117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Increasing Access to Biosimilars Act of 2021''.

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

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

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

(b) PARTICIPATION.—

(1) IN GENERAL.—Participation in 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 for failure to comply with the requirements of the demonstration project.

(2) APPLICATION AND SELECTION.—To participate in 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) PARTICIPATION IN INNOVATION CENTER MODELS.—Participation in the demonstration project shall not preclude an eligible provider from also participating in any model authorized under section 1115A of the Social Security Act (42 U.S.C. 1315a), including the Oncology Care Model and the Oncology Care First Model, or impact metrics or expenditures with respect to an eligible provider under any model authorized under such section.

(c) COVERAGE.—Except as otherwise provided in this section, payment may be made under the demonstration project for a biosimilar biological product only if such product is covered under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) and such payment shall be made in the same manner as payment is provided for such a product under such part.

(d) ADDITIONAL PAYMENT.—

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

determined by the Secretary, that reflects a portion of any difference between such amount of payment under such part, as compared to the amount of payment that would have been made under such part if the reference biological product had been furnished or dispensed to the beneficiary.

(2) MEDICARE BENEFICIARY COINSURANCE LIABILITY.—The additional payment provided under paragraph (1) shall not be taken into account when determining the amount of coinsurance under section 1833(a)(1)(S) of the Social Security Act (42 U.S.C. 1395l(a)(1)(S)) for a biosimilar biological product furnished or dispensed to a Medicare beneficiary by a participating provider under the demonstration project. The Secretary may use a portion of the difference described in such paragraph to waive or reduce the amount of coinsurance otherwise applicable under such section for such a biosimilar biological.

(3) EXCEPTION TO ADDITIONAL PAYMENT.—A participating provider may only receive the additional payment described in paragraph (1) with respect to a biosimilar biological product furnished or dispensed by the participating provider to a Medicare beneficiary under the demonstration project, if

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

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

(f) DATA COLLECTION.—

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

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

(g) REPORTS.—

(1) INTERIM EVALUATION AND REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to Congress a 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.

(4) MEDICARE BENEFICIARY.—The term ''Medicare beneficiary'' means an individual who is enrolled for benefits under such part.

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

(6) REFERENCE BIOLOGICAL PRODUCT.—The term ''reference biological product'' has the meaning given that term in section 1847A(c)(6)(I) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(I)).

(7) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.