

# Union Calendar No. 801

118TH CONGRESS  
2D SESSION

# H. R. 1691

**[Report No. 118–952, Part I]**

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

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 22, 2023

Mr. WENSTRUP (for himself, Ms. DELBENE, Mr. BILIRAKIS, Mr. CÁRDENAS, Mr. MOORE of Utah, Ms. SEWELL, Mr. GUTHRIE, and Ms. ESHOO) 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

DECEMBER 24, 2024

Additional sponsors: Mr. JOYCE of Pennsylvania, Ms. KUSTER, Mr. CRENSHAW, Mr. KILMER, Mrs. MILLER of West Virginia, Ms. CRAIG, Mrs. STEEL, Ms. DEAN of Pennsylvania, Mr. BACON, Mr. PETERS, Mr. BALDERSON, Mr. AUCHINCLOSS, Mr. CURTIS, Ms. HOULAHAN, Mr. BUCSHON, Mr. FITZPATRICK, Mr. YAKYM, Ms. LOFGREN, Ms. SCHRIER, Mrs. TRAHAN, Mr. LIEU, Mr. MCGOVERN, Mr. BOYLE of Pennsylvania, Ms. WILD, Mr. BERA, Mr. CORREA, Ms. PORTER, Mr. SWALWELL, Mr. CISCOMANI, Mr. FERGUSON, Mr. CAREY, Mr. SIMPSON, Mrs. KIM of California, Mr. PAPPAS, Mr. BURGESS, Mrs. MILLER-MEEKS, Ms. SCANLON, Mr. PANETTA, Mr. DUNN of Florida, Mr. MULLIN, Ms. ROSS, Mr. KELLY of Pennsylvania, Ms. DEGETTE, Ms. LEE of Florida, Mr. GOTTHEIMER, Mr. PHILLIPS, Ms. TENNEY, Mr. BARR, Mr. KEAN of New Jersey, Mr. NEGUSE, Mr. PENCE, Mrs. FISCHBACH, Mr. MAST, Mr. JOHNSON of Ohio, Mr. LANGWORTHY, Ms. VAN DUYN, Ms. PETERSEN, Mr. FINSTAD, Mr. LAHOOD, Mr. SCHNEIDER, Mr. OWENS, Mr. SMUCKER, Mr. THOMPSON of Pennsylvania, Ms. CARAVEO, Mr. RUTHERFORD, Mr. CROW, Mr. WESTERMAN, Mr. ARMSTRONG, Mr. COHEN, Mr. SOTO, Mr. CARTER of Georgia, Mr. NICKEL, Mr. OBERNOLTE, Mr. SMITH of Nebraska, Mr. JAMES, Ms. MALOY, Ms.

BARRAGÁN, Mr. DAVIS of North Carolina, Ms. SLOTKIN, Mr. DAVIS of Illinois, Ms. STRICKLAND, and Ms. STEVENS

DECEMBER 24, 2024

Reported from the Committee on Ways and Means with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

DECEMBER 24, 2024

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on March 22, 2023]

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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, 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 Access*  
5 *to Critical Breakthrough Products Act of 2024”.*

6 **SEC. 2. ENSURING PROMPT COVERAGE OF BREAKTHROUGH**  
7 **DEVICES UNDER THE MEDICARE PROGRAM.**

8 *(a) ENSURING COVERAGE THROUGH A TRANSITIONAL*  
9 *COVERAGE PERIOD.—*

10 *(1) IN GENERAL.—Section 1862(a)(1) of the So-*  
11 *cial Security Act (42 U.S.C. 1395y(a)(1)) is amend-*  
12 *ed—*

13 *(A) in subparagraph (O), by striking “and”*  
14 *at the end;*

15 *(B) in subparagraph (P), by adding “and”*  
16 *at the end; and*

17 *(C) by inserting after subparagraph (P) the*  
18 *following new subparagraph:*

19 *“(Q) in the case of a breakthrough device (as de-*  
20 *fined in section 1861(nnn)) furnished during the*  
21 *transitional coverage period (as so defined) with re-*  
22 *spect to such device, which is not furnished in accord-*  
23 *ance with the Food and Drug Administration-ap-*  
24 *proved labeling for such device or that the Secretary*  
25 *determines, based on a review of clinical data, pre-*

