

115TH CONGRESS
1ST SESSION

S. 1194

To provide for the coverage of medically necessary food and vitamins 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 22, 2017

Mr. CASEY (for himself and Mr. GRASSLEY) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To provide for the coverage of medically necessary food and vitamins 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 2017”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Specialized food is often medically necessary
2 for the safe and effective management of many di-
3 gestive and inherited metabolic disorders that impact
4 digestion, absorption, and metabolism of nutrients.

5 (2) Although medically necessary food is essen-
6 tial for patients, it is often expensive and not uni-
7 formly reimbursed by health insurance, leaving many
8 families with an insurmountable financial burden.

9 (3) As a result, many patients who cannot af-
10 ford medically necessary food may experience ad-
11 verse health consequences from suboptimal disease
12 management, including hospitalization, intellectual
13 impairment, behavioral dysfunction, inadequate
14 growth, nutrient deficiencies, and even death.

15 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD AND**
16 **VITAMINS FOR DIGESTIVE AND INHERITED**
17 **METABOLIC DISORDERS UNDER FEDERAL**
18 **HEALTH PROGRAMS AND PRIVATE HEALTH**
19 **INSURANCE.**

20 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

21 (1) MEDICALLY NECESSARY FOOD.—

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 (FF), by striking
2 “and” at the end;

3 (ii) in subparagraph (GG), by insert-
4 ing “and” at the end; and

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

7 “(HH) medically necessary food (as defined in
8 subsection (jjj)) and the medical equipment and sup-
9 plies necessary to administer such food (other than
10 medical equipment and supplies described in sub-
11 section (n));”.

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

16 “Medically Necessary Food

17 “(jjj)(1) Subject to paragraph (2), the term ‘medi-
18 cally necessary food’ means food, including a low protein
19 modified food product and an amino acid preparation
20 product, that is—

21 “(A) furnished pursuant to the prescription,
22 order, or recommendation (as applicable) of a physi-
23 cian or other health care professional qualified to
24 make such prescription, order, or recommendation,

1 for the dietary management of a covered disease or
2 condition;

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

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

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

18 “(E) intended only for an individual receiving
19 active and ongoing medical supervision wherein the
20 individual requires medical care on a recurring basis
21 for, among other things, instructions on the use of
22 the food.

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

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

6 “(B) Foods marketed as gluten-free for the
7 management of celiac disease or non-celiac gluten
8 sensitivity.

9 “(C) Foods marketed for the management of
10 diabetes.

11 “(D) Other products determined appropriate by
12 the Secretary.

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

15 “(A) Inherited metabolic disorders, including
16 the following:

17 “(i) Disorders classified as metabolic dis-
18 orders on the Recommended Uniform Screening
19 Panel Core Conditions list of the Secretary of
20 Health and Human Services’ Advisory Com-
21 mittee on Heritable Disorders in Newborns and
22 Children.

23 “(ii) N-acetyl glutamate synthase defi-
24 ciency.

1 “(iii) Ornithine transcarbamylase defi-
2 ciency.

3 “(iv) Carbamoyl phosphate synthetase de-
4 ficiency.

5 “(v) Inherited disorders of mitochondrial
6 functioning.

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

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

15 “(ii) Malabsorption due to liver or pan-
16 creatic disease.

17 “(C) Immunoglobulin E and non-Immunoglobu-
18 lin E-mediated allergies to food proteins, including
19 the following:

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

22 “(ii) Food protein-induced enterocolitis
23 syndrome.

24 “(iii) Eosinophilic disorders, including
25 eosinophilic esophagitis, eosinophilic gastroen-

1 teritis, eosinophilic colitis, and post-transplant
2 eosinophilic disorders.

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

5 “(i) Inflammatory bowel disease, including
6 Crohn’s disease, ulcerative colitis, and indeter-
7 minate colitis.

8 “(ii) Gastroesophageal reflux disease that
9 is nonresponsive to standard medical therapies.

10 “(E) Any other disease or condition determined
11 appropriate by the Secretary.

12 “(4) In this subsection, the term ‘ low protein modi-
13 fied food product’ means a product formulated to have less
14 than one gram of protein per serving.”.

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

18 (i) by striking “and” before “(BB)”;

19 and

20 (ii) by inserting before the semicolon
21 at the end the following: “, and (CC) with
22 respect to medically necessary food (as de-
23 fined in section 1861(jjj)), the amount
24 paid shall be an amount equal to 80 per-
25 cent of the lesser of the actual charge for

1 the services or the amount determined
 2 under a fee schedule established by the
 3 Secretary for purposes of this subpara-
 4 graph.”.

