

116TH CONGRESS  
2D SESSION

# H. R. 8467

To amend titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to provide for coverage of certain drugs used in the treatment or management of a rare disease or condition, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 30, 2020

Mr. THOMPSON of California (for himself and Mr. KELLY of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to provide for coverage of certain drugs used in the treatment or management of a rare disease or condition, 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 “Access to Rare Indica-  
5       tions Act of 2020”.

1 **SEC. 2. COVERAGE OF CERTAIN DRUGS USED IN TREAT-**  
2 **MENT OR MANAGEMENT OF RARE DISEASE**  
3 **OR CONDITION.**

4 (a) **MEDICARE.**—

5 (1) **IN GENERAL.**—Section 1861(t)(2) of the  
6 Social Security Act (42 U.S.C. 1395x(t)(2)) is  
7 amended—

8 (A) in subparagraph (A), by inserting after  
9 “regimen” the following: “, or in the treatment  
10 or management of a disease or condition affect-  
11 ing 200,000 or fewer individuals in the United  
12 States,”; and

13 (B) in subparagraph (B)(ii)—

14 (i) in subclause (I), by striking “, or”  
15 at the end and inserting a semicolon;

16 (ii) in subclause (II), by striking the  
17 period at the end and inserting “; or”; and

18 (iii) by adding at the end the fol-  
19 lowing new subclause:

20 “(III) in the case that the drug is used in the  
21 treatment or management of a disease or condition  
22 affecting 200,000 or fewer individuals in the United  
23 States, such use is supported by peer-reviewed lit-  
24 erature, clinical guidelines, or expert opinion within  
25 the National Institutes of Health Rare Diseases

1 Clinical Research Network consortia or its partici-  
2 pating clinical centers.”.

3 (2) PROHIBITION OF COVERAGE EXCLUSIONS  
4 FOR FORMULARIES UNDER MEDICARE PART D.—Sec-  
5 tion 1860D–4(b)(3) of the Social Security Act (42  
6 U.S.C. 1395w–104(b)(3)) is amended by adding at  
7 the end the following new subparagraph:

8 “(I) PROHIBITION OF CERTAIN COVERAGE  
9 EXCLUSIONS.—

10 “(i) IN GENERAL.—If the PDP spon-  
11 sor of a prescription drug plan uses a for-  
12 mulary, such sponsor may not impose a  
13 limitation or exclusion of benefits with re-  
14 spect to coverage of a rare disease covered  
15 part D drug (as defined in clause (ii)) in-  
16 cluded in such formulary.

17 “(ii) RARE DISEASE COVERED PART D  
18 DRUG.—For purposes of this subpara-  
19 graph, the term ‘rare disease covered part  
20 D drug’ means a covered part D drug—

21 “(I) used in the treatment or  
22 management of a disease or condition  
23 affecting 200,000 or fewer individuals  
24 in the United States; and

1                   “(II) the use of which is sup-  
2                   ported by peer-reviewed literature,  
3                   clinical guidelines, or expert opinion  
4                   within the National Institutes of  
5                   Health Rare Diseases Clinical Re-  
6                   search Network consortia or its par-  
7                   ticipating clinical centers.”.

8                   (3) EFFECTIVE DATE.—The amendments made  
9                   by this subsection apply with respect to items and  
10                  services furnished on or after the date that is 30  
11                  days after the date of the enactment of this Act.

12                  (b) MEDICAID.—

13                  (1) IN GENERAL.—Section 1927(k)(6) of the  
14                  Social Security Act (42 U.S.C. 1396r–8(k)(6)) is  
15                  amended—

16                         (A) by striking “, or” and inserting a  
17                         comma; and

18                         (B) by inserting before the period the fol-  
19                         lowing: “, or the use of which is related to the  
20                         treatment or management of a disease or condi-  
21                         tion affecting 200,000 or fewer individuals in  
22                         the United States and is supported by peer-re-  
23                         viewed literature, clinical guidelines, or expert  
24                         opinion within the National Institutes of Health

1 Rare Diseases Clinical Research Network con-  
2 sortia or its participating clinical centers”.

3 (2) PROHIBITION OF COVERAGE EXCLUSIONS  
4 FOR FORMULARIES.—Section 1927(d)(4) of the So-  
5 cial Security Act (42 U.S.C. 1396r–8(d)(4)) is  
6 amended—

7 (A) in subparagraph (C), by striking “A  
8 covered outpatient drug” and inserting “Sub-  
9 ject to subparagraph (E), a covered outpatient  
10 drug”;

11 (B) by redesignating subparagraph (E) as  
12 subparagraph (F); and

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

15 “(E) Notwithstanding subparagraph (C),  
16 the State may not impose a limitation or exclu-  
17 sion of benefits with respect to coverage of a  
18 covered outpatient drug that is—

19 “(i) used in the treatment or manage-  
20 ment of a disease or condition affecting  
21 200,000 or fewer individuals in the United  
22 States; and

23 “(ii) the use of which is supported by  
24 peer-reviewed literature, clinical guidelines,  
25 or expert opinion within the National Insti-

1           tutes of Health Rare Diseases Clinical Re-  
2           search Network consortia or its partici-  
3           pating clinical centers.”.

4           (3) EFFECTIVE DATE.—The amendments made  
5           by this subsection apply with respect to covered out-  
6           patient drugs furnished on or after the date that is  
7           30 days after the date of the enactment of this Act.

8           (c) PRIVATE HEALTH INSURANCE.—

9           (1) IN GENERAL.—Subpart II of part A of title  
10          XXVII of the Public Health Service Act (42 U.S.C.  
11          300gg–11 et seq.) is amended by adding at the end  
12          the following new section:

13         **“SEC. 2730. COVERAGE OF CERTAIN DRUGS USED IN TREAT-**  
14                         **MENT OR MANAGEMENT OF RARE DISEASE**  
15                         **OR CONDITION.**

16          “(a) IN GENERAL.—A group health plan or a health  
17          insurance issuer offering group or individual health insur-  
18          ance coverage shall provide coverage for a drug—

19                 “(1) approved by the Food and Drug Adminis-  
20                 tration;

21                 “(2) used in the treatment or management of  
22                 a disease or condition affecting 200,000 or fewer in-  
23                 dividuals in the United States; and

24                 “(3) the use of which is supported by peer-re-  
25                 viewed literature, clinical guidelines, or expert opin-

1 ion within the National Institutes of Health Rare  
2 Diseases Clinical Research Network consortia or its  
3 participating clinical centers.

4 “(b) PROHIBITION OF CERTAIN COVERAGE EXCLU-  
5 SIONS.—A group health plan or a health insurance issuer  
6 offering group or individual health insurance coverage  
7 may not impose a limitation or exclusion of benefits with  
8 respect to coverage of a drug described in subsection (a)  
9 other than a limitation or exclusion of benefits with re-  
10 spect to a use of such drug identified as contraindicated  
11 by the Food and Drug Administration.”.

12 (2) EFFECTIVE DATE.—The amendment made  
13 by this subsection applies with respect to plan years  
14 beginning on or after the date that is 30 days after  
15 the date of the enactment of this Act.

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