

111TH CONGRESS
1ST SESSION

S. 2766

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 10, 2009

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 2009”.

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 30 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.—

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

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

(ii) in subparagraph (EE), by inserting “and” at the end; and

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

“(FF) medically necessary food (as defined in subsection (hhh)) and food modified to be low protein that is formulated to be consumed or administered under the supervision of a qualified medical provider, for the treatment of conditions as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children, and the medical equipment and supplies necessary to administer such food.”.

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

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

“(A) means a food which is formulated to be consumed or administered enterally under the supervision of a qualified medical provider and which is

1 intended for the specific dietary management of a
 2 disease or condition for which distinctive nutritional
 3 requirements, based on recognized scientific prin-
 4 ciples, are established by medical evaluation; and

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

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

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

16 (i) by striking “and” before “(W)”;

17 and

18 (ii) by inserting before the semicolon
 19 at the end the following: “, and (X) with
 20 respect to medically necessary food and
 21 pharmacological doses of vitamins and
 22 amino acids under section 1861(s)(2)(FF),
 23 the amounts paid shall be 80 percent of
 24 the lesser of the actual charge for the serv-
 25 ices or 85 percent of the amount deter-

1 mined under the fee schedule established
 2 under section 1848(b) for the same serv-
 3 ices if furnished by a physician”.

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

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

10 (i) in subparagraph (A), by striking
 11 “or”;

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

15 (iii) by adding at the end the fol-
 16 lowing new subparagraph:

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

24 (B) EFFECTIVE DATE.—The amendments
 25 made by subparagraph (A) shall apply to plan

1 years beginning on or after the date that is 6
2 months after date of enactment of this Act.

3 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

4 (1) DEFINITION OF MEDICAL ASSISTANCE.—

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

7 (A) in subsection (a)—

8 (i) by redesignating paragraph (28) as
9 paragraph (30);

10 (ii) in paragraph (27), by striking at
11 the end “and”; and

12 (iii) by inserting after paragraph (27)
13 the following new paragraphs:

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

23 “(29) pharmacological doses of vitamins and
24 amino acids used for the treatment of inborn errors
25 of metabolism, for the treatment of conditions as

recommended by the Advisory Committee on Heritable Disorders in Newborns and Children and as prescribed by a qualified medical provider; and”; and

(B) by adding at the end the following new subsection:

“(y) MEDICALLY NECESSARY FOOD DEFINED.—

“(1) IN GENERAL.—For purposes of subsection (a)(28), the term ‘medically necessary food’—

“(A) means a food which is formulated to be consumed or administered enterally under the supervision of a qualified medical provider and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation; and

“(B) includes nutritionally modified counterparts of traditional foods and other forms of foods such as formulas, pills, capsules and bars, so long as consumed or administered enterally.

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

1 (2) MANDATORY BENEFITS.—Section
 2 1902(a)(10)(A) of the Social Security Act (42
 3 U.S.C. 1396a(a)(10)(A)) is amended, in the matter
 4 preceding clause (i), by striking “and (21)” and in-
 5 serting “, (21), (28), and (29)”.

6 (3) CONFORMING AMENDMENTS.—

7 (A) MEDICALLY NEEDY.—Section
 8 1902(a)(10)(C)(iv) of such Act (42 U.S.C.
 9 1396a(a)(10)(C)(iv)) is amended by striking
 10 “and (17) of section 1905(a) or the care and
 11 services listed in any 7 of the paragraphs num-
 12 bered (1) through (24)” and inserting “(17),
 13 (28), and (29) of section 1905(a) or the care
 14 and services listed in any 7 of the paragraphs
 15 numbered (1) through (24) or (28) or (29)”.

16 (B) EXCEPTION TO REBATE EXCLUSION.—
 17 Section 1927(d)(2)(F) of the Social Security
 18 Act (42 U.S.C. 1396r–8(d)(2)(F)) is amended
 19 by inserting “, pharmacological doses of vita-
 20 mins and amino acids used for the treatment of
 21 inborn errors of metabolism, for the treatment
 22 of conditions as recommended by the Advisory
 23 Committee on Heritable Disorders in Newborns
 24 and Children and as prescribed by a qualified
 25 medical provider,” after “prenatal vitamins”.

