AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 1352

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Increasing Access to 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) CLARIFICATION.—Participation under the demonstration project shall not preclude eligible providers 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 Oncology Care First Model, or impact eligible providers metrics or expenditures within other models authorized under such section.

(c) COVERAGE.—Except as otherwise provided in this section, payment may be made under the demonstration project for a biosimlar biological product only if such product is covered under part B of title XVIII of the Social Security Act 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.—Under the demonstration project, subject to paragraph (3), in addition to the payment that would otherwise be made under part B of title XVIII of the Social Security Act for a biosimilar biological product furnished or dispensed by a participating provider to a Medicare beneficiary, there shall be made an additional payment, in an amount determined by the Secretary, that is based on the difference, if any, (or portion of such difference) between the costs to the provider in furnishing the biosimilar biological product and the costs to the provider if the provider had furnished the reference biological product.

(2) NO INCREASE TO MEDICARE COINSURANCE.—The additional payment described under paragraph (1) shall not increase a Medicare beneficiary's cost-sharing liability, as described in section 1833 of the Social Security Act (42 U.S.C. 1395l).

(3) EXCEPTION.—An eligible provider may only receive the additional payment described in paragraph (1), with respect to a biosimilar biological product, if the payment amount under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) for such product is less than the pay-

ment amount under part B of title XVIII of such Act for the reference biological product.

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

(f) ENSURING NO INCREASE IN MEDICARE EXPENDITURES.—The Secretary may not implement the demonstration project described in subsection (a) unless the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that implementation of such model will not result in an increase in expenditures under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(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 appropriateness of expanding or extending the demonstration project and, to the extent such analysis determines such an expansion or extension appropriate, rec-

ommendations for such expansion or extension, respectively.

(2) FINAL EVALUATION AND REPORT.—Not later than one 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) DEMONSTRATION PROJECT.—The term ''demonstration project'' means the demonstration project conducted under this Act.

(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term ''biosimilar biological product'' means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(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 for furnishing or dispensing biosimilar biological products.

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

(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'' means the biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) that is referred to in the application described in paragraph (2) of the biosimilar biological product.

☒