

112TH CONGRESS
1ST SESSION

S. 311

To provide for the coverage of medically necessary food under Federal health programs and private health insurance.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 8, 2011

Mr. KERRY (for himself and Mr. CASEY) 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 under Federal health programs and private health insurance.

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 Foods Equity
5 Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Newborns are screened for inborn errors of
9 metabolism, but treatment for such conditions is not
10 uniformly covered by insurance.

1 (2) Each year approximately 2,550 children in
 2 the United States are diagnosed with an inborn
 3 error of metabolism disorder, requiring foods modi-
 4 fied to be void of the nutrient or nutrients the
 5 child’s body is incapable of processing, or requiring
 6 supplementation with vitamins or amino acids.

7 (3) More than 35 States have passed laws to at
 8 least partially address the inequity in coverage for
 9 medically necessary foods, critical treatment for such
 10 disorders.

11 (4) The cost associated with providing medically
 12 necessary foods presents a large financial burden for
 13 many families.

14 (5) There is no current cure for inborn errors
 15 of metabolism disorders and treatment is necessary
 16 during the entire lifespan of the individual.

17 **SEC. 3. COVERAGE IN FEDERAL HEALTH PROGRAMS OF**
 18 **MEDICALLY NECESSARY FOOD AND FOOD**
 19 **MODIFIED TO BE LOW PROTEIN.**

20 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

21 (1) COVERAGE OF MEDICALLY NECESSARY
 22 FOOD UNDER THE ORIGINAL MEDICARE FEE-FOR-
 23 SERVICE PROGRAM.—

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 (EE), by striking
5 “and” at the end;

6 (ii) in subparagraph (FF), by insert-
7 ing “and” at the end; and

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

10 “(GG) medically necessary food (as defined in
11 subsection (iii)) and food modified to be low protein
12 that is formulated to be consumed or administered
13 under the supervision of a qualified medical pro-
14 vider, for the treatment of conditions as rec-
15 ommended by the Advisory Committee on Heritable
16 Disorders in Newborns and Children, and the med-
17 ical equipment and supplies necessary to administer
18 such food;”.

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

23 “(iii)(1) The term ‘medically necessary food’—

24 “(A) means a food which is formulated to be
25 consumed or administered enterally under the super-

1 vision of a physician and which is intended for the
2 specific dietary management of a disease or condi-
3 tion for which distinctive nutritional requirements,
4 based on recognized scientific principles, are estab-
5 lished by medical evaluation; and

6 “(B) includes nutritionally modified counter-
7 parts of traditional foods and other forms of foods
8 such as formulas, pills, capsules, and bars, so long
9 as consumed or administered enterally.

10 “(2) For purposes of paragraph (1), the term
11 ‘enterally’ refers to consumption or administration
12 through the gastrointestinal tract, whether orally or by
13 tube.”.

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

17 (i) by striking “and” before “(Z)”;

18 and

19 (ii) by inserting before the semicolon
20 at the end the following: “, and (AA) with
21 respect to medically necessary food and
22 pharmacological doses of vitamins and
23 amino acids under section 1861(s)(2)(GG),
24 the amounts paid shall be 80 percent of
25 the lesser of the actual charge for the serv-

1 ices or 85 percent of the amount deter-
2 mined under the fee schedule established
3 under section 1848(b) for the same serv-
4 ices if furnished by a physician”.

5 (2) INCLUSION OF PHARMACOLOGICAL DOSES
6 OF VITAMINS AND AMINO ACIDS AS A COVERED PART
7 D DRUG.—

8 (A) IN GENERAL.—Section 1860D–2(e)(1)
9 of the Social Security Act (42 U.S.C. 1395w–
10 102(e)(1)) is amended—

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

13 (ii) in subparagraph (B), by striking
14 the comma at the end and inserting “; or”;
15 and

16 (iii) by inserting after subparagraph
17 (B) the following new subparagraph:

18 “(C) pharmacological doses of vitamins
19 and amino acids used for the treatment of in-
20 born errors of metabolism, for the treatment of
21 conditions as recommended by the Advisory
22 Committee on Heritable Disorders in Newborns
23 and Children and as prescribed by a qualified
24 medical provider,”.