1        *sents an undue risk of harm that outweighs the poten-*  
 2        *tial clinical benefits for individuals entitled to bene-*  
 3        *fits under 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 adding*  
 6        *at the end the following new subsection:*

7        *“(nnn) BREAKTHROUGH DEVICE.—*

8            *“(1) IN GENERAL.—The term ‘breakthrough de-*  
 9        *vice’ means a device so designated by the Secretary*  
 10        *under section 1899C.*

11            *“(2) TRANSITIONAL COVERAGE PERIOD.—The*  
 12        *term ‘transitional coverage period’ means, with re-*  
 13        *spect to a breakthrough device, the 4-year period that*  
 14        *begins on the date that such device is so designated*  
 15        *by the Secretary under section 1899C.”.*

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

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

21        *“(a) IN GENERAL.—Beginning 18 months after the*  
 22        *date of the enactment of this section, upon application of*  
 23        *a manufacturer of a device (as defined in section 201 of*  
 24        *the Federal Food, Drug, and Cosmetic Act) that is cleared,*  
 25        *classified, or approved under section 510(k), 513(f)(2), or*

1 515 of such Act on or after the date of the enactment of  
2 this section, the Secretary shall designate such device as a  
3 breakthrough device if the Secretary determines that such  
4 device meets the criteria specified in subsection (b).

5 “(b) *CRITERIA.*—For purposes of subsection (a), the  
6 criteria specified in this subsection are, with respect to a  
7 device, the following:

8 “(1) *The device is provided with priority review*  
9 *pursuant to section 515B of the Federal Food, Drug,*  
10 *and Cosmetic Act.*

11 “(2) *In the case such device is cleared under sec-*  
12 *tion 510(k) of such Act, such device is so cleared based*  
13 *on clinical trial information from an applicable de-*  
14 *vice clinical trial (as such terms are defined in sec-*  
15 *tion 402(j) of such Act) that enrolled individuals enti-*  
16 *tled to benefits under part A or enrolled under part*  
17 *B.*

18 “(3) *The device is not a clinical diagnostic lab-*  
19 *oratory test.*

20 “(c) *DETERMINATION PROCESS.*—

21 “(1) *IN GENERAL.*—The Secretary shall make a  
22 determination with respect to a device that is the sub-  
23 ject of an application described in subsection (a) not  
24 later than 6 months after such application is sub-  
25 mitted to the Secretary.

1           “(2) *EXPLANATION REQUIRED IN CASE OF DE-*  
2           *TERMINATION THAT DEVICE DOES NOT MEET CRI-*  
3           *TERIA FOR DESIGNATION.*—*In the case that the Sec-*  
4           *retary determines that a device that is the subject of*  
5           *an application described in subsection (a) does not*  
6           *meet the criteria specified in subsection (b), the Sec-*  
7           *retary shall notify the manufacturer of such device of*  
8           *such determination and include in such notification*  
9           *an explanation identifying the specific criterion or*  
10          *criteria that such device failed to meet.*

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

13                 “(1) *the number of applications received under*  
14                 *this section during such year;*

15                 “(2) *the number of devices designated as break-*  
16                 *through devices under this section during such year;*  
17                 *and*

18                 “(3) *the number of applications for a designa-*  
19                 *tion for a device under this section with respect to*  
20                 *which the Secretary determined that such device did*  
21                 *not meet the criteria specified in subsection (b) dur-*  
22                 *ing such year.”.*

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

1 1395y(l)(2)) is amended by adding at the end the following  
2 new flush sentence:

3 “In the case of a request for a national coverage de-  
4 termination with respect to a breakthrough device (as  
5 defined in section 1861(nnn)), the Secretary shall en-  
6 sure that a final decision is made on such request  
7 prior to the end of the transitional coverage period  
8 (as so defined) for such device if such request was sub-  
9 mitted to the Secretary before the date that is 9  
10 months (or 12 months, in the case such request is a  
11 request to which subparagraph (B) applies) before the  
12 last day of such period.”.

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

Union Calendar No. 801

118<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

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