

117TH CONGRESS  
1ST SESSION

# H. R. 56

To amend the Orphan Drug Act with respect to the definition of medical food, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 4, 2021

Mr. BIGGS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Armed Services, 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 the Orphan Drug Act with respect to the definition of medical food, 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 “Patient Access to Med-  
5 ical Foods Act”.

1 **SEC. 2. DEFINITION OF MEDICAL FOOD FOR PURPOSES OF**  
2 **ORPHAN DRUG ACT.**

3 (a) IN GENERAL.—Section 5(b)(3) of the Orphan  
4 Drug Act (21 U.S.C. 360ee(b)(3)) is amended to read as  
5 follows:

6 “(3) The term ‘medical food’ means a food  
7 which—

8 “(A) is formulated to be consumed or ad-  
9 ministered enterally, including tube feeding and  
10 oral intake, and dispensed upon a written pre-  
11 scription of a practitioner licensed under the  
12 laws of the State in which such practitioner  
13 practices to administer drugs; and

14 “(B)(i) is intended for the specific dietary  
15 management of a disease or condition for which  
16 distinctive nutritional requirements, including  
17 conditions of inborn errors of metabolism, based  
18 on recognized scientific principles, are estab-  
19 lished by medical evaluation; or

20 “(ii) in the case of an individual for whom  
21 the prescribing physician determines the indi-  
22 vidual has failed on traditional therapies or de-  
23 termines continuing the traditional therapy is  
24 inappropriate for the patient due to  
25 comorbidities or severe side effects that endan-  
26 ger the health of the individual—

1 “(I) has been shown to provide clin-  
 2 ical benefit in well-controlled peer-reviewed  
 3 clinical trials to patients with a disease or  
 4 condition specified in clause (i); and

5 “(II) is determined by the prescribing  
 6 physician to be a safer therapeutic option  
 7 or the only effective clinical option for the  
 8 individual.”.

9 (b) NATIONAL DRUG CODE NUMBER.—Section 5 of  
 10 the Orphan Drug Act (21 U.S.C. 360ee) is amended—

11 (1) by redesignating subsection (c) as sub-  
 12 section (d); and

13 (2) by inserting after subsection (b) the fol-  
 14 lowing:

15 “(c) NATIONAL DRUG CODE NUMBER.—Medical  
 16 foods shall be eligible for a National Drug Code number.”.

17 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD**  
 18 **UNDER FEDERAL HEALTH PROGRAMS AND**  
 19 **PRIVATE HEALTH INSURANCE.**

20 (a) COVERAGE UNDER MEDICARE PROGRAM.—

21 (1) PART B COVERAGE.—

22 (A) IN GENERAL.—Section 1861(s)(2) of  
 23 the Social Security Act (42 U.S.C. 1395x(s)(2))  
 24 is amended—

1 (i) in subparagraph (GG), by striking  
2 “and” at the end;

3 (ii) in subparagraph (HH), by strik-  
4 ing the period at the end and inserting “;  
5 and”; and

6 (iii) by adding at the end the fol-  
7 lowing new subparagraph:

8 “(II) medically necessary food (as defined in  
9 subsection (kkk));”.

10 (B) DEFINITION.—Section 1861 of the So-  
11 cial Security Act (42 U.S.C. 1395x) is amended  
12 by adding at the end the following new sub-  
13 section:

14 “Medically Necessary Food  
15 “(kkk) The term ‘medically necessary food’ has the  
16 meaning given the term ‘medical food’ in section 5(b)(3)  
17 of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).”.

18 (C) PAYMENT.—Section 1833(a)(1) of the  
19 Social Security Act (42 U.S.C. 1395l(a)(1)) is  
20 amended—

21 (i) by striking “and” before “(DD)”;  
22 and

23 (ii) by inserting before the semicolon  
24 at the end the following: “, and (EE) with  
25 respect to medically necessary food (as de-

1           fined in section 1861(kkk)), the amount  
 2           paid shall be an amount equal to 80 per-  
 3           cent of the actual charge for the services.”.

4           (D) EFFECTIVE DATE.—The amendments  
 5           made by this paragraph shall apply to items  
 6           and services furnished on or after January 1,  
 7           2022.

8           (2) COVERAGE AS COVERED PART D DRUG.—

9           (A) IN GENERAL.—Section 1860D–2(e)(1)  
 10          of the Social Security Act (42 U.S.C. 1395w–  
 11          102(e)(1)) is amended—

12                   (i) in subparagraph (A), by striking at  
 13                   the end “or”;

14                   (ii) in subparagraph (B), by striking  
 15                   at the end the comma and inserting “; or”;  
 16                   and

17                   (iii) by inserting after subparagraph  
 18                   (B) the following new subparagraph:

19                   “(C) a medically necessary food (as defined  
 20                   in section 1861(kkk)),”.