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

5 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

6 (1) IN GENERAL.—Section 1905 of the Social
7 Security Act (42 U.S.C. 1396d) is amended—

8 (A) in subsection (a)—

9 (i) in paragraph (12), by inserting
10 “including pharmacological doses of vita-
11 mins and amino acids used for the treat-
12 ment of inborn errors of metabolism, for
13 the treatment of conditions as rec-
14 ommended by the Advisory Committee on
15 Heritable Disorders in Newborns and Chil-
16 dren and as prescribed by a qualified med-
17 ical provider,” after “prescribed drugs,”;

18 (ii) in paragraph (28), by striking
19 “and” at the end;

20 (iii) in paragraph (29), by striking the
21 comma at the end and inserting “; and”;
22 and

23 (iv) by inserting after paragraph (29)
24 the following new paragraph:

1 “(30) medically necessary food (as defined in
 2 subsection (ee)) and food modified to be low protein
 3 that is formulated to be consumed or administered
 4 under the supervision of a qualified medical pro-
 5 vider, for the treatment of conditions as rec-
 6 ommended by the Advisory Committee on Heritable
 7 Disorders in Newborns and Children, and the med-
 8 ical equipment and supplies necessary to administer
 9 such food,”; and

10 (B) by adding at the end the following new

11 subsection:

12 “(ee) MEDICALLY NECESSARY FOOD DEFINED.—

13 “(1) IN GENERAL.—For purposes of subsection
 14 (a)(30), the term ‘medically necessary food’—

15 “(A) means a food which is formulated to
 16 be consumed or administered enterally under
 17 the supervision of a physician and which is in-
 18 tended for the specific dietary management of
 19 a disease or condition for which distinctive nu-
 20 tritional requirements, based on recognized sci-
 21 entific principles, are established by medical
 22 evaluation; and

23 “(B) includes nutritionally modified coun-
 24 terparts of traditional foods and other forms of
 25 foods such as formulas, pills, capsules, and

1 bars, so long as consumed or administered
2 enterally.

3 “(2) ENTERALLY.—For purposes of paragraph
4 (1), the term ‘enterally’ refers to consumption or ad-
5 ministration through the gastrointestinal tract,
6 whether orally or by tube.”.

7 (2) EXCEPTION TO REBATE EXCLUSION.—Sec-
8 tion 1927(d)(2)(E) of the Social Security Act (42
9 U.S.C. 1396r–8(d)(2)(E)) is amended by inserting
10 “, pharmacological doses of vitamins and amino
11 acids used for the treatment of inborn errors of me-
12 tabolism, for the treatment of conditions as rec-
13 ommended by the Advisory Committee on Heritable
14 Disorders in Newborns and Children and as pre-
15 scribed by a qualified medical provider,” after “pre-
16 natal vitamins”.

17 (3) CONFORMING AMENDMENT.—Section
18 1902(a)(10)(A) of the Social Security Act (42
19 U.S.C. 1396a(a)(10)(A)) is amended, in the matter
20 preceding clause (i), by striking “and (28)” and in-
21 sserting “(28), and (30)”.

22 (4) EXCEPTION TO EFFECTIVE DATE IF STATE
23 LEGISLATION REQUIRED.—In the case of a State
24 plan for medical assistance under title XIX of the
25 Social Security Act which the Secretary of Health

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

17 (c) COVERAGE UNDER CHIP.—

18 (1) IN GENERAL.—

19 (A) MEDICALLY NECESSARY FOOD.—Sec-
20 tion 2103(c) of the Social Security Act (42
21 U.S.C. 1397cc(c)) is amended by adding at the
22 end the following:

23 “(9) MEDICALLY NECESSARY FOOD.—

24 “(A) IN GENERAL.—The child health as-
25 sistance provided to a targeted low-income child

1 under the plan shall include coverage of medi-
2 cally necessary food and food modified to be low
3 protein that is formulated to be consumed or
4 administered under the supervision of a quali-
5 fied medical provider, for the treatment of con-
6 ditions as recommended by the Advisory Com-
7 mittee on Heritable Disorders in Newborns and
8 Children, and the medical equipment and sup-
9 plies necessary to administer such food.

