

116TH CONGRESS
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H. R. 2501

To provide for the coverage of medically necessary food and vitamins and individual amino acids for digestive and inherited metabolic disorders under Federal health programs and private health insurance, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 2, 2019

Mr. MCGOVERN (for himself, Ms. HERRERA BEUTLER, Mr. FITZPATRICK, and Mr. KENNEDY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, and Oversight and Reform, 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

A BILL

To provide for the coverage of medically necessary food and vitamins and individual amino acids for digestive and inherited metabolic disorders under Federal health programs and private health insurance, 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 “Medical Nutrition Eq-
5 uity Act of 2019”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Each year, thousands of children and adults
4 in the United States are diagnosed with certain di-
5 gestive or inherited metabolic disorders that prevent
6 their bodies from digesting or metabolizing the food
7 they need to survive. For them, medically necessary
8 food, which can often be administered as an orally
9 consumed formula, is their treatment.

10 (2) Without medically necessary food, these pa-
11 tients risk malnutrition, surgery, and repeated hos-
12 pitalizations. They may suffer intellectual disability
13 or even death. Risks in pediatric populations are
14 particularly profound and often severe and also in-
15 clude inadequate growth, abnormal development,
16 cognitive impairment, and behavioral disorders. Spe-
17 cialized medically necessary food is standard-of-care
18 therapy for these patients and is essential to pre-
19 venting such outcomes.

20 (3) While not every person diagnosed with these
21 conditions needs to be treated with medically nec-
22 essary food for a prolonged period, it is critical that
23 patients and their physicians be able to consider the
24 full range of options and select the treatment that
25 will be most effective for each patient.

1 (4) Insurance companies will typically cover
2 pharmaceuticals or biologics for treatment of some
3 of these conditions. However, these types of treat-
4 ments may not be the first-line therapy a physician
5 would recommend, do not work for all patients, and
6 can have undesirable risks, such as cancer or sup-
7 pression of the immune system, which can increase
8 a patient's risk of infection.

9 (5) Even when an insurance company does
10 cover medically necessary food, it often comes with
11 the stipulation that the formula be administered
12 through a feeding tube, which requires expensive
13 surgery and carries additional risks for the patient.

14 (6) Testing for select inborn errors of metabo-
15 lism is required in all States, and more than 7,000
16 babies per year are diagnosed with an inherited met-
17 abolic disorder. Yet, policies on medically necessary
18 food vary significantly and do not always make it
19 possible for families to get sufficient nutrition for
20 their affected children.

1 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITA-**
2 **MINS, AND INDIVIDUAL AMINO ACIDS FOR DI-**
3 **GESTIVE AND INHERITED METABOLIC DIS-**
4 **ORDERS UNDER FEDERAL HEALTH PRO-**
5 **GRAMS AND PRIVATE HEALTH INSURANCE.**

6 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

7 (1) MEDICALLY NECESSARY FOOD.—

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

11 (i) in subparagraph (GG), by striking

12 “and” at the end;

13 (ii) in subparagraph (HH), by insert-
14 ing “and” at the end; and

15 (iii) by adding at the end the fol-
16 lowing new subparagraph:

17 “(II) medically necessary food (as defined in
18 subsection (kkk)) and the medical equipment and
19 supplies necessary to administer such food (other
20 than medical equipment and supplies described in
21 subsection (n));”.

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

1 “Medically Necessary Food

2 “(kkk)(1) Subject to paragraph (2), the term ‘medi-
3 cally necessary food’ means food, including a low protein
4 modified food product, an amino acid preparation product,
5 a modified fat preparation product, or a nutritional for-
6 mula (including such a formula that does not require a
7 prescription), that is—

8 “(A) furnished pursuant to the prescription,
9 order, or recommendation (as applicable) of a physi-
10 cian or other health care professional qualified to
11 make such prescription, order, or recommendation,
12 for the dietary management of a covered disease or
13 condition;

14 “(B) a specially formulated and processed prod-
15 uct (as opposed to a naturally occurring foodstuff
16 used in its natural state) for the partial or exclusive
17 feeding of an individual by means of oral intake or
18 enteral feeding by tube;

19 “(C) intended for the dietary management of
20 an individual who, because of therapeutic or chronic
21 medical needs, has limited or impaired capacity to
22 ingest, digest, absorb, or metabolize ordinary food-
23 stuffs or certain nutrients, or who has other special
24 medically determined nutrient requirements, the die-

1 tary management of which cannot be achieved by the
2 modification of the normal diet alone;

3 “(D) intended to be used under medical super-
4 vision, which may include in a home setting; and

5 “(E) intended only for an individual receiving
6 active and ongoing medical supervision wherein the
7 individual requires medical care on a recurring basis
8 for, among other things, instructions on the use of
9 the food.

