118TH CONGRESS
2D SESSION

S. 5029

To amend title XI of the Social Security Act to establish a research and development-intensive small biotech manufacturer exception from the Medicare drug price negotiation program.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 12, 2024

Mr. CASSIDY 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 establish a research and development-intensive small biotech manufacturer exception from the Medicare drug price negotiation 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 ''Small Biotech Innovation Act''.

SEC. 2. RESEARCH AND DEVELOPMENT-INTENSIVE SMALL BIOTECH MANUFACTURER EXCEPTION FROM MEDICARE DRUG PRICE NEGOTIATION PROGRAM.

Section 1192(d)(2) of the Social Security Act (42 U.S.C. 1320f–1(d)(2)) is amended by adding at the end the following new subparagraph:

"(D) RESEARCH AND DEVELOPMENT-INTENSIVE SMALL BIOTECH MANUFACTURER EXCEPTION FOR 2029 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL.—With respect to initial price applicability years (beginning with initial price applicability year 2029), subject to the succeeding provisions of this subparagraph, the term 'negotiation eligible drug' shall not include a qualifying single source drug (as defined in subsection (e)) of a research and development-intensive small biotech manufacturer (as defined in clause (ii)).

"(ii) DEFINITIONS.—In this subparagraph:

"(I) APPLICABLE PERCENT.—The term 'applicable percent' means—

"(aa) in the case of a small biotech manufacturer that has 1 qualifying single source drug, 30 percent;

"(bb) in the case of a small biotech manufacturer that has 2 qualifying single source drugs, 40 percent;

"(cc) in the case of a small biotech manufacturer that has 3 qualifying single source drugs, 50 percent;

"(dd) in the case of a small biotech manufacturer that has 4 qualifying single source drugs, 60 percent; and

"(ee) in the case of a small biotech manufacturer that has 5 qualifying single source drugs, 70 percent.

"(II) SMALL BIOTECH MANUFACTURER DEFINED.—The term 'small biotech manufacturer' means a manufacturer that has 5 or less qualifying single source drugs.

"(III) RESEARCH AND DEVELOPMENT-INTENSIVE SMALL BIOTECH MANUFACTURER DEFINED.—The term 'research and development-intensive small biotech manufacturer' means a small biotech manufacturer that invests at least the applicable percent of their net revenue from the average of the previous three years in research and development (determined based on generally accepted accounting principles).

"(iii) TREATMENT IN CASE OF ACQUISITION.—A drug shall not be considered to be a qualifying single source drug of a research and development-intensive small biotech manufacturer if the manufacturer of such drug is acquired after 2029 by another manufacturer that does not meet the definition of a research and development-intensive small biotech manufacturer, effective at the beginning of the plan year immediately following such acquisition.

"(iv) ANNUAL APPLICATION.—In order for a qualifying single source drug of

a research and development-intensive small biotech manufacturer to be eligible for the exception under this subparagraph with respect to an initial price applicability year (beginning with initial price applicability year 2029), the manufacturer shall submit an application to the Secretary (at a time specified by the Secretary) containing—

''(I) information on the net product revenue and research and development expenditures of the manufacturer during the relevant time period;

''(II) a certification that the information submitted by the manufacturer under subclause (I) is accurate and complete to the best of the manufacturer's knowledge; and

''(III) such other information as the Secretary may specify.

''(v) DISPUTE RESOLUTION.—The Secretary shall develop a process under which a manufacturer may appeal a determination by the Secretary that the manufacturer is not a research and development-intensive small biotech manufacturer.

Such process shall conclude, with respect to a manufacturer, not later than the selected drug publication date with respect to the initial price applicability year for which the manufacturer submitted an application under clause (iv).''.

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