10 “(B) DEFINITIONS.—In this paragraph—

11 “(i) the term ‘medically necessary
12 food’—

13 “(I) means a food which is for-
14 mulated to be consumed or adminis-
15 tered enterally under the supervision
16 of a physician and which is intended
17 for the specific dietary management of
18 a disease or condition for which dis-
19 tinctive nutritional requirements,
20 based on recognized scientific prin-
21 ciples, are established by medical eval-
22 uation; and

23 “(II) includes nutritionally modi-
24 fied counterparts of traditional foods
25 and other forms of foods such as for-

1 mulas, pills, capsules, and bars, so
2 long as consumed or administered
3 enterally; and

4 “(ii) the term ‘enterally’ refers to con-
5 sumption or administration through the
6 gastrointestinal tract, whether orally or by
7 tube.”.

8 (B) VITAMINS AND AMINO ACIDS.—Section
9 2110(a)(6) of the Social Security Act (42
10 U.S.C. 1397jj(a)(6)) is amended by striking
11 “and biologicals and the administration of such
12 drugs and biologicals, only if such drugs and
13 biologicals” and inserting “, pharmacological
14 doses of vitamins and amino acids used for the
15 treatment of inborn errors of metabolism, for
16 the treatment of conditions as recommended by
17 the Advisory Committee on Heritable Disorders
18 in Newborns and Children and as prescribed by
19 a qualified medical provider, and biologicals,
20 and the administration of such drugs, vitamins
21 and amino acids, and biologicals, only if such
22 drugs, vitamins and amino acids, and
23 biologicals”.

24 (2) CONFORMING AMENDMENT.—Section
25 2103(a) of the Social Security Act (42 U.S.C.

1 1397cc(a)) is amended, in the matter preceding
2 paragraph (1), by striking “, and (7)” and inserting
3 “, (7), and (9)”.

4 (d) AVAILABILITY OF MEDICALLY NECESSARY FOOD,
5 FOOD MODIFIED TO BE LOW PROTEIN, AND RELATED
6 ITEMS UNDER THE TRICARE PROGRAM.—Section
7 1077(a)(8) of title 10, United States Code, is amended
8 by striking “including” and all that follows and inserting
9 “including the following:

10 “(A) Well-baby care that includes one
11 screening of an infant for the level of lead in
12 the blood of the infant.

13 “(B) Medically necessary food (as defined
14 in section 1861(iii) of the Social Security Act)
15 and food modified to be low protein that is for-
16 mulated to be consumed or administered under
17 the supervision of a qualified medical provider,
18 for the treatment of conditions as recommended
19 by the Advisory Committee on Heritable Dis-
20 orders in Newborns and Children, and the med-
21 ical equipment and supplies necessary to admin-
22 ister such food.

23 “(C) Pharmacological doses of vitamins
24 and amino acids used for the treatment of in-
25 born errors of metabolism and other conditions

1 as recommended by the Advisory Committee on
 2 Heritable Disorders in Newborns and Chil-
 3 dren.”.

4 **SEC. 4. COVERAGE IN THE PRIVATE INSURANCE MARKET**
 5 **OF MEDICALLY NECESSARY FOOD AND FOOD**
 6 **MODIFIED TO BE LOW PROTEIN.**

7 (a) GROUP HEALTH PLANS.—

8 (1) AMENDMENTS TO ERISA.—

9 (A) IN GENERAL.—Subpart B of part 7 of
 10 title I of the Employee Retirement Income Se-
 11 curity Act of 1974 (29 U.S.C. 1185 et seq.) is
 12 amended by adding at the end the following:

13 **“SEC. 716. COVERAGE OF MEDICALLY NECESSARY FOOD**
 14 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

15 “(a) DEFINITION.—In this section—

16 “(1) the term ‘medically necessary food’—

17 “(A) means a food which is formulated to
 18 be consumed or administered enterally under
 19 the supervision of a physician and which is in-
 20 tended for the specific dietary management of
 21 a disease or condition for which distinctive nu-
 22 tritional requirements, based on recognized sci-
 23 entific principles, are established by medical
 24 evaluation; and

1 “(B) includes nutritionally modified coun-
2 terparts of traditional foods and other forms of
3 foods such as formulas, pills, capsules, and
4 bars, so long as consumed or administered
5 enterally; and

6 “(2) the term ‘enterally’ refers to consumption
7 or administration through the gastrointestinal tract,
8 whether orally or by tube.