10 “(2) For purposes of paragraph (1), the term ‘medi-
11 cally necessary food’ does not include the following:

12 “(A) Foods taken as part of an overall diet de-
13 signed to reduce the risk of a disease or medical con-
14 dition or as weight loss products, even if they are
15 recommended by a physician or other health profes-
16 sional.

17 “(B) Foods marketed as gluten-free for the
18 management of celiac disease or non-celiac gluten
19 sensitivity.

20 “(C) Foods marketed for the management of
21 diabetes.

22 “(D) Other products determined appropriate by
23 the Secretary.

24 “(3) In this subsection, the term ‘covered disease or
25 condition’ means the following diseases or conditions:

1 “(A) Inherited metabolic disorders, including
2 the following:

3 “(i) Disorders classified as metabolic dis-
4 orders on the Recommended Uniform Screening
5 Panel Core Conditions list of the Secretary of
6 Health and Human Services’ Advisory Com-
7 mittee on Heritable Disorders in Newborns and
8 Children.

9 “(ii) N-acetyl glutamate synthase defi-
10 ciency.

11 “(iii) Ornithine transcarbamylase defi-
12 ciency.

13 “(iv) Carbamoyl phosphate synthetase de-
14 ficiency.

15 “(v) Inherited disorders of mitochondrial
16 functioning.

17 “(B) Medical and surgical conditions of mal-
18 absorption, including the following:

19 “(i) Impaired absorption of nutrients
20 caused by disorders affecting the absorptive
21 surface, functional length, and motility of the
22 gastrointestinal tract, including short bowel
23 syndrome and chronic intestinal pseudo-obstruc-
24 tion.

1 “(ii) Malabsorption due to liver or pan-
2 creatic disease.

3 “(C) Immunoglobulin E and non-Immunoglobu-
4 lin E-mediated allergies to food proteins, including
5 the following:

6 “(i) Immunoglobulin E and non-Immuno-
7 globulin E-mediated allergies to food proteins.

8 “(ii) Food protein-induced enterocolitis
9 syndrome.

10 “(iii) Eosinophilic disorders, including
11 eosinophilic esophagitis, eosinophilic gastroen-
12 teritis, eosinophilic colitis, and post-transplant
13 eosinophilic disorders.

14 “(D) Inflammatory or immune mediated condi-
15 tions of the alimentary tract, including the following:

16 “(i) Inflammatory bowel disease, including
17 Crohn’s disease, ulcerative colitis, and indeter-
18 minate colitis.

19 “(ii) Gastroesophageal reflux disease that
20 is nonresponsive to standard medical therapies.

21 “(E) Any other disease or condition determined
22 appropriate by the Secretary.

23 “(4)(A) In this subsection, the term ‘low protein
24 modified food product’ means a type of medical food that
25 is modified to be low in protein and formulated for oral

1 consumption for individuals with inborn errors of protein
2 metabolism.

3 “(B) Such term does not include foods that are natu-
4 rally low in protein, such as some fruits or vegetables.”.

5 (C) PAYMENT.—Section 1833(a)(1) of the
6 Social Security Act (42 U.S.C. 1395l(a)(1)) is
7 amended—

8 (i) by striking “and” before “(CC)”;
9 and

10 (ii) by inserting before the semicolon
11 at the end the following: “, and (DD) with
12 respect to medically necessary food (as de-
13 fined in section 1861(kkk)), the amount
14 paid shall be an amount equal to 80 per-
15 cent of the lesser of the actual charge for
16 the services or the amount determined
17 under a fee schedule established by the
18 Secretary for purposes of this subpara-
19 graph.”.

20 (D) EFFECTIVE DATE.—The amendments
21 made by this subsection shall apply to items
22 and services furnished on or after the date that
23 is 1 year after the date of the enactment of this
24 Act.

1 (2) INCLUSION OF MEDICALLY NECESSARY VI-
2 TAMINS AND INDIVIDUAL AMINO ACIDS AS A COV-
3 ERED PART D DRUG.—

4 (A) IN GENERAL.—Section 1860D–2(e)(1)
5 of the Social Security Act (42 U.S.C. 1395w–
6 102(e)(1)) is amended—

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

9 (ii) in subparagraph (B), by striking
10 the comma at the end and inserting “; or”;
11 and

12 (iii) by inserting after subparagraph
13 (B) the following new subparagraph:

14 “(C) medically necessary vitamins and in-
15 dividual amino acids used for the management
16 of a covered disease or condition (as defined in
17 section 1861(kkk)(3)) pursuant to the prescrip-
18 tion, order, or recommendation (as applicable)
19 of a physician or other health care professional
20 qualified to make such prescription, order, or
21 recommendation,”.

