

118TH CONGRESS
2D SESSION

S. 5349

To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 20, 2024

Mr. YOUNG (for himself and Mr. PADILLA) 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 ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Ensuring Patient Ac-
5 cess to Critical Breakthrough Products Act of 2024”.

6 **SEC. 2. ENSURING PROMPT COVERAGE OF BREAK-**
7 **THROUGH DEVICES UNDER THE MEDICARE**
8 **PROGRAM.**

9 (a) ENSURING COVERAGE THROUGH A TRANSI-
10 TIONAL COVERAGE PERIOD.—

1 (1) IN GENERAL.—Section 1862(a)(1) of the
2 Social Security Act (42 U.S.C. 1395y(a)(1)) is
3 amended—

4 (A) in subparagraph (O), by striking
5 “and” at the end;

6 (B) in subparagraph (P), by adding “and”
7 at the end; and

8 (C) by inserting after subparagraph (P)
9 the following new subparagraph:

10 “(Q) in the case of a breakthrough device (as
11 defined in section 1861(nnn)) furnished during the
12 transitional coverage period (as so defined) with re-
13 spect to such device, which is not furnished in ac-
14 cordance with the Food and Drug Administration-
15 approved labeling for such device or that the Sec-
16 retary determines, based on a review of clinical data,
17 presents an undue risk of harm that outweighs the
18 potential clinical benefits for individuals entitled to
19 benefits under part A or enrolled under part B;”.

20 (2) DEFINITIONS.—Section 1861 of the Social
21 Security Act (42 U.S.C. 1395x) is amended by add-
22 ing at the end the following new subsection:

23 “(nnn) BREAKTHROUGH DEVICE.—

1 “(1) IN GENERAL.—The term ‘breakthrough
2 device’ means a device so designated by the Sec-
3 retary under section 1899C.

4 “(2) TRANSITIONAL COVERAGE PERIOD.—The
5 term ‘transitional coverage period’ means, with re-
6 spect to a breakthrough device, the 4-year period
7 that begins on the date that such device is so des-
8 ignated by the Secretary under section 1899C.”.

9 (3) BREAKTHROUGH DEVICE DETERMINA-
10 TIONS.—Part E of title XVIII of the Social Security
11 Act (42 U.S.C. 1395x et seq.) is amended by adding
12 at the end the following new section:

13 **“SEC. 1899C. DESIGNATION OF BREAKTHROUGH DEVICES.**

14 “(a) IN GENERAL.—Beginning 18 months after the
15 date of the enactment of this section, upon application of
16 a manufacturer of a device (as defined in section 201 of
17 the Federal Food, Drug, and Cosmetic Act) that is
18 cleared, classified, or approved under section 510(k),
19 513(f)(2), or 515 of such Act on or after the date of the
20 enactment of this section, the Secretary shall designate
21 such device as a breakthrough device if the Secretary de-
22 termines that such device meets the criteria specified in
23 subsection (b).

24 “(b) CRITERIA.—For purposes of subsection (a), the
25 criteria specified in this subsection is, with respect to a

1 device, that the device is provided with priority review pur-
2 suant to section 515B of the Federal Food, Drug, and
3 Cosmetic Act.

4 “(c) DETERMINATION PROCESS.—

5 “(1) IN GENERAL.—The Secretary shall make a
6 determination with respect to a device that is the
7 subject of an application described in subsection (a)
8 not later than 6 months after such application is
9 submitted to the Secretary.

10 “(2) EXPLANATION REQUIRED IN CASE OF DE-
11 TERMINATION THAT DEVICE DOES NOT MEET CRI-
12 TERIA FOR DESIGNATION.—In the case that the Sec-
13 retary determines that a device that is the subject
14 of an application described in subsection (a) does
15 not meet the criteria specified in subsection (b), the
16 Secretary shall notify the manufacturer of such de-
17 vice of such determination and include in such noti-
18 fication an explanation identifying the specific cri-
19 terion or criteria that such device failed to meet.

20 “(d) REPORTS.—The Secretary shall submit to Con-
21 gress on an annual basis a report specifying—

22 “(1) the number of applications received under
23 this section during such year;

1 “(2) the number of devices designated as break-
 2 through devices under this section during such year;
 3 and

4 “(3) the number of applications for a designa-
 5 tion for a device under this section with respect to
 6 which the Secretary determined that such device did
 7 not meet the criteria specified in subsection (b) dur-
 8 ing such year.”.

9 (b) ENSURING ISSUANCE OF NATIONAL COVERAGE
 10 DETERMINATION DURING TRANSITION PERIOD.—Section
 11 1862(l)(2) of the Social Security Act (42 U.S.C.
 12 1395y(l)(2)) is amended by adding at the end the fol-
 13 lowing new flush sentence:

14 “In the case of a request for a national coverage de-
 15 termination with respect to a breakthrough device
 16 (as defined in section 1861(nnn)), the Secretary
 17 shall ensure that a final decision is made on such re-
 18 quest prior to the end of the transitional coverage
 19 period (as so defined) for such device if such request
 20 was submitted to the Secretary before the date that
 21 is 9 months (or 12 months, in the case such request
 22 is a request to which subparagraph (B) applies) be-
 23 fore the last day of such period.”.

24 (c) FUNDING.—In addition to amounts otherwise
 25 available, there are appropriated to the Centers for Medi-

1 care & Medicaid Services Program Management Account,
2 out of any monies in the Treasury not otherwise appro-
3 priated, \$10,000,000 for each of fiscal years 2025 through
4 2030, to remain available until expended, to carry out the
5 amendments made by this section.

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