

112TH CONGRESS
1ST SESSION

H. R. 1311

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 2011

Ms. BALDWIN (for herself, Mr. POLIS, Ms. JACKSON LEE of Texas, Ms. EDDIE BERNICE JOHNSON of Texas, and Mr. JOHNSON of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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:

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

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

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

14 (4) The cost associated with providing medically
15 necessary foods presents a large financial burden for
16 many families.

17 (5) There is no current cure for inborn errors
18 of metabolism disorders and treatment is necessary
19 during the entire lifespan of the individual.

20 **SEC. 3. COVERAGE IN FEDERAL HEALTH PROGRAMS OF**
21 **MEDICALLY NECESSARY FOOD AND FOOD**
22 **MODIFIED TO BE LOW PROTEIN.**

23 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

1 (1) COVERAGE OF MEDICALLY NECESSARY
2 FOOD UNDER THE ORIGINAL MEDICARE FEE-FOR-
3 SERVICE PROGRAM.—

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

7 (i) in subparagraph (EE), by striking
8 “and” at the end;

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

11 (iii) by adding at the end the fol-
12 lowing new subparagraph:

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

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

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

2 “(A) means a food which is formulated to be
3 consumed or administered enterally under the super-
4 vision of a physician and which is intended for the
5 specific dietary management of a disease or condi-
6 tion for which distinctive nutritional requirements,
7 based on recognized scientific principles, are estab-
8 lished by medical evaluation; and

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

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

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

20 (i) by striking “and” before “(Z)”;
21

21 and

22 (ii) by inserting before the semicolon
23 at the end the following: “, and (AA) with
24 respect to medically necessary food and
25 pharmacological doses of vitamins and

1 amino acids under section 1861(s)(2)(GG),
2 the amounts paid shall be 80 percent of
3 the lesser of the actual charge for the serv-
4 ices or 85 percent of the amount deter-
5 mined under the fee schedule established
6 under section 1848(b) for the same serv-
7 ices if furnished by a physician”.

8 (2) INCLUSION OF PHARMACOLOGICAL DOSES
9 OF VITAMINS AND AMINO ACIDS AS A COVERED PART
10 D DRUG.—

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

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

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

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

21 “(C) pharmacological doses of vitamins
22 and amino acids used for the treatment of in-
23 born errors of metabolism, for the treatment of
24 conditions as recommended by the Advisory
25 Committee on Heritable Disorders in Newborns

1 and Children and as prescribed by a qualified
2 medical provider,”.

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

7 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

10 (A) in subsection (a)—

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

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

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

1 (iv) by inserting after paragraph (29)
2 the following new paragraph:

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

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

14 “(ee) MEDICALLY NECESSARY FOOD DEFINED.—

15 “(1) IN GENERAL.—For purposes of subsection
16 (a)(30), 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.

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

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

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

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) IN GENERAL.—

23 (A) MEDICALLY NECESSARY FOOD.—Sec-
24 tion 2103(c) of the Social Security Act (42

1 U.S.C. 1397cc(c) is amended by adding at the
2 end the following:

3 “(9) MEDICALLY NECESSARY FOOD.—

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

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

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

18 “(I) means a food which is for-
19 mulated to be consumed or adminis-
20 tered enterally under the supervision
21 of a physician and which is intended
22 for the specific dietary management of
23 a disease or condition for which dis-
24 tinctive nutritional requirements,
25 based on recognized scientific prin-

1 ciples, are established by medical eval-
2 uation; and

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

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

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

1 and amino acids, and biologicals, only if such
2 drugs, vitamins and amino acids, and
3 biologicals”.

4 (2) CONFORMING AMENDMENT.—Section
5 2103(a) of the Social Security Act (42 U.S.C.
6 1397cc(a)) is amended, in the matter preceding
7 paragraph (1), by striking “, and (7)” and inserting
8 “, (7), and (9)”.

9 (d) AVAILABILITY OF MEDICALLY NECESSARY FOOD,
10 FOOD MODIFIED TO BE LOW PROTEIN, AND RELATED
11 ITEMS UNDER THE TRICARE PROGRAM.—Section
12 1077(a)(8) of title 10, United States Code, is amended
13 by striking “including” and all that follows and inserting
14 “including the following:

15 “(A) Well-baby care that includes one
16 screening of an infant for the level of lead in
17 the blood of the infant.

