

119TH CONGRESS  
1ST SESSION

# H. R. 5343

To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 2025

Mr. MOORE of Utah (for himself, Ms. DELBENE, Mr. YAKYM, Ms. SEWELL, Mr. BILIRAKIS, and Mrs. TRAHAN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program.

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”.

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 adding “and”  
12 at the end; 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 for the  
19 diagnosis or treatment of illness or injury or to im-  
20 prove the functioning of a malformed body member  
21 in accordance with the Food and Drug Administra-  
22 tion-approved labeling for such device and for the in-  
23 dication for which such device was provided priority  
24 review under section 515B of the Federal Food,  
25 Drug, and Cosmetic Act, or that the Secretary finds,  
26 based on a review of clinical data, presents an undue

1 risk of harm that outweighs the potential clinical  
2 benefits for individuals entitled to benefits under  
3 part A or enrolled under part B;”.

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

7 “(nnn) BREAKTHROUGH DEVICE.—

8 “(1) IN GENERAL.—The term ‘breakthrough  
9 device’ means a device that—

10 “(A) is so designated by the Secretary  
11 under section 1899D; and

12 “(B) is furnished at such frequency as  
13 specified in the Food and Drug Administration-  
14 approved labeling for such device (or, in the  
15 case such device has no frequency so specified,  
16 at such frequency as determined appropriate by  
17 the Secretary).

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

23 (3) BREAKTHROUGH DEVICE DETERMINA-  
24 TIONS.—Part E of title XVIII of the Social Security

1 Act (42 U.S.C. 1395x et seq.) is amended by adding  
2 at the end the following new section:

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

4 “(a) IN GENERAL.—Beginning 18 months after the  
5 date of the enactment of this section, upon application of  
6 a manufacturer of a device (as defined in section 201 of  
7 the Federal Food, Drug, and Cosmetic Act) that is  
8 cleared, classified, or approved under section 510(k),  
9 513(f)(2), or 515 of such Act on or after the date of the  
10 enactment of this section, the Secretary shall designate  
11 such device as a breakthrough device if the Secretary de-  
12 termines that such device meets the criteria specified in  
13 subsection (b).

14 “(b) CRITERIA.—For purposes of subsection (a), the  
15 criteria specified in this subsection are, with respect to a  
16 device, the following:

17 “(1) The device is provided with priority review  
18 pursuant to section 515B of the Federal Food,  
19 Drug, and Cosmetic Act.

20 “(2) In the case such device is cleared under  
21 section 510(k) of such Act, such device is so cleared  
22 based on clinical data, which may include clinical  
23 trial information from an applicable device clinical  
24 trial (as such terms are defined in section 402(j) of

1 such Act), that included individuals entitled to bene-  
2 fits under part A or enrolled under part B.

3 “(3) The device would, without application of  
4 section 1862(a), otherwise be covered under part A  
5 or B.

6 “(4) The device does not, based on a review of  
7 clinical data, present an undue risk of harm that  
8 outweighs the potential clinical benefits for individ-  
9 uals entitled to benefits under part A or enrolled  
10 under part B, as determined by the Secretary.

11 “(c) DETERMINATION PROCESS.—

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

17 “(2) EXPLANATION REQUIRED IN CASE OF  
18 NONDESIGNATION.—With respect to a device that is  
19 the subject of an application described in subsection  
20 (a), in the case that the Secretary determines that  
21 such device does not meet the criteria specified in  
22 subsection (b), the Secretary shall notify the manu-  
23 facturer of such device of such determination and in-  
24 clude in such notification an identification of the  
25 specific criterion or criteria that such device failed to

1 meet and an explanation of why such device failed  
2 to meet such criterion or criteria.

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

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

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

10 “(3) the number of applications for a designa-  
11 tion for a device under this section with respect to  
12 which the Secretary determined that such device did  
13 not meet the criteria specified in subsection (b) dur-  
14 ing such year.

15 “(e) REVIEW OF ABERRANT BILLING.—The Sec-  
16 retary may conduct a review of the medical necessity and  
17 reasonableness of a breakthrough device furnished by a  
18 provider of service or supplier that the Secretary deter-  
19 mines has an aberrant billing pattern with respect to such  
20 a device or otherwise is an outlier with respect to the fur-  
21 nishing of such device compared to similarly situated pro-  
22 viders of services and suppliers.”.

23 (b) ENSURING ISSUANCE OF NATIONAL COVERAGE  
24 DETERMINATION DURING TRANSITION PERIOD.—Section  
25 1862(l)(2) of the Social Security Act (42 U.S.C.

1 1395y(1)(2)) is amended by adding at the end the fol-  
2 lowing new flush sentence:

3 “In the case of a request for a national coverage de-  
4 termination with respect to a breakthrough device  
5 (as defined in section 1861(nnn)), the Secretary  
6 shall ensure that a final decision is made on such re-  
7 quest (or determine that such device is otherwise  
8 covered under this title) prior to the end of the tran-  
9 sitional coverage period (as so defined) for such de-  
10 vice if such request was submitted to the Secretary  
11 before the date that is 9 months (or 12 months, in  
12 the case such request is a request to which subpara-  
13 graph (B) applies) before the last day of such pe-  
14 riod.”.

15 (c) FUNDING.—In addition to amounts otherwise  
16 available, there are appropriated to the Centers for Medi-  
17 care & Medicaid Services Program Management Account,  
18 out of any monies in the Treasury not otherwise appro-  
19 priated, \$10,000,000 for each of fiscal years 2025 through  
20 2030, to remain available until expended, to carry out the  
21 amendments made by this section.

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