

116TH CONGRESS
2D SESSION

S. 3657

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 SENATE OF THE UNITED STATES

MAY 7, 2020

Mr. CASEY (for himself and Ms. ERNST) 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, 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 2020”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

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

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

24 (4) Insurance companies will typically cover
25 pharmaceuticals or biologics for treatment of some

of these conditions. However, these types of treatments may not be the first-line therapy a physician would recommend, do not work for all patients, and can have undesirable risks, such as cancer or suppression of the immune system, which can increase a patient's risk of infection.

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

(6) Testing for select inborn errors of metabolism is required in all States, and more than 7,000 babies per year are diagnosed with an inherited metabolic disorder. Yet, policies on medically necessary food vary significantly and do not always make it possible for families to get sufficient nutrition for their affected children.

SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITAMINS, AND INDIVIDUAL AMINO ACIDS FOR DIGESTIVE AND INHERITED METABOLIC DISORDERS UNDER FEDERAL HEALTH PROGRAMS AND PRIVATE HEALTH INSURANCE.

(a) COVERAGE UNDER THE MEDICARE PROGRAM.—

(1) MEDICALLY NECESSARY FOOD.—

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

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

(ii) in subparagraph (HH), by striking the period and inserting “and”; and

(iii) by adding at the end the following new subparagraph:

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

(B) DEFINITION.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

“Medically Necessary Food

“(kkk)(1) Subject to paragraph (2), the term ‘medically necessary food’ means food, including a low protein modified food product, an amino acid preparation product, a modified fat preparation product, or a nutritional formula (including such a formula that does not require a prescription), that is—

1 “(A) furnished pursuant to the prescription,
2 order, or recommendation (as applicable) of a physi-
3 cian or other health care professional qualified to
4 make such prescription, order, or recommendation,
5 for the dietary management of a covered disease or
6 condition;

7 “(B) a specially formulated and processed prod-
8 uct (as opposed to a naturally occurring foodstuff
9 used in its natural state) for the partial or exclusive
10 feeding of an individual by means of oral intake or
11 enteral feeding by tube;

12 “(C) intended for the dietary management of
13 an individual who, because of therapeutic or chronic
14 medical needs, has limited or impaired capacity to
15 ingest, digest, absorb, or metabolize ordinary food-
16 stuffs or certain nutrients, or who has other special
17 medically determined nutrient requirements, the die-
18 tary management of which cannot be achieved by the
19 modification of the normal diet alone;

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

22 “(E) intended only for an individual receiving
23 active and ongoing medical supervision wherein the
24 individual requires medical care on a recurring basis

1 for, among other things, instructions on the use of
2 the food.

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

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

10 “(B) Foods marketed as gluten-free for the
11 management of celiac disease or non-celiac gluten
12 sensitivity.

13 “(C) Foods marketed for the management of
14 diabetes.

15 “(D) Other products determined appropriate by
16 the Secretary.

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

19 “(A) Inherited metabolic disorders, including
20 the following:

21 “(i) Disorders classified as metabolic dis-
22 orders on the Recommended Uniform Screening
23 Panel Core Conditions list of the Secretary of
24 Health and Human Services’ Advisory Com-

1 mittee on Heritable Disorders in Newborns and
2 Children.

3 “(ii) N-acetyl glutamate synthase defi-
4 ciency.

5 “(iii) Ornithine transcarbamylase defi-
6 ciency.

7 “(iv) Carbamoyl phosphate synthetase de-
8 ficiency.

9 “(v) Inherited disorders of mitochondrial
10 functioning.

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

13 “(i) Impaired absorption of nutrients
14 caused by disorders affecting the absorptive
15 surface, functional length, and motility of the
16 gastrointestinal tract, including short bowel
17 syndrome and chronic intestinal pseudo-obstruc-
18 tion.

19 “(ii) Malabsorption due to liver or pan-
20 creatic disease.

21 “(C) Immunoglobulin E and non-Immunoglobu-
22 lin E-mediated allergies to food proteins, including
23 the following:

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

1 “(ii) Food protein-induced enterocolitis
2 syndrome.

3 “(iii) Eosinophilic disorders, including
4 eosinophilic esophagitis, eosinophilic gastroen-
5 teritis, eosinophilic colitis, and post-transplant
6 eosinophilic disorders.

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

9 “(i) Inflammatory bowel disease, including
10 Crohn’s disease, ulcerative colitis, and indeter-
11 minate colitis.

12 “(ii) Gastroesophageal reflux disease that
13 is nonresponsive to standard medical therapies.