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

21 (c) COVERAGE UNDER CHIP.—

22 (1) REQUIRED COVERAGE.—Section 2103(c) of
23 the Social Security Act (42 U.S.C. 1397cc(c)) is
24 amended by inserting after paragraph (8) the fol-
25 lowing:

1 “(9) MEDICALLY NECESSARY FOOD.—

2 “(A) IN GENERAL.—The child health as-
 3 sistance provided to a targeted low-income child
 4 under the plan shall include coverage of medi-
 5 cally necessary food and food modified to be low
 6 protein that is formulated to be consumed or
 7 administered under the supervision of a quali-
 8 fied medical provider, for the treatment of con-
 9 ditions as recommended by the Advisory Com-
 10 mittee on Heritable Disorders in Newborns and
 11 Children, and the medical equipment and sup-
 12 plies necessary to administer such food.

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

14 “(i) the term ‘medically necessary
 15 food’—

16 “(I) means a food which is for-
 17 mulated to be consumed or adminis-
 18 tered enterally under the supervision
 19 of a qualified medical provider and
 20 which is intended for the specific die-
 21 tary management of a disease or con-
 22 dition for which distinctive nutritional
 23 requirements, based on recognized sci-
 24 entific principles, are established by
 25 medical evaluation; and

1 “(II) includes nutritionally modi-
 2 fied counterparts of traditional foods
 3 and other forms of foods such as for-
 4 mulas, pills, capsules and bars, so
 5 long as consumed or administered
 6 enterally; and

7 “(ii) the term ‘enterally’ refers to con-
 8 sumption or administration through the
 9 gastrointestinal tract, whether orally or by
 10 tube.

11 “(10) VITAMINS AND AMINO ACIDS.—The child
 12 health assistance provided to a targeted low-income
 13 child under the plan shall include coverage of phar-
 14 macological doses of vitamins and amino acids used
 15 for the treatment of inborn errors of metabolism, for
 16 the treatment of conditions as recommended by the
 17 Advisory Committee on Heritable Disorders in
 18 Newborns and Children and as prescribed by a
 19 qualified medical provider.”.

20 (2) CONFORMING AMENDMENTS.—

21 (A) MANDATORY BENEFITS.—Section
 22 2103(a) of the Social Security Act (42 U.S.C.
 23 1397cc(a)) is amended, in the matter preceding
 24 paragraph (1), by striking “, and (7)” and in-
 25 serting “, (7), (9), and (10)”.

1 (B) DEFINITION OF CHILD HEALTH AS-
 2 SISTANCE.—Section 2110(a) of such Act (42
 3 U.S.C. 1397jj) is amended—

4 (i) by redesignating paragraph (28) as
 5 paragraph (30); and

6 (ii) by inserting after paragraph (27)
 7 the following:

8 “(28) Medically necessary food (as defined in
 9 section 2103(c)(9)(B)(i)) and food modified to be
 10 low protein that is formulated to be consumed or ad-
 11 ministered under the supervision of a qualified med-
 12 ical provider, for the treatment of conditions as rec-
 13 ommended by the Advisory Committee on Heritable
 14 Disorders in Newborns and Children, and the med-
 15 ical equipment and supplies necessary to administer
 16 such food.

17 “(29) Pharmacological doses of vitamins and
 18 amino acids used for the treatment of inborn errors
 19 of metabolism, for the treatment of conditions as
 20 recommended by the Advisory Committee on Heri-
 21 table Disorders in Newborns and Children and as
 22 prescribed by a qualified medical provider.”.

23 (d) AVAILABILITY OF MEDICALLY NECESSARY FOOD,
 24 FOOD MODIFIED TO BE LOW PROTEIN, AND RELATED
 25 ITEMS UNDER THE TRICARE PROGRAM.—Section

1 1077(a)(8) of title 10, United States Code, is amended
2 by striking “including” and all that follows and inserting
3 “including the following:

4 “(A) Well-baby care that includes one
5 screening of an infant for the level of lead in
6 the blood of the infant.

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

17 “(C) Pharmacological doses of vitamins
18 and amino acids used for the treatment of in-
19 born errors of metabolism and other conditions
20 as recommended by the Advisory Committee on
21 Heritable Disorders in Newborns and Chil-
22 dren.”.

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

4 (a) GROUP HEALTH PLANS.—

5 (1) AMENDMENTS TO ERISA.—

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

10 **“SEC. 715. COVERAGE OF MEDICALLY NECESSARY FOOD**
 11 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

12 “(a) DEFINITION.—In this section—

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

14 “(A) means a food which is formulated to
 15 be consumed or administered enterally under
 16 the supervision of a qualified medical provider
 17 and which is intended for the specific dietary
 18 management of a disease or condition for which
 19 distinctive nutritional requirements, based on
 20 recognized scientific principles, are established
 21 by medical evaluation; and

22 “(B) includes nutritionally modified coun-
 23 terparts of traditional foods and other forms of
 24 foods such as formulas, pills, capsules and bars,
 25 so long as consumed or administered enterally.