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

10 (2) INCLUSION OF MEDICALLY NECESSARY VI-
 11 TAMINS AS A COVERED PART D DRUG.—

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

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

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

20 (iii) by inserting after subparagraph
 21 (B) the following new subparagraph:

22 “(C) medically necessary vitamins used for
 23 the management of a covered disease or condi-
 24 tion (as defined in section 1861(jjj)(3)) pursu-
 25 ant to the prescription, order, or recommenda-

1 tion (as applicable) of a physician or other
2 health care professional qualified to make such
3 prescription, order, or recommendation.”

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

8 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

12 (A) in paragraph (28), by striking “and”
13 at the end;

14 (B) by redesignating paragraph (29) as
15 paragraph (31); and

16 (C) by inserting after paragraph (28) the
17 following new paragraphs:

18 “(29) medically necessary food (as defined in
19 section 1861(jjj)) and the medical equipment and
20 supplies necessary to administer such food;

21 “(30) medically necessary vitamins used for the
22 management of a covered disease or condition (as
23 defined in section 1861(jjj)(3)) pursuant to the pre-
24 scription, order, or recommendation (as applicable)
25 of a physician or other health care professional

1 qualified to make such prescription, order, or rec-
2 ommendation; and”.

3 (2) CONFORMING AMENDMENTS.—

4 (A) MANDATORY BENEFITS.—Section
5 1902(a)(10)(A) of the Social Security Act (42
6 U.S.C. 1396a(a)(10)(A)) is amended, in the
7 matter preceding clause (i), by striking “and
8 (28)” and inserting “(28), (29), and (30)”.

9 (B) EXCEPTION TO COVERAGE RESTRIC-
10 TION.—Section 1927(d)(2)(E) of the Social Se-
11 curity Act (42 U.S.C. 1396r–8(d)(2)(E)) is
12 amended by inserting “and except for medically
13 necessary vitamins described in section
14 1905(a)(30)” before the period at the end.

15 (3) EFFECTIVE DATE.—

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

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

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

16 (c) COVERAGE UNDER CHIP.—

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

20 “(9) MEDICALLY NECESSARY FOOD.—The child
21 health assistance provided to a targeted low-income
22 child under the plan shall include coverage of medi-
23 cally necessary food (as defined in section 1861(jjj))
24 and the medical equipment and supplies necessary to
25 administer such food.

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

10 (2) CONFORMING AMENDMENT.—Section
11 2103(a) of the Social Security Act (42 U.S.C.
12 1397cc(a)) is amended, in the matter preceding
13 paragraph (1), by striking “and (7)” and inserting
14 “(7), (9), and (10)”.

15 (3) EFFECTIVE DATE.—

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

20 (B) EXCEPTION TO EFFECTIVE DATE IF
21 STATE LEGISLATION REQUIRED.—In the case of
22 a State child health plan for child health assist-
23 ance under title XXI of the Social Security Act
24 which the Secretary of Health and Human
25 Services determines requires State legislation

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

17 (d) MODIFICATION OF DISEASES AND CONDITIONS
18 COVERED UNDER TRICARE PROGRAM.—Section

19 1077(h)(3) of title 10, United States Code, is amended—

20 (1) in subparagraph (D), by striking “and”;

21 (2) by redesignating subparagraph (E) as sub-
22 paragraph (F); and

23 (3) by inserting after subparagraph (D) the fol-
24 lowing:

1 “(E) Immunoglobulin E or non-Immunoglobulin
2 E mediated allergies to food proteins.”.

3 (e) COVERAGE UNDER FEHBP.—

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

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

9 “(1) medically necessary food (as defined in
10 section 1861(jjj) of the Social Security Act) and the
11 medical equipment and supplies necessary to admin-
12 ister such food; and

13 “(2) medically necessary vitamins in the same
14 manner provided for under section 1860D–
15 2(e)(1)(C) of the Social Security Act.”.

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

20 (f) COVERAGE UNDER PRIVATE HEALTH INSUR-
21 ANCE.—

22 (1) IN GENERAL.—Subpart II of part A of title
23 XXVII of the Public Health Service Act (42 U.S.C.
24 300gg–11 et seq.) is amended by adding at the end
25 the following:

1 **“SEC. 2729. COVERAGE OF MEDICALLY NECESSARY FOOD**
2 **AND VITAMINS.**

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(jjj) 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 in the same
11 manner provided for under section 1860D-
12 2(e)(1)(C) of the Social Security Act.”.

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

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