9 “(b) COVERAGE.—

10 “(1) MEDICALLY NECESSARY FOOD AND FOOD
11 MODIFIED TO BE LOW PROTEIN.—A group health
12 plan, or a health insurance issuer that provides
13 health insurance coverage in connection with a group
14 health plan, shall provide coverage for medically nec-
15 essary food and food modified to be low protein that
16 is formulated to be consumed or administered under
17 the supervision of a qualified medical provider, for
18 the treatment of conditions as recommended by the
19 Advisory Committee on Heritable Disorders in
20 Newborns and Children, and the medical equipment
21 and supplies necessary to administer such food.

22 “(2) VITAMINS AND AMINO ACIDS.—A group
23 health plan, or a health insurance issuer that pro-
24 vides health insurance coverage in connection with a
25 group health plan, that provides prescription drug

1 coverage shall provide coverage for pharmacological
 2 doses of vitamins and amino acids used for the
 3 treatment of inborn errors of metabolism, for the
 4 treatment of conditions as recommended by the Ad-
 5 visory Committee on Heritable Disorders in
 6 Newborns and Children and as prescribed by a
 7 qualified medical provider, to the same extent as
 8 other prescription drug coverage under such plan or
 9 coverage.”.

10 (B) CONFORMING AMENDMENT.—The
 11 table of contents in section 1 of such Act is
 12 amended by inserting after the item relating to
 13 section 714 the following new items:

“Sec. 715. Additional market reforms.

“Sec. 716. Coverage of medically necessary food and food modified to be low
 protein.”.

14 (2) AMENDMENTS TO THE PUBLIC HEALTH
 15 SERVICE ACT.—Subpart 2 of part A of title XXVII
 16 of the Public Health Service Act (42 U.S.C. 300gg–
 17 4 et seq.) is amended by adding at the end the fol-
 18 lowing new section:

19 **“SEC. 2729. COVERAGE OF MEDICALLY NECESSARY FOOD**
 20 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

21 “(a) DEFINITIONS.—In this section—

22 “(1) the term ‘medically necessary food’—

23 “(A) means a food which is formulated to
 24 be consumed or administered enterally under

1 the supervision of a physician and which is in-
2 tended for the specific dietary management of
3 a disease or condition for which distinctive nu-
4 tritional requirements, based on recognized sci-
5 entific principles, are established by medical
6 evaluation, and

7 “(B) includes nutritionally modified coun-
8 terparts of traditional foods and other forms of
9 foods such as formulas, pills, capsules, and
10 bars, so long as consumed or administered
11 enterally; and

12 “(2) the term ‘enterally’ refers to consumption
13 or administration through the gastrointestinal tract,
14 whether orally or by tube.

15 “(b) COVERAGE.—

16 “(1) MEDICALLY NECESSARY FOOD AND FOOD
17 MODIFIED TO BE LOW PROTEIN.—A group health
18 plan, or a health insurance issuer that provides
19 health insurance coverage in connection with a group
20 health plan, shall provide coverage for medically nec-
21 essary food and food modified to be low protein that
22 is formulated to be consumed or administered under
23 the supervision of a qualified medical provider, for
24 the treatment of conditions as recommended by the
25 Advisory Committee on Heritable Disorders in

1 Newborns and Children, and the medical equipment
2 and supplies necessary to administer such food.

3 “(2) VITAMINS AND AMINO ACIDS.—A group
4 health plan, or a health insurance issuer that pro-
5 vides health insurance coverage in connection with a
6 group health plan, that provides prescription drug
7 coverage, shall provide coverage for pharmacological
8 doses of vitamins and amino acids used for the
9 treatment of inborn errors of metabolism, for the
10 treatment of conditions as recommended by the Ad-
11 visory Committee on Heritable Disorders in
12 Newborns and Children and as prescribed by a
13 qualified medical provider, to the same extent as
14 other prescription drug coverage under such plan or
15 coverage.”.

16 (3) AMENDMENTS TO THE INTERNAL REVENUE
17 CODE.—

18 (A) IN GENERAL.—Subchapter B of chap-
19 ter 100 of the Internal Revenue Code of 1986
20 (relating to other group health plan require-
21 ments) is amended by inserting after section
22 9813 the following new section:

23 **“SEC. 9814. COVERAGE OF MEDICALLY NECESSARY FOOD**
24 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

25 “(a) DEFINITIONS.—In this section—

1 “(1) the term ‘medically necessary food’—

2 “(A) means a food which is formulated to
3 be consumed or administered enterally under
4 the supervision of a physician and which is in-
5 tended for the specific dietary management of
6 a disease or condition for which distinctive nu-
7 tritional requirements, based on recognized sci-
8 entific principles, are established by medical
9 evaluation; and

10 “(B) includes nutritionally modified coun-
11 terparts of traditional foods and other forms of
12 foods such as formulas, pills, capsules, and
13 bars, so long as consumed or administered
14 enterally; and

15 “(2) the term ‘enterally’ refers to consumption
16 or administration through the gastrointestinal tract,
17 whether orally or by tube.