14 “(E) Any other disease or condition determined
15 appropriate by the Secretary.

16 “(4)(A) In this subsection, the term ‘low protein
17 modified food product’ means a type of medical food that
18 is modified to be low in protein and formulated for oral
19 consumption for individuals with inborn errors of protein
20 metabolism.

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

23 (C) PAYMENT.—Section 1833(a)(1) of the
24 Social Security Act (42 U.S.C. 1395l(a)(1)) is
25 amended—

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

2 and

3 (ii) by inserting before the semicolon
 4 at the end the following: “and (EE) with
 5 respect to medically necessary food (as de-
 6 fined in section 1861(kkk)), the amount
 7 paid shall be an amount equal to 80 per-
 8 cent of the lesser of the actual charge for
 9 the services or the amount determined
 10 under a fee schedule established by the
 11 Secretary for purposes of this subpara-
 12 graph.”.

13 (D) EFFECTIVE DATE.—The amendments
 14 made by this subsection shall apply to items
 15 and services furnished on or after the date that
 16 is 1 year after the date of the enactment of this
 17 Act.

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

21 (A) IN GENERAL.—Section 1860D–2(e)(1)
 22 of the Social Security Act (42 U.S.C. 1395w–
 23 102(e)(1)) is amended—

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

1 (ii) in subparagraph (B), by striking
 2 the comma at the end and inserting “; or”;
 3 and

4 (iii) by inserting after subparagraph
 5 (B) the following new subparagraph:

6 “(C) medically necessary vitamins and in-
 7 dividual amino acids used for the management
 8 of a covered disease or condition (as defined in
 9 section 1861(kkk)(3)) pursuant to the prescrip-
 10 tion, order, or recommendation (as applicable)
 11 of a physician or other health care professional
 12 qualified to make such prescription, order, or
 13 recommendation.”.

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

18 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

22 (A) in paragraph (29)—

23 (i) by adjusting the left margin so as
 24 to align with the left margin of paragraph
 25 (28); and

1 (ii) by striking “and” at the end;

2 (B) by redesignating paragraph (30) as
3 paragraph (32); and

4 (C) by inserting after paragraph (29) the
5 following new paragraphs:

6 “(30) medically necessary food (as defined in
7 section 1861(kkk)) and the medical equipment and
8 supplies necessary to administer such food;

9 “(31) medically necessary vitamins and indi-
10 vidual amino acids used for the management of a
11 covered disease or condition (as defined in section
12 1861(kkk)(3)) pursuant to the prescription, order,
13 or recommendation (as applicable) of a physician or
14 other health care professional qualified to make such
15 prescription, order, or recommendation; and”.

16 (2) CONFORMING AMENDMENTS.—

17 (A) MANDATORY BENEFITS.—Section
18 1902(a)(10)(A) of the Social Security Act (42
19 U.S.C. 1396a(a)(10)(A)) is amended, in the
20 matter preceding clause (i), by striking “and
21 (29)” and inserting “(29), (30), and (31)”.

22 (B) EXCEPTION TO COVERAGE RESTRIC-
23 TION.—Section 1927(d)(2)(E) of the Social Se-
24 curity Act (42 U.S.C. 1396r–8(d)(2)(E)) is
25 amended by inserting “and except for medically

1 necessary vitamins and individual amino acids
2 described in section 1905(a)(31)” before the pe-
3 riod at the end.

4 (3) EFFECTIVE DATE.—

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

9 (B) EXCEPTION TO EFFECTIVE DATE IF
10 STATE LEGISLATION REQUIRED.—In the case of
11 a State plan for medical assistance under title
12 XIX of the Social Security Act which the Sec-
13 retary of Health and Human Services deter-
14 mines requires State legislation (other than leg-
15 islation appropriating funds) in order for the
16 plan to meet the additional requirements im-
17 posed by the amendments made by this sub-
18 section, the State plan shall not be regarded as
19 failing to comply with the requirements of such
20 title solely on the basis of its failure to meet
21 this additional requirement before the first day
22 of the first calendar quarter beginning after the
23 close of the first regular session of the State
24 legislature that begins after the date of the en-
25 actment of this Act. For purposes of the pre-

1 vious sentence, in the case of a State that has
 2 a 2-year legislative session, each year of such
 3 session shall be deemed to be a separate regular
 4 session of the State legislature.