22 (B) EFFECTIVE DATE.—The amendments
23 made by subparagraph (A) shall apply to plan
24 years beginning on or after the date that is 1
25 year after the date of the enactment of this Act.

1 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

5 (A) in paragraph (29)—

6 (i) by adjusting the left margin so as
7 to align with the left margin of paragraph
8 (28); and

9 (ii) by striking “and” at the end;

10 (B) by redesignating paragraph (30) as
11 paragraph (32); and

12 (C) by inserting after paragraph (29) the
13 following new paragraphs:

14 “(30) medically necessary food (as defined in
15 section 1861(kkk)) and the medical equipment and
16 supplies necessary to administer such food;

17 “(31) medically necessary vitamins and indi-
18 vidual amino acids used for the management of a
19 covered disease or condition (as defined in section
20 1861(kkk)(3)) pursuant to the prescription, order,
21 or recommendation (as applicable) of a physician or
22 other health care professional qualified to make such
23 prescription, order, or recommendation; and”.

24 (2) CONFORMING AMENDMENTS.—

1 (A) MANDATORY BENEFITS.—Section
2 1902(a)(10)(A) of the Social Security Act (42
3 U.S.C. 1396a(a)(10)(A)) is amended, in the
4 matter preceding clause (i), by striking “and
5 (29)” and inserting “(29), (30), and (31)”.

6 (B) EXCEPTION TO COVERAGE RESTRIC-
7 TION.—Section 1927(d)(2)(E) of the Social Se-
8 curity Act (42 U.S.C. 1396r–8(d)(2)(E)) is
9 amended by inserting “and except for medically
10 necessary vitamins and individual amino acids
11 described in section 1905(a)(31)” before the pe-
12 riod at the end.

13 (3) EFFECTIVE DATE.—

14 (A) IN GENERAL.—Subject to subpara-
15 graph (B), the amendments made by this sub-
16 section shall take effect on the date that is 1
17 year after the date of the enactment of this Act.

18 (B) EXCEPTION TO EFFECTIVE DATE IF
19 STATE LEGISLATION REQUIRED.—In the case of
20 a State plan for medical assistance under title
21 XIX of the Social Security Act which the Sec-
22 retary of Health and Human Services deter-
23 mines requires State legislation (other than leg-
24 islation appropriating funds) in order for the
25 plan to meet the additional requirements im-

1 posed by the amendments made by this sub-
2 section, the State plan shall not be regarded as
3 failing to comply with the requirements of such
4 title solely on the basis of its failure to meet
5 this additional requirement before the first day
6 of the first calendar quarter beginning after the
7 close of the first regular session of the State
8 legislature that begins after the date of the en-
9 actment of this Act. For purposes of the pre-
10 vious sentence, in the case of a State that has
11 a 2-year legislative session, each year of such
12 session shall be deemed to be a separate regular
13 session of the State legislature.

14 (c) COVERAGE UNDER CHIP.—

15 (1) IN GENERAL.—Section 2103(c) of the So-
16 cial Security Act (42 U.S.C. 1397cc(c)), as amended
17 by section 5022(b)(1) of the CHIP Mental Health
18 and Substance Use Disorder Parity Act (Public Law
19 115–271), is amended by adding at the end the fol-
20 lowing:

21 “(10) MEDICALLY NECESSARY FOOD.—The
22 child health assistance provided to a targeted low-in-
23 come child under the plan shall include coverage of
24 medically necessary food (as defined in section

1 1861(kkk)) and the medical equipment and supplies
2 necessary to administer such food.

3 “(11) CERTAIN VITAMINS AND INDIVIDUAL
4 AMINO ACIDS.—The child health assistance provided
5 to a targeted low-income child under the plan shall
6 include coverage of medically necessary vitamins and
7 individual amino acids used for the management of
8 a covered disease or condition (as defined in section
9 1861(kkk)(3)) pursuant to the prescription, order,
10 or recommendation (as applicable) of a physician or
11 other health care professional qualified to make such
12 prescription, order, or recommendation.”.

13 (2) CONFORMING AMENDMENT.—Section
14 2103(a) of the Social Security Act (42 U.S.C.
15 1397cc(a)), as amended by section 5022(b)(2)(A) of
16 the CHIP Mental Health and Substance Use Dis-
17 order Parity Act (Public Law 115–271), is amended,
18 in the matter preceding paragraph (1), by striking
19 “and (8)” and inserting “(8), (10), and (11)”.

20 (3) EFFECTIVE DATE.—

21 (A) IN GENERAL.—Subject to subpara-
22 graph (B), the amendments made by this sub-
23 section shall take effect on the date that is 1
24 year after the date of the enactment of this Act.

