

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.

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## 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

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## 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

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

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

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

19 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITA-**  
20 **MINS, AND INDIVIDUAL AMINO ACIDS FOR DI-**  
21 **GESTIVE AND INHERITED METABOLIC DIS-**  
22 **ORDERS UNDER FEDERAL HEALTH PRO-**  
23 **GRAMS AND PRIVATE HEALTH INSURANCE.**

24 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

25 (1) MEDICALLY NECESSARY FOOD.—

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

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

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

8 (iii) by adding at the end the fol-  
9 lowing new subparagraph:

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

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

19 “Medically Necessary Food

20 “(kkk)(1) Subject to paragraph (2), the term ‘medi-  
21 cally necessary food’ means food, including a low protein  
22 modified food product, an amino acid preparation product,  
23 a modified fat preparation product, or a nutritional for-  
24 mula (including such a formula that does not require a  
25 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 transcarbamlyase 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(e)) 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.

○