21           (B) EFFECTIVE DATE.—The amendments  
 22           made by subparagraph (A) shall apply with re-  
 23           spect to plan years beginning on or after Janu-  
 24           ary 1, 2022.

25          (b) COVERAGE UNDER MEDICAID PROGRAM.—

1           (1) IN GENERAL.—Section 1905(a) of the So-  
2           cial Security Act (42 U.S.C. 1396d(a)) is amend-  
3           ed—

4                   (A) in paragraph (29), by striking “and”  
5           at the end;

6                   (B) by redesignating paragraph (30) as  
7           paragraph (31); and

8                   (C) by inserting after paragraph (29) the  
9           following new paragraph:

10           “(30) medically necessary food (as defined in  
11           section 1861(kkk)); and”.

12           (2)       MANDATORY       BENEFIT.—Section  
13           1902(a)(10)(A) of the Social Security Act (42  
14           U.S.C. 1396a(a)(10)(A)) is amended, in the matter  
15           preceding clause (i), by striking “and (29)” and in-  
16           serting “(29), and (30)”.

17           (3) EFFECTIVE DATE.—

18                   (A) IN GENERAL.—Subject to subpara-  
19           graph (B), the amendments made by this sub-  
20           section shall apply with respect to medical as-  
21           sistance furnished on or after July 1, 2022.

22                   (B) EXCEPTION IF STATE LEGISLATION  
23           REQUIRED.—In the case of a State plan for  
24           medical assistance under title XIX of the Social  
25           Security Act which the Secretary of Health and

1 Human Services determines requires State leg-  
 2 islation (other than legislation appropriating  
 3 funds) in order for the plan to meet the addi-  
 4 tional requirement imposed by the amendments  
 5 made by this subsection, the State plan shall  
 6 not be regarded as failing to comply with the  
 7 requirements of such title solely on the basis of  
 8 its failure to meet this additional requirement  
 9 before the first day of the first calendar quarter  
 10 beginning after the close of the first regular  
 11 session of the State legislature that begins after  
 12 the date of the enactment of this Act. For pur-  
 13 poses of the previous sentence, in the case of a  
 14 State that has a 2-year legislative session, each  
 15 year of such session shall be deemed to be a  
 16 separate regular session of the State legislature.

17 (c) COVERAGE UNDER CHIP.—

18 (1) IN GENERAL.—Section 2103(c) of the So-  
 19 cial Security Act (42 U.S.C. 1397cc(c)) is amended  
 20 by adding at the end the following:

21 “(11) MEDICALLY NECESSARY FOOD.—The  
 22 child health assistance provided to a targeted low-in-  
 23 come child shall include coverage of medically nec-  
 24 essary food (as defined in section 1861(kkk)).”.

(2) CONFORMING AMENDMENT.—Section 2103(a) of the Social Security Act (42 U.S.C. 1397cc(a)) is amended, in the matter preceding paragraph (1), by striking “and (8)” and inserting “, (8), and (11)”.

(3) EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), the amendments made by this subsection shall apply with respect to child health assistance furnished on or after July 1, 2022.

(B) EXCEPTION IF STATE LEGISLATION REQUIRED.—In the case of a State child health plan for child health assistance under title XXI of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendments made by this subsection, the State child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State



1 legislature that begins after the date of the en-  
2 actment of this Act. For purposes of the pre-  
3 vious sentence, in the case of a State that has  
4 a 2-year legislative session, each year of such  
5 session shall be deemed to be a separate regular  
6 session of the State legislature.

7 (d) COVERAGE UNDER TRICARE.—Paragraph (2)  
8 of section 1077(h) of title 10, United States Code, is  
9 amended to read as follows:

10 “(2) In this section, the term ‘medically necessary  
11 food’ has the meaning given the term ‘medical food’ in  
12 section 5(b)(3) of the Orphan Drug Act.”.

13 (e) COVERAGE UNDER PRIVATE HEALTH INSUR-  
14 ANCE.—

15 (1) IN GENERAL.—Subpart II of part A of title  
16 XXVII of the Public Health Service Act (42 U.S.C.  
17 300gg–11 et seq.) is amended by adding at the end  
18 the following:

19 **“SEC. 2730. COVERAGE OF MEDICALLY NECESSARY FOOD.**

20 “A group health plan and group or individual health  
21 insurance coverage offered by a health insurance issuer  
22 shall provide coverage for medically necessary food (as de-  
23 fined in section 1861(kkk) of the Social Security Act).”.

1           (2) EFFECTIVE DATE.—The amendment made  
2       by paragraph (1) shall apply to plan years beginning  
3       on or after January 1, 2022.

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