18 “(B) Medically necessary food (as defined
19 in section 1861(iii) of the Social Security Act)
20 and food modified to be low protein that is for-
21 mulated to be consumed or administered under
22 the supervision of a qualified medical provider,
23 for the treatment of conditions as recommended
24 by the Advisory Committee on Heritable Dis-
25 orders in Newborns and Children, and the med-

1 ical equipment and supplies necessary to admin-
2 ister such food.

3 “(C) Pharmacological doses of vitamins
4 and amino acids used for the treatment of in-
5 born errors of metabolism and other conditions
6 as recommended by the Advisory Committee on
7 Heritable Disorders in Newborns and Chil-
8 dren.”.

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

12 (a) GROUP HEALTH PLANS.—

13 (1) AMENDMENTS TO ERISA.—

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

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

20 “(a) DEFINITION.—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 physician and which is in-
25 tended for the specific dietary management of

1 a disease or condition for which distinctive nu-
2 tritional requirements, based on recognized sci-
3 entific principles, are established by medical
4 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
8 bars, so long as consumed or administered
9 enterally; and

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

13 “(b) COVERAGE.—

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

18 (2) AMENDMENTS TO THE PUBLIC HEALTH
19 SERVICE ACT.—Subpart 2 of part A of title XXVII
20 of the Public Health Service Act (42 U.S.C. 300gg–
21 4 et seq.) is amended by adding at the end the fol-
22 lowing new section:

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

3 “(a) DEFINITIONS.—In this section—

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

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

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

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

21 “(b) COVERAGE.—

22 “(1) MEDICALLY NECESSARY FOOD AND FOOD
23 MODIFIED TO BE LOW PROTEIN.—A group health
24 plan, or a health insurance issuer that provides
25 health insurance coverage in connection with a group
26 health plan, shall provide coverage for medically nec-

1 essary food and food modified to be low protein that
2 is formulated to be consumed or administered under
3 the supervision of a qualified medical provider, for
4 the treatment of conditions as recommended by the
5 Advisory Committee on Heritable Disorders in
6 Newborns and Children, and the medical equipment
7 and supplies necessary to administer such food.

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

21 (3) AMENDMENTS TO THE INTERNAL REVENUE
22 CODE.—

23 (A) IN GENERAL.—Subchapter B of chap-
24 ter 100 of the Internal Revenue Code of 1986
25 (relating to other group health plan require-

1 ments) is amended by inserting after section
2 9813 the following new section:

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

5 “(a) DEFINITIONS.—In this section—

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

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

15 “(B) includes nutritionally modified coun-
16 terparts of traditional foods and other forms of
17 foods such as formulas, pills, capsules, and
18 bars, so long as consumed or administered
19 enterally; and

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

23 “(b) COVERAGE.—

24 “(1) MEDICALLY NECESSARY FOOD AND FOOD
25 MODIFIED TO BE LOW PROTEIN.—A group health

1 plan, or a health insurance issuer that provides
2 health insurance coverage in connection with a group
3 health plan, shall provide coverage for necessary
4 medically necessary food and food modified to be low
5 protein that is formulated to be consumed or admin-
6 istered under the supervision of a qualified medical
7 provider, for the treatment of conditions as rec-
8 ommended by the Advisory Committee on Heritable
9 Disorders in Newborns and Children, and the med-
10 ical equipment and supplies necessary to administer
11 such food.

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

1 (B) CONFORMING AMENDMENT.—The
2 table of sections for subchapter B of chapter
3 100 of such Code is amended by inserting after
4 the item relating to section 9813 the following
5 new item:

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

6 (b) INDIVIDUAL MARKET.—Subpart 2 of part B of
7 title XXVII of the Public Health Service Act (42 U.S.C.
8 300gg–51 et seq.) is amended by adding at the end the
9 following new section:

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

12 “The provisions of section 2729 shall apply to health
13 insurance coverage offered by a health insurance issuer
14 in the individual market in the same manner as they apply
15 to health insurance coverage offered by a health insurance
16 issuer in connection with a group health plan in the small
17 or large group market.”.

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

22 “(K) Medically necessary food, as defined
23 in section 2729 of the Public Health Service
24 Act.”.

1 **SEC. 5. EFFECTIVE DATE; DETERMINATION OF MINIMUM**
2 **YEARLY COVERAGE.**

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

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

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

22 (2) **NO PREEMPTION.**—The minimum yearly
23 coverage determined by the Secretary under para-
24 graph (1) shall not preempt any State standards

- 1 that require a higher minimum yearly coverage level
- 2 for the same services and benefits.

