II

118TH CONGRESS
2D SESSION

S. 5459

To amend title XI of the Social Security Act to alter when biosimilar biological products are eligible for price negotiations under the Medicare program.

IN THE SENATE OF THE UNITED STATES

DECEMBER 9, 2024

Mrs. BLACKBURN introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XI of the Social Security Act to alter when biosimilar biological products are eligible for price negotiations 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 ''Biosimilars Access and Affordability Act''.

SEC. 2. CHANGE OF WHEN BIOSIMILARS ARE ELIGIBLE FOR PRICE NEGOTIATIONS.

(a) IN GENERAL.—Section 1192 of the Social Security Act (42 U.S.C. 1320f–1) is amended—

(1) in subsection (c)—

(A) in paragraph (1), in the matter before subparagraph (A), by striking ''beginning before the first year that begins at least 9 months after the date on which'' and inserting ''during the price applicability period, except that a drug shall no longer be a selected drug for a particular year if, before the first day of such year,'';

(B) in paragraph (2)—

(i) in subparagraph (b), by inserting ''or after the end of such negotiation period but before the first day of the initial price applicability year'' after ''such initial price applicability year''; and

(ii) in the flush matter following subparagraph (B), by inserting ''or any future publication of the maximum fair price under section 1195 or any application of such price'' after ''such negotiation period'';

(2) in subsection (f)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking ''an extended monopoly drug (as defined in section 1194(c)(4)''; and

(II) by striking ''before the date'' and inserting ''on or before December 31 of the year'';

(ii) in subparagraph (B)—

(I) in the heading, by striking ''REQUEST REQUIRED'' and inserting ''PROCEDURES'';

(II) by redesignating clauses (i) and (ii) as clauses (ii) and (iii) respectively;

(III) by inserting before clause (ii) (as so redesignated) the following:

''(i) AUTOMATIC DELAY.—The Secretary shall apply, with respect to a biological product described in subparagraph (A), the rules described in subparagraph (A) of paragraph (2) (subject to subparagraphs (B) and (C) of such paragraph) if, prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product

may have been included as a selected drug on such list but for paragraph (2)(A), the manufacturer of a biosimilar biological product for which such biological product will be the reference product has publicly disclosed in a press release or other communication, or the Secretary determines from information from any other source—

"(I) that such manufacturer's application for licensure under section 351(k) of the Public Health Service Act for the biosimilar biological product was accepted for review or approved by the Food and Drug Administration;

"(II) that such manufacturer's clinical study of the biosimilar biological product as described in section 351(k)(2)(A)(i)(I)(cc) of the Public Health Service Act was initiated and remains ongoing; or

"(III) such manufacturer expects that the biosimilar biological product will be marketed on or before December 31 of the year that is 2 years

after the selected drug publication date with respect to such initial price applicability year.'';

(IV) in clause (ii) (as so redesignated)—

(aa) by striking subclause (II);

(bb) by striking ''IN GENERAL'' and all that follows through ''unless'' and inserting ''DELAY UPON REQUEST.— The Secretary shall provide for a delay under paragraph (2)(A) if''; and

(cc) by striking ''subparagraph (2)(A) or;'' and inserting ''paragraph (2)(A), provided that a determination of high likelihood is made under paragraph (3).''; and

(V) in clause (iii) (as so redesignated)—

(aa) in the heading, by inserting ''FOR A DELAY UPON REQUEST'' after ''DOCUMENTS'';

(bb) in subclause (I), in the matter before item (aa), by striking ''clause (i)'' and inserting ''clause (ii)''; and

(cc) in subclause (III)(bb), by striking ''year (or the 2 years, as applicable)'' and inserting ''applicable period''; and

(iii) in subparagraph (C)(i), by striking ''paragraph (2)(D)(iv)'' and inserting ''paragraph (2)(C)(iii)'';

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in the heading, by striking ''1 YEAR'' and inserting ''2 YEARS'';