1 (B) EXCEPTION TO EFFECTIVE DATE IF
2 STATE LEGISLATION REQUIRED.—In the case of
3 a State child health plan for child health assist-
4 ance under title XXI of the Social Security Act
5 which the Secretary of Health and Human
6 Services determines requires State legislation
7 (other than legislation appropriating funds) in
8 order for the plan to meet the additional re-
9 quirements imposed by the amendments made
10 by this subsection, the State child health plan
11 shall not be regarded as failing to comply with
12 the requirements of such title solely on the
13 basis of its failure to meet this additional re-
14 quirement before the first day of the first cal-
15 endar quarter beginning after the close of the
16 first regular session of the State legislature that
17 begins after the date of the enactment of this
18 Act. For purposes of the previous sentence, in
19 the case of a State that has a 2-year legislative
20 session, each year of such session shall be
21 deemed to be a separate regular session of the
22 State legislature.

23 (d) MODIFICATION OF DEFINITION OF MEDICALLY
24 NECESSARY FOOD AND COVERED DISEASE OR CONDI-
25 TION UNDER THE TRICARE PROGRAM.—

1 (1) IN GENERAL.—Section 1077(h) of title 10,
2 United States Code, is amended—

3 (A) in paragraph (2)(A), in the matter
4 preceding clause (i), by striking “or an amino
5 acid preparation product” and inserting “, an
6 amino acid preparation product, a modified fat
7 preparation product, or a nutritional formula
8 (including such a formula that does not require
9 a prescription)”; and

10 (B) in paragraph (3)—

11 (i) in subparagraph (D), by striking
12 “and” at the end;

13 (ii) by redesignating subparagraph
14 (E) as subparagraph (F); and

15 (iii) by inserting after subparagraph
16 (D) the following:

17 “(E) Immunoglobulin E or non-Immunoglobulin
18 E mediated allergies to food proteins; and”.

19 (2) EFFECTIVE DATE.—The amendments made
20 by paragraph (1) shall apply to health care provided
21 under chapter 55 of title 10, United States Code, on
22 or after the date that is one year after the date of
23 the enactment of this Act.

24 (e) COVERAGE UNDER FEHBP.—

1 (1) IN GENERAL.—Section 8902 of title 5,
2 United States Code, is amended by adding at the
3 end the following:

4 “(p) A contract for a plan under this chapter shall
5 require the carrier to provide coverage for—

6 “(1) medically necessary food (as defined in
7 section 1861(kkk) of the Social Security Act) and
8 the medical equipment and supplies necessary to ad-
9 minister such food; and

10 “(2) medically necessary vitamins and indi-
11 vidual amino acids in the same manner provided for
12 under section 1860D–2(e)(1)(C) of the Social Secu-
13 rity Act.”.

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall apply with respect to contract
16 years beginning on or after the date that is 1 year
17 after the date of enactment of this Act.

18 (f) COVERAGE UNDER PRIVATE HEALTH INSUR-
19 ANCE.—

20 (1) IN GENERAL.—Subpart II of part A of title
21 XXVII of the Public Health Service Act (42 U.S.C.
22 300gg–11 et seq.) is amended by adding at the end
23 the following:

1 **“SEC. 2729A. COVERAGE OF MEDICALLY NECESSARY FOOD,**
2 **VITAMINS, AND INDIVIDUAL AMINO ACIDS.**

3 “A health insurance issuer offering group or indi-
4 vidual health insurance coverage shall provide coverage
5 for—

6 “(1) medically necessary food (as defined in
7 section 1861(kkk) of the Social Security Act) and
8 the medical equipment and supplies necessary to ad-
9 minister such food; and

10 “(2) medically necessary vitamins and indi-
11 vidual amino acids in the same manner provided for
12 under section 1860D–2(e)(1)(C) of the Social Secu-
13 rity Act.”.

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall apply to plan years beginning
16 on or after the date that is 1 year after the date of
17 the enactment of this Act.

18 (g) NONPREEMPTION OF STATE LAWS THAT PRO-
19 VIDE GREATER COVERAGE.—Nothing in the provisions of,
20 or the amendments made by, this section shall preempt
21 a State law that requires coverage of medically necessary
22 food and vitamins and individual amino acids for digestive
23 and inherited metabolic disorders that exceeds the require-
24 ments for coverage under such provisions and amend-
25 ments.

1 (h) MEDICALLY NECESSARY NUTRITION COVERAGE
2 INCLUDES COMBINATIONS AND SUPPLIES.—Nothing in
3 the provisions of, or the amendments made by, this section
4 shall limit coverage of a medically necessary food (as de-
5 fined in subsection (kkk) of section 1861 of the Social Se-
6 curity Act, as added by subsection (a)) or the medical
7 equipment and supplies necessary to administer such food
8 when prescribed, ordered, or recommended in combination
9 with another medically necessary food (as so defined) or
10 other necessary medical equipment and supplies.

○