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

4 “(b) COVERAGE.—

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

17 “(2) VITAMINS AND AMINO ACIDS.—A group
18 health plan, or a health insurance issuer that pro-
19 vides health insurance coverage in connection with a
20 group health plan, that provides prescription drug
21 coverage shall provide coverage for pharmacological
22 doses of vitamins and amino acids used for the
23 treatment of inborn errors of metabolism, for the
24 treatment of conditions as recommended by the Ad-
25 visory Committee on Heritable Disorders in

1 Newborns and Children and as prescribed by a
 2 qualified medical provider, to the same extent as
 3 other prescription drug coverage under such plan or
 4 coverage.”.

5 (B) CONFORMING AMENDMENT.—The
 6 table of contents in section 1 of such Act is
 7 amended by inserting after the item relating to
 8 section 714 the following new item:

“Sec. 715. Coverage of medically necessary food and food modified to be low
 protein.”.

9 (2) AMENDMENTS TO THE PUBLIC HEALTH
 10 SERVICE ACT.—Subpart 2 of part A of title XXVII
 11 of the Public Health Service Act (42 U.S.C. 300gg–
 12 4 et seq.) is amended by adding at the end the fol-
 13 lowing new section:

14 **“SEC. 2708. COVERAGE OF MEDICALLY NECESSARY FOOD**
 15 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

16 “(a) DEFINITIONS.—In this section—

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

18 “(A) means a food which is formulated to
 19 be consumed or administered enterally under
 20 the supervision of a qualified medical provider
 21 and which is intended for the specific dietary
 22 management of a disease or condition for which
 23 distinctive nutritional requirements, based on

1 recognized scientific principles, are established
2 by medical evaluation; and

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

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

10 “(b) COVERAGE.—

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

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

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

11 (3) AMENDMENTS TO THE INTERNAL REVENUE
 12 CODE.—

13 (A) IN GENERAL.—Subchapter B of chap-
 14 ter 100 of the Internal Revenue Code of 1986
 15 (relating to other group health plan require-
 16 ments) is amended by inserting after section
 17 9813 the following new section:

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

20 “(a) DEFINITIONS.—In this section—

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

22 “(A) means a food which is formulated to
 23 be consumed or administered enterally under
 24 the supervision of a qualified medical provider
 25 and which is intended for the specific dietary

1 management of a disease or condition for which
 2 distinctive nutritional requirements, based on
 3 recognized scientific principles, are established
 4 by medical evaluation; and

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

9 “(2) the term ‘enterally’ refers to consumption
 10 or administration through the gastrointestinal tract,
 11 whether orally or by tube.

12 “(b) COVERAGE.—

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

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

14 (B) CONFORMING AMENDMENT.—The
 15 table of sections for subchapter B of chapter
 16 100 of such Code is amended by inserting after
 17 the item relating to section 9813 the following
 18 new item:

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

19 (b) INDIVIDUAL MARKET.—Subpart 3 of part B of
 20 title XXVII of the Public Health Service Act (42 U.S.C.
 21 300gg–51 et seq.) is amended by adding at the end the
 22 following new section:

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

3 “The provisions of section 2708 shall apply to health
4 insurance coverage offered by a health insurance issuer
5 in the individual market in the same manner as they apply
6 to health insurance coverage offered by a health insurance
7 issuer in connection with a group health plan in the small
8 or large group market.”.

9 **SEC. 5. EFFECTIVE DATE; DETERMINATION OF MINIMUM**
10 **YEARLY COVERAGE.**

11 (a) **EFFECTIVE DATE.**—The amendments made by
12 sections 3 and 4 shall apply to plan years beginning after
13 the date that is 180 days after the date of enactment of
14 this Act.

15 (b) **DETERMINATION BY SECRETARY.**—

16 (1) **IN GENERAL.**—Prior to the date described
17 under subsection (a), the Secretary of Health and
18 Human Services (referred to in this Act as the “Sec-
19 retary”) shall determine the minimum yearly cov-
20 erage for all health insurance plans pursuant to the
21 amendments made by this Act. Such minimum year-
22 ly coverage shall apply to an individual during any
23 period when the individual is covered under the plan
24 and for as long as deemed medically necessary. The
25 Secretary may establish age-specific minimum levels
26 of coverage and periodically update these levels

1 based on a standard cost of living index, the actual
2 cost of treatment, and other appropriate measures
3 as determined by the Secretary.

4 (2) NO PREEMPTION.—The minimum yearly
5 coverage determined by the Secretary under para-
6 graph (1) shall not preempt any State standards
7 that require a higher minimum yearly coverage level
8 for the same services and benefits.

○