18 “(b) COVERAGE.—

19 “(1) MEDICALLY NECESSARY FOOD AND FOOD
20 MODIFIED TO BE LOW PROTEIN.—A group health
21 plan, or a health insurance issuer that provides
22 health insurance coverage in connection with a group
23 health plan, shall provide coverage for necessary
24 medically necessary food and food modified to be low
25 protein that is formulated to be consumed or admin-

1 istered under the supervision of a qualified medical
2 provider, for the treatment of conditions as rec-
3 ommended by the Advisory Committee on Heritable
4 Disorders in Newborns and Children, and the med-
5 ical equipment and supplies necessary to administer
6 such food.

7 “(2) VITAMINS AND AMINO ACIDS.—A group
8 health plan, or a health insurance issuer that pro-
9 vides health insurance coverage in connection with a
10 group health plan, that provides prescription drug
11 coverage, shall provide coverage for pharmacological
12 doses of vitamins and amino acids used for the
13 treatment of inborn errors of metabolism, for the
14 treatment of conditions as recommended by the Ad-
15 visory Committee on Heritable Disorders in
16 Newborns and Children and as prescribed by a
17 qualified medical provider, to the same extent as
18 other prescription drug coverage under such plan or
19 coverage.”.

20 (B) CONFORMING AMENDMENT.—The
21 table of sections for subchapter B of chapter
22 100 of such Code is amended by inserting after
23 the item relating to section 9813 the following
24 new item:

“Sec. 9814. Coverage of medically necessary food and food modified to be low
protein.”.

1 (b) INDIVIDUAL MARKET.—Subpart 2 of part B of
 2 title XXVII of the Public Health Service Act (42 U.S.C.
 3 300gg–51 et seq.) is amended by adding at the end the
 4 following new section:

5 **“SEC. 2754. COVERAGE OF MEDICALLY NECESSARY FOOD**
 6 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

7 “The provisions of section 2729 shall apply to health
 8 insurance coverage offered by a health insurance issuer
 9 in the individual market in the same manner as they apply
 10 to health insurance coverage offered by a health insurance
 11 issuer in connection with a group health plan in the small
 12 or large group market.”.

13 (c) AMENDMENT TO PPACA.—Section 1302(b)(1) of
 14 the Patient Protection and Affordable Care Act (42
 15 U.S.C. 18022(b)(1)) is amended by adding at the end the
 16 following:

17 “(K) Medically necessary food, as defined
 18 in section 2729 of the Public Health Service
 19 Act.”.

20 **SEC. 5. EFFECTIVE DATE; DETERMINATION OF MINIMUM**
 21 **YEARLY COVERAGE.**

22 (a) EFFECTIVE DATE.—The amendments made by
 23 sections 3 and 4 shall apply to plan years beginning after
 24 the date that is 180 days after the date of enactment of
 25 this Act.

1 (b) DETERMINATION BY SECRETARY.—

2 (1) IN GENERAL.—Prior to the date described
3 under subsection (a), the Secretary of Health and
4 Human Services (referred to in this Act as the “Sec-
5 retary”) shall determine the minimum yearly cov-
6 erage for all health insurance plans pursuant to the
7 amendments made by this Act. Such minimum year-
8 ly coverage shall apply to an individual during any
9 period when the individual is covered under the plan
10 and for as long as deemed medically necessary. The
11 Secretary may establish age-specific minimum levels
12 of coverage and periodically update these levels
13 based on a standard cost of living index, the actual
14 cost of treatment, and other appropriate measures
15 as determined by the Secretary.

16 (2) NO PREEMPTION.—The minimum yearly
17 coverage determined by the Secretary under para-
18 graph (1) shall not preempt any State standards
19 that require a higher minimum yearly coverage level
20 for the same services and benefits.

○