(II) by inserting ''or paragraph (1)(B)(i) applies'' after ''under paragraph (3)''; and

(III) by striking ''1 year'' and inserting ''2 years'';

(ii) by striking subparagraph (B) and inserting the following:

''(B) IF NOT LICENSED AND MARKETED DURING THE DELAY.—If, during the time period between the selected drug publication date

on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A), and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(ii) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 351(k) of the Public Health Service Act—

''(i) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

''(ii) if such biosimilar biological product has not been licensed and marketed under section 351(k) of the Public Health Service Act on or before December 31 of the year that is 2 years after the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A), the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).'';

(iii) by striking subparagraph (C);

(iv) by redesignating subparagraph (D) as subparagraph (C); and

(v) in subparagraph (C) (as so redesignated)—

(I) by striking clause (ii);

(II) by redesignating clauses (iii) and (iv) as clauses (ii) and (iii), respectively;

(III) in clause (ii) (as so redesignated)—

(aa) in the heading, by striking ''1 YEAR'' and inserting ''2 YEARS''; and

(bb) by striking ''1 year has'' and inserting ''2 years have''; and

(IV) in clause (iii)(II) (as so redesignated), by striking ''paragraph (1)(B)(ii)(I)(bb)'' and inserting ''paragraph (1)(B)(iii)(I)(bb)'';

(C) by striking paragraph (3) and inserting the following:

''(3) HIGH LIKELIHOOD.—For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that information from items described in subclauses (I)(bb) and (III) of paragraph (1)(B)(iii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph or information submitted to the Secretary by any other party or otherwise available to the Secretary from any other source provides clear and convincing evidence that such biosimilar biological product will,

within the time period specified under paragraph (1)(A) be marketed.''; and

(D) in paragraph (4)—

(i) in subparagraph (A)—

(I) by striking ''subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2)'' and inserting ''paragraph (2)(B)(ii)''; and

(II) by inserting ''not earlier than January 1 of the year that is 3 years after the selected drug publication date of the list on which the biological product would have been included as a selected drug but for a delay under paragraph (2)(A)'' after ''at such time''; and

(ii) in subparagraph (B)—

(I) in clause (i), by striking subclause (I) and inserting the following:

''(I) 75 percent of the amount by which the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1927 (or, if not reported by such manufacturer under section 1927, as

reported by such manufacturer to the Secretary pursuant to the agreement under section 1193(a)) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds—

"(aa) for the initial price applicability year that would have applied but for a delay under paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

"(bb) for the second year of such delay and the remaining period of such delay ending on December 31 of the year that is 2 years after the selected drug publication date of the list on which the biological product would have been included as a selected drug but for a delay under paragraph

(2)(A), such maximum fair price, increased as described in section 1195(b)(1)(A); and''; and

(II) in clause (ii), by striking subclause (I) and inserting the following:

''(I) 80 percent of the amount by which the payment amount for such biological product under section 1847A(b), with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds—

''(aa) for the initial price applicability year that would have applied but for a delay under paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

''(bb) for the second year of such delay and the remaining period of such delay ending on December 31 of the year that is 2

years after the selected drug publication date of the list on which the biological product would have been included as a selected drug but for a delay under paragraph (2)(A), such maximum fair price, increased as described in section 1195(b)(1)(A); and''; and

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

''(g) DEFINITION OF MARKET.—In this section, the term 'market' means to introduce or deliver a drug or biological product (including a biosimilar biological product) for introduction into interstate commerce.''.

(b) CONFORMING AND TECHNICAL AMENDMENTS.—Such Act is amended—

(1) in section 1192(b)(3) (42 U.S.C. 1320f–1(b)(3)), by striking ''subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2)'' and inserting ''subsection (f)(2)(B)(ii)''; and

(2) in section 1198(2) (42 U.S.C. 1320f–7(2)), by striking ''1192(f),'' and inserting ''1192(f)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to initial price applica-

bility years beginning with initial price applicability year 2027.

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