II

116TH CONGRESS
2D SESSION

S. 3466

To amend title XVIII of the Social Security Act to eliminate cost sharing for biosimilar biological products furnished under part B of the Medicare program during the first 5 years such products are marketed.

IN THE SENATE OF THE UNITED STATES

MARCH 12, 2020

Ms. MCSALLY (for herself and Mr. JONES) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend title XVIII of the Social Security Act to eliminate cost sharing for biosimilar biological products furnished under part B of the Medicare program during the first 5 years such products are marketed.

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 ''Acting to Cancel Copays and Ensure Substantial Savings for Biosimilars Act of 2020'' or the ''ACCESS for Biosimilars Act of 2020''.

SEC. 2. ELIMINATING COST SHARING FOR BIOSIMILAR BIOLOGICAL PRODUCTS FURNISHED UNDER PART B OF THE MEDICARE PROGRAM.

Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)(1)(S), by inserting ''(or, in the case of such a biological that is a specified biosimilar biological product (as defined in subsection (cc)) furnished during a year (beginning with 2021) to an individual who is a cost-sharing reduction eligible individual (as defined in such subsection) with respect to such year, 100 percent)'' after ''80 percent''; and

(2) by adding at the end the following new subsection:

''(cc) SPECIFIED BIOSIMILAR BIOLOGICAL PRODUCT REDUCED COST-SHARING PROVISIONS.—

''(1) DEFINITIONS.—

''(A) COST-SHARING REDUCTION ELIGIBLE INDIVIDUAL DEFINED.—For purposes of subsection (a)(1)(S) and with respect to a year, the term 'cost-sharing reduction eligible individual' means an individual who, as of January 1 of such year—

''(i) is enrolled under this part; and

"(ii) does not have qualifying coverage (as defined in subparagraph (B)).

"(B) QUALIFYING COVERAGE.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the term 'qualifying coverage' means, with respect to an individual, coverage—

"(I) under—

"(aa) a group health plan or health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act);

"(bb) a Federal health care program (as defined in section 1128B(f)), other than the program established under this title;

"(cc) the health insurance program under chapter 89 of title 5, United States Code;

"(dd) a medicare supplemental policy under section 1882; or

"(ee) an MA or MA–PD plan; and

"(II) that meets—

"(aa) in the case of coverage described in any of items (aa) through (dd) of subclause (I), the condition described in clause (ii); and

"(bb) in the case of coverage described in item (ee) of subclause (I), the condition described in clause (iii).

"(ii) CONDITION FOR COVERAGE OTHER THAN PART C COVERAGE.—For purposes of clause (i)(II)(aa), the condition described in this clause, with respect to an individual enrolled in coverage described in any of items (aa) through (dd) of clause (i)(I) during a year, is that such coverage provides for the payment of all cost sharing owed by such individual under this part (or, if applicable, under an MA or MA–PD plan) with respect to a specified biosimilar biological product (as defined in subparagraph (C)) furnished under this part (or, if applicable, under an MA or MA–PD plan) during such year, not taking

into account the application of any deductible under such coverage.

"(iii) CONDITION FOR PART C COVERAGE.—For purposes of clause (i)(II)(bb), the condition described in this clause, with respect to an individual enrolled in an MA or MA–PD plan during a year, is that such plan provides for no cost sharing for such individual with respect to a specified biological biosimilar product (as defined in subparagraph (C)) furnished under such plan during such year.

"(C) SPECIFIED BIOSIMILAR BIOLOGICAL PRODUCT.—For purposes of subsection (a)(1)(S), the term 'specified biosimilar biological product' means a biosimilar biological product (as defined in subsection (c)(6) of section 1847A)—

"(i) for which the payment amount determined under subsection (b)(8) of such section for such product is less than the payment amount determined under subsection (b)(4) of such section for the reference biological product (as defined in subsection (c)(6) of such section); and

"(ii) that is furnished during the 5-year period beginning on the later of—

"(I) January 1, 2021; or

"(II) the date on which the biosimilar biological product is first marketed.

"(2) DETERMINATIONS.—The Secretary shall establish a process—

"(A) for determining whether an individual is a cost-sharing reduction eligible individual for a year; and

"(B) for notifying MA organizations of such a determination made with respect to an individual enrolled under an MA plan or MA–PD plan offered by such organization during such year.".

○