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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, to ensure State and Federal protection for existing coverage, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 10, 2021

Mr. CASEY (for himself, Ms. ERNST, Mr. GRASSLEY, and Ms. ROSEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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, to ensure State and Federal protection for existing coverage, 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 2021”.

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 many
3 of these conditions, if there is a Food and Drug Ad-
4 ministration-approved therapy. However, these types
5 of treatments may not be the first-line therapy a
6 physician would recommend, do not work for all pa-
7 tients, and can have undesirable risks, such as can-
8 cer or suppression of the immune system, which can
9 increase a patient's risk of infection.

10 (5) Even when an insurance company does
11 cover medically necessary food, it can come with the
12 stipulation the formula be administered through a
13 feeding tube, placed through the nose into the stom-
14 ach or surgically placed directly into the stomach or
15 jejunum, even if a patient is capable of taking the
16 formula orally without these devices. Surgical place-
17 ment of feeding tubes unnecessarily results in in-
18 creased risk to the patient and increased cost to the
19 healthcare system.

20 (6) Testing for select inherited metabolic dis-
21 orders is required in all States, and approximately
22 2,000 babies per year are diagnosed with one of
23 these disorders that requires treatment through
24 medically necessary food. Yet, policies on medically
25 necessary food vary significantly and do not always

1 make it possible for families to get sufficient nutri-
 2 tion for their affected children which can lead to de-
 3 layed development, brain damage, and even death.

4 (7) The worsening of food insecurity during the
 5 COVID–19 pandemic has had a significant impact
 6 on patients who rely on medical nutrition, and the
 7 cost of meeting their dietary needs has been a major
 8 burden to individuals facing financial challenges as
 9 a result of the pandemic.

10 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITA-**
 11 **MINS, AND INDIVIDUAL AMINO ACIDS FOR DI-**
 12 **GESTIVE AND INHERITED METABOLIC DIS-**
 13 **ORDERS UNDER FEDERAL HEALTH PRO-**
 14 **GRAMS AND PRIVATE HEALTH INSURANCE.**

15 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

16 (1) MEDICALLY NECESSARY FOOD.—

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

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

22 (ii) in subparagraph (HH), by strik-
 23 ing the period and inserting “and”; and

24 (iii) by adding at the end the fol-
 25 lowing new subparagraph:

1 “(II) medically necessary food (as defined in
2 subsection (III)) and, if required, the medical equip-
3 ment and supplies necessary to administer such food
4 (other than medical equipment and supplies de-
5 scribed in subsection (n));”.

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

10 “Medically Necessary Food

11 “(III)(1) Subject to paragraph (2), the term ‘medi-
12 cally necessary food’ means food, including a low protein
13 modified food product, an amino acid preparation product,
14 a modified fat preparation product, or a nutritional for-
15 mula (including such a formula that does not require a
16 prescription), that is—

17 “(A) furnished pursuant to the prescription,
18 order, or recommendation (as applicable) of a physi-
19 cian or other health care professional qualified to
20 make such prescription, order, or recommendation,
21 for the dietary management of a covered disease or
22 condition;

23 “(B) a specially formulated and processed prod-
24 uct (as opposed to a naturally occurring foodstuff
25 used in its natural state) for the partial or exclusive

1 feeding of an individual by means of oral intake or
2 enteral feeding by tube;

3 “(C) intended for the dietary management of
4 an individual who, because of a specified disease or
5 condition, has limited or impaired capacity to ingest,
6 digest, absorb, or metabolize ordinary foodstuffs or
7 certain nutrients, or who has other special medically
8 determined nutrient requirements, the dietary man-
9 agement of which cannot be achieved by the modi-
10 fication of the normal diet alone;

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

13 “(E) intended only for an individual receiving
14 active and ongoing medical supervision wherein the
15 individual requires medical care on a recurring basis
16 for, among other things, instructions on the use of
17 the food.

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

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

1 “(B) Foods marketed as gluten-free for the
2 management of celiac disease or non-celiac gluten
3 sensitivity.

4 “(C) Foods marketed for the management of
5 diabetes.

6 “(D) Other products determined appropriate by
7 the Secretary.

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

10 “(A) Inherited metabolic disorders, including
11 the following:

12 “(i) Disorders classified as metabolic dis-
13 orders on the Recommended Uniform Screening
14 Panel Conditions list of the Secretary of Health
15 and Human Services’ Advisory Committee on
16 Heritable Disorders in Newborns and Children.

17 “(ii) N-acetyl glutamate synthase defi-
18 ciency.

19 “(iii) Ornithine transcarbamlyase defi-
20 ciency.

21 “(iv) Carbamoyl phosphate synthetase de-
22 ficiency.

23 “(v) Inherited disorders of mitochondrial
24 functioning.

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

3 “(i) Impaired absorption of nutrients
4 caused by disorders affecting the absorptive
5 surface, functional length, and motility of the
6 gastrointestinal tract, including short bowel
7 syndrome and chronic intestinal pseudo-obstruc-
8 tion.

9 “(ii) Malabsorption due to liver or pan-
10 creatic disease.

11 “(C) Immunoglobulin E and non-
12 Immunoglobulin E-mediated allergies to food pro-
13 teins, including the following:

14 “(i) Immunoglobulin E and non-
15 Immunoglobulin E-mediated allergies to food
16 proteins.

17 “(ii) Food protein-induced enterocolitis
18 syndrome.

19 “(iii) Eosinophilic disorders, including
20 eosinophilic esophagitis, eosinophilic
21 gastroenteritis, eosinophilic colitis, and post-
22 transplant eosinophilic disorders.

