

[DISCUSSION DRAFT]

119TH CONGRESS
1ST SESSION

H. R. _____

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 HOUSE OF REPRESENTATIVES

M____. _____ introduced the following bill; which was referred to the
Committee on _____

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 2025”.

1 **SEC. 2. ENSURING PROMPT COVERAGE OF BREAK-**
2 **THROUGH DEVICES UNDER THE MEDICARE**
3 **PROGRAM.**

4 (a) ENSURING COVERAGE THROUGH A TRANSI-
5 TIONAL COVERAGE PERIOD.—

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

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

11 (B) in subparagraph (P), by striking the
12 semicolon at the end and inserting “, and”; and

13 (C) by inserting after subparagraph (P)
14 the following new subparagraph:

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

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

4 “(nnn) BREAKTHROUGH DEVICE.—

5 “(1) IN GENERAL.—The term ‘breakthrough
6 device’ means a device so designated by the Sec-
7 retary under section 1899D.

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

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

17 **“SEC. 1899D. DESIGNATION OF BREAKTHROUGH DEVICES.**

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

1 terminates that such device meets the criterion specified in
2 subsection (b).

3 “(b) CRITERION.—For purposes of subsection (a),
4 the criterion specified in this subsection is, with respect
5 to a device, that the device is provided with priority review
6 pursuant to section 515B of the Federal Food, Drug, and
7 Cosmetic Act.

8 “(c) DETERMINATION PROCESS.—

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

14 “(2) NOTIFICATION REQUIRED IN CASE OF DE-
15 TERMINATION THAT DEVICE DOES NOT MEET CRI-
16 TERION FOR DESIGNATION.—In the case that the
17 Secretary determines that a device that is the sub-
18 ject of an application described in subsection (a)
19 does not meet the criterion specified in subsection
20 (b), the Secretary shall notify the manufacturer of
21 such device of such determination.

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

24 “(1) the number of applications received under
25 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 criterion specified in subsection (b)
8 during 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 2026 through
4 2031, to remain available until expended, to carry out the
5 amendments made by this section.