMONSTRATION PROJECT.—The term
2 ''demonstration project'' means the demonstration
3 project conducted under this Act.

4 (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
5 term "biosimilar biological product" means a biologi-
6 cal product approved under an abbreviated applica-
7 tion for a license of a biological product that relies
8 in part on data or information in an application for
9 another biological product licensed under section 351
10 of the Public Health Service Act (42 U.S.C. 262).

11 (3) ELIGIBLE PROVIDER.—The term "eligible
12 provider" means a provider of services or supplier
13 that is eligible to receive payment under part B of
14 title XVIII of the Social Security Act for furnishing
15 or dispensing biosimilar biological products.

16 (4) MEDICARE BENEFICIARY.—The term
17 ''Medicare beneficiary'' means an individual who is
18 enrolled for benefits under part B of title XVIII of
19 the Social Security Act.

20 (5) PARTICIPATING PROVIDER.—The term
21 ''participating provider'' means an eligible provider
22 that has been selected for participation under the
23 project under subsection (b)(2) and with respect to
24 whom such participation has not been terminated.

1   (6) REFERENCE BIOLOGICAL PRODUCT.—The
2   term ''reference biological product'' means the bio-
3   logical product licensed under section 351 of the
4   Public Health Service Act (42 U.S.C. 262) that is
5   referred to in the application described in paragraph
6   (2) of the biosimilar biological product.

7 **SEC. 3. EXTENDING ELIGIBILITY FOR CERTAIN PAYMENT**
8   **INCREASES FOR BIOSIMILAR BIOLOGICAL**
9   **PRODUCTS UNDER THE MEDICARE PRO-**
10   **GRAM.**

11   Section 1847A(b)(8)(B)(ii)(II) of the Social Security
12 Act (42 U.S.C. 1395w–3a(b)(8)(B)(ii)(II)) is amended by
13 striking ''2027'' and inserting ''2032''.

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