5 (c) COVERAGE UNDER CHIP.—

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

9 “(11) MEDICALLY NECESSARY FOOD.—The
 10 child health assistance provided to a targeted low-in-
 11 come child under the plan shall include coverage of
 12 medically necessary food (as defined in section
 13 1861(kkk)) and the medical equipment and supplies
 14 necessary to administer such food.

15 “(12) CERTAIN VITAMINS AND INDIVIDUAL
 16 AMINO ACIDS.—The child health assistance provided
 17 to a targeted low-income child under the plan shall
 18 include coverage of medically necessary vitamins and
 19 individual amino acids used for the management of
 20 a covered disease or condition (as defined in section
 21 1861(kkk)(3)) pursuant to the prescription, order,
 22 or recommendation (as applicable) of a physician or
 23 other health care professional qualified to make such
 24 prescription, order, or recommendation.”.

1 (2) CONFORMING AMENDMENT.—Section
2 2103(a) of the Social Security Act (42 U.S.C.
3 1397cc(a)) is amended, in the matter preceding
4 paragraph (1), by striking “and (8)” and inserting
5 “(8), (11), and (12)”.

6 (3) EFFECTIVE DATE.—

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

11 (B) EXCEPTION TO EFFECTIVE DATE IF
12 STATE LEGISLATION REQUIRED.—In the case of
13 a State child health plan for child health assist-
14 ance under title XXI of the Social Security Act
15 which the Secretary of Health and Human
16 Services determines requires State legislation
17 (other than legislation appropriating funds) in
18 order for the plan to meet the additional re-
19 quirements imposed by the amendments made
20 by this subsection, the State child health plan
21 shall not be regarded as failing to comply with
22 the requirements of such title solely on the
23 basis of its failure to meet this additional re-
24 quirement before the first day of the first cal-
25 endar quarter beginning after the close of the

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

8 (d) MODIFICATION OF DEFINITION OF MEDICALLY
9 NECESSARY FOOD AND COVERED DISEASE OR CONDI-
10 TION UNDER THE TRICARE PROGRAM.—

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

13 (A) in paragraph (2)(A), in the matter
14 preceding clause (i), by striking “or an amino
15 acid preparation product” and inserting “, an
16 amino acid preparation product, a modified fat
17 preparation product, or a nutritional formula
18 (including such a formula that does not require
19 a prescription)”; and

20 (B) in paragraph (3)—

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

23 (ii) by redesignating subparagraph
24 (E) as subparagraph (F); and

1 (iii) by inserting after subparagraph
 2 (D) the following:

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

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

10 (e) COVERAGE UNDER FEHBP.—

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

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

16 “(1) medically necessary food (as defined in
 17 section 1861(kkk) of the Social Security Act) and
 18 the medical equipment and supplies necessary to ad-
 19 minister such food; and

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

24 (2) EFFECTIVE DATE.—The amendment made
 25 by paragraph (1) shall apply with respect to contract

1 years beginning on or after the date that is 1 year
 2 after the date of enactment of this Act.

3 (f) COVERAGE UNDER PRIVATE HEALTH INSUR-
 4 ANCE.—

5 (1) IN GENERAL.—Subpart II of part A of title
 6 XXVII of the Public Health Service Act (42 U.S.C.
 7 300gg–11 et seq.) is amended by adding at the end
 8 the following:

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

11 “A health insurance issuer offering group or indi-
 12 vidual health insurance coverage shall provide coverage
 13 for—

14 “(1) medically necessary food (as defined in
 15 section 1861(kkk) of the Social Security Act) and
 16 the medical equipment and supplies necessary to ad-
 17 minister such food; and

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

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

1 (g) NONPREEMPTION OF STATE LAWS THAT PRO-
2 VIDE GREATER COVERAGE.—Nothing in the provisions of,
3 or the amendments made by, this section shall preempt
4 a State law that requires coverage of medically necessary
5 food and vitamins and individual amino acids for digestive
6 and inherited metabolic disorders that exceeds the require-
7 ments for coverage under such provisions and amend-
8 ments.

9 (h) MEDICALLY NECESSARY NUTRITION COVERAGE
10 INCLUDES COMBINATIONS AND SUPPLIES.—Nothing in
11 the provisions of, or the amendments made by, this section
12 shall limit coverage of a medically necessary food (as de-
13 fined in subsection (kkk) of section 1861 of the Social Se-
14 curity Act, as added by subsection (a)) or the medical
15 equipment and supplies necessary to administer such food
16 when prescribed, ordered, or recommended in combination
17 with another medically necessary food (as so defined) or
18 other necessary medical equipment and supplies.

○