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

1 “(i) Inflammatory bowel disease, including
2 Crohn’s disease, ulcerative colitis, and indeter-
3 minate colitis.

4 “(ii) Gastroesophageal reflux disease that
5 is nonresponsive to standard medical therapies.

6 “(E) Any other disease or condition determined
7 appropriate by the Secretary in consultation with ap-
8 propriate scientific entities, such as the Agency for
9 Healthcare Research and Quality.

10 “(4)(A) In this subsection, the term ‘low protein
11 modified food product’ means a type of medical food that
12 is modified to be low in protein and formulated for oral
13 consumption for individuals with inborn errors of protein
14 metabolism.

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

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

20 (i) by striking “and” before “(DD)”;

21 and

22 (ii) by inserting before the semicolon
23 at the end the following: “and (EE) with
24 respect to medically necessary food (as de-
25 fined in section 1861(l)), the amount paid

1 shall be an amount equal to 80 percent of
2 the lesser of the actual charge for the serv-
3 ices or the amount determined under a fee
4 schedule established by the Secretary for
5 purposes of this subparagraph.”.

6 (D) EFFECTIVE DATE.—The amendments
7 made by this subsection shall apply to items
8 and services furnished on or after the date that
9 is 1 year after the date of the enactment of this
10 Act.

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

14 (A) IN GENERAL.—Section 1860D–2(e)(1)
15 of the Social Security Act (42 U.S.C. 1395w–
16 102(e)(1)) is amended—

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

19 (ii) in subparagraph (B), by striking
20 the comma at the end and inserting “; or”;
21 and

22 (iii) by inserting after subparagraph
23 (B) the following new subparagraph:

24 “(C) medically necessary vitamins and in-
25 dividual amino acids used for the management

1 of a covered disease or condition (as defined in
2 section 1861(III)(3)) pursuant to the prescrip-
3 tion, order, or recommendation (as applicable)
4 of a physician or other health care professional
5 qualified to make such prescription, order, or
6 recommendation.”.

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

11 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

15 (A) in paragraph (30), by striking “and”
16 at the end;

17 (B) by redesignating paragraph (31) as
18 paragraph (33); and

19 (C) by inserting after paragraph (30) the
20 following new paragraphs:

21 “(31) medically necessary food (as defined in
22 section 1861(III)) and the medical equipment and
23 supplies necessary to administer such food;

24 “(32) medically necessary vitamins and indi-
25 vidual amino acids used for the management of a

1 covered disease or condition (as defined in section
2 1861(III)(3)) pursuant to the prescription, order, or
3 recommendation (as applicable) of a physician or
4 other health care professional qualified to make such
5 prescription, order, or recommendation; and”.

6 (2) CONFORMING AMENDMENTS.—

7 (A) MANDATORY BENEFITS.—Section
8 1902(a)(10)(A) of the Social Security Act (42
9 U.S.C. 1396a(a)(10)(A)) is amended, in the
10 matter preceding clause (i), by striking “and
11 (30)” and inserting “(30), (31), and (32)”.

12 (B) EXCEPTION TO COVERAGE RESTRIC-
13 TION.—Section 1927(d)(2)(E) of the Social Se-
14 curity Act (42 U.S.C. 1396r–8(d)(2)(E)) is
15 amended by inserting “and except for medically
16 necessary vitamins and individual amino acids
17 described in section 1905(a)(32)” before the pe-
18 riod at the end.

19 (3) EFFECTIVE DATE.—

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

24 (B) EXCEPTION TO EFFECTIVE DATE IF
25 STATE LEGISLATION REQUIRED.—In the case of

1 a State plan for medical assistance under title
2 XIX of the Social Security Act which the Sec-
3 retary of Health and Human Services deter-
4 mines requires State legislation (other than leg-
5 islation appropriating funds) in order for the
6 plan to meet the additional requirements im-
7 posed by the amendments made by this sub-
8 section, the State plan shall not be regarded as
9 failing to comply with the requirements of such
10 title solely on the basis of its failure to meet
11 this additional requirement before the first day
12 of the first calendar quarter beginning after the
13 close of the first regular session of the State
14 legislature that begins after the date of the en-
15 actment of this Act. For purposes of the pre-
16 vious sentence, in the case of a State that has
17 a 2-year legislative session, each year of such
18 session shall be deemed to be a separate regular
19 session of the State legislature.

20 (c) COVERAGE UNDER CHIP.—

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

24 “(12) MEDICALLY NECESSARY FOOD.—The
25 child health assistance provided to a targeted low-in-

1 come child under the plan shall include coverage of
2 medically necessary food (as defined in section
3 1861(III)) and the medical equipment and supplies
4 necessary to administer such food.

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

15 (2) CONFORMING AMENDMENT.—Section
16 2103(a) of the Social Security Act (42 U.S.C.
17 1397cc(a)) is amended, in the matter preceding
18 paragraph (1), by striking “and (8)” and inserting
19 “(8), (12), and (13)”.

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 “(q) 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(l)(3) of the Social Security Act) and the
8 medical equipment and supplies necessary to admin-
9 ister 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(III) of the Social Security Act) and the
8 medical equipment and supplies necessary to admin-
9 ister 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 (lll) of section 1861 of the Social Secu-
6 rity Act, as added by subsection (a)) or the medical equip-
7 ment and supplies necessary to administer such food when
8 prescribed, ordered, or recommended in combination with
9 another medically necessary food (as so defined) or other
10 necessary medical equipment and supplies.

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