

111TH CONGRESS
2^D SESSION

H. R. 4926

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 24, 2010

Ms. BALDWIN (for herself, Mr. EDWARDS of Texas, Mr. POLIS of Colorado, Mr. SARBANES, 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, Education and Labor, and Armed Services, 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 2010”.

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 30 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 (DD), by striking
8 “and” at the end;

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

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

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

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

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

1 “(A) means a food which is formulated to be
2 consumed or administered enterally under the super-
3 vision of a qualified medical provider and which is
4 intended for the specific dietary management of a
5 disease or condition for which distinctive nutritional
6 requirements, based on recognized scientific prin-
7 ciples, are established by medical evaluation; and

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

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

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

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

20 and

21 (ii) by inserting before the semicolon
22 at the end the following: “, and (X) with
23 respect to medically necessary food and
24 pharmacological doses of vitamins and
25 amino acids under section 1861(s)(2)(FF),

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

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

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

13 (i) in subparagraph (A), by striking
14 “or”;

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

18 (iii) by adding at the end the fol-
19 lowing new subparagraph:

20 “(C) pharmacological doses of vitamins
21 and amino acids used for the treatment of in-
22 born errors of metabolism, for the treatment of
23 conditions as recommended by the Advisory
24 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) DEFINITION OF MEDICAL ASSISTANCE.—
9 Section 1905 of the Social Security Act (42 U.S.C.
10 1396d) is amended—

11 (A) in subsection (a)—

12 (i) by redesignating paragraph (28) as
13 paragraph (30);

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

16 (iii) by inserting after paragraph (27)
17 the following new paragraphs:

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

1 ical equipment and supplies necessary to administer
2 such food;

3 “(29) pharmacological doses of vitamins and
4 amino acids used for the treatment of inborn errors
5 of metabolism, for the treatment of conditions as
6 recommended by the Advisory Committee on Heri-
7 table Disorders in Newborns and Children and as
8 prescribed by a qualified medical provider; and”;

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

11 “(y) MEDICALLY NECESSARY FOOD DEFINED.—

12 “(1) IN GENERAL.—For purposes of subsection
13 (a)(28), 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) ENTERALLY.—For purposes of paragraph
2 (1), the term ‘enterally’ refers to consumption or ad-
3 ministration through the gastrointestinal tract,
4 whether orally or by tube.”.

5 (2) MANDATORY BENEFITS.—Section
6 1902(a)(10)(A) of the Social Security Act (42
7 U.S.C. 1396a(a)(10)(A)) is amended, in the matter
8 preceding clause (i), by striking “and (21)” and in-
9 serting “, (21), (28), and (29)”.

10 (3) CONFORMING AMENDMENTS.—

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

20 (B) EXCEPTION TO REBATE EXCLUSION.—
21 Section 1927(d)(2)(F) of the Social Security
22 Act (42 U.S.C. 1396r-8(d)(2)(F)) is amended
23 by inserting “, pharmacological doses of vita-
24 mins and amino acids used for the treatment of
25 inborn errors of metabolism, for the treatment

1 of conditions as recommended by the Advisory
2 Committee on Heritable Disorders in Newborns
3 and Children and as prescribed by a qualified
4 medical provider,” after “prenatal vitamins”.

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

25 (c) COVERAGE UNDER CHIP.—

1 (1) REQUIRED COVERAGE.—Section 2103(e) of
2 the Social Security Act (42 U.S.C. 1397cc(e)) is
3 amended by inserting after paragraph (8) the fol-
4 lowing:

5 “(9) MEDICALLY NECESSARY FOOD.—

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

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

18 “(i) the term ‘medically necessary
19 food’—

20 “(I) means a food which is for-
21 mulated to be consumed or adminis-
22 tered enterally under the supervision
23 of a qualified medical provider and
24 which is intended for the specific die-
25 tary management of a disease or con-

1 dition for which distinctive nutritional
2 requirements, based on recognized sci-
3 entific principles, are established by
4 medical evaluation; and

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

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

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

24 **(2) CONFORMING AMENDMENTS.**—

1 (A) MANDATORY BENEFITS.—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 (7)” and in-
5 serting “, (7), (9), and (10)”.

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

9 (i) by redesignating paragraph (28) as
10 paragraph (30); and

11 (ii) by inserting after paragraph (27)
12 the following:

13 “(28) Medically necessary food (as defined in
14 section 2103(c)(9)(B)(i)) and food modified to be
15 low protein that is formulated to be consumed or ad-
16 ministered under the supervision of a qualified med-
17 ical provider, 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 “(29) Pharmacological doses of vitamins and
23 amino acids used for the treatment of inborn errors
24 of metabolism, for the treatment of conditions as
25 recommended by the Advisory Committee on Heri-

1 table Disorders in Newborns and Children and as
2 prescribed by a qualified medical provider.”.

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

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

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

22 “(C) Pharmacological doses of vitamins
23 and amino acids used for the treatment of in-
24 born errors of metabolism and other conditions
25 as recommended by the Advisory Committee on

1 Heritable Disorders in Newborns and Chil-
2 dren.”.

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

6 (a) GROUP HEALTH PLANS.—

7 (1) AMENDMENTS TO ERISA.—

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

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

14 “(a) DEFINITION.—In this section—

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

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

24 “(B) includes nutritionally modified coun-
25 terparts of traditional foods and other forms of

1 foods such as formulas, pills, capsules and bars,
2 so long as consumed or administered enterally.

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

6 “(b) COVERAGE.—

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

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

1 treatment of conditions as recommended by the Ad-
 2 visory Committee on Heritable Disorders in
 3 Newborns and Children and as prescribed by a
 4 qualified medical provider, to the same extent as
 5 other prescription drug coverage under such plan or
 6 coverage.”.

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

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

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

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

18 “(a) DEFINITIONS.—In this section—

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

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

1 distinctive nutritional requirements, based on
2 recognized scientific principles, are established
3 by medical evaluation; and

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

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

11 “(b) COVERAGE.—

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

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

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

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

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

19 **“SEC. 9814. 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
 25 the supervision of a qualified medical provider

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

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

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 necessary
19 medically necessary food and food modified to be low
20 protein that is formulated to be consumed or admin-
21 istered under the supervision of a qualified medical
22 provider, for the treatment of conditions as rec-
23 ommended by the Advisory Committee on Heritable
24 Disorders in Newborns and Children, and the med-

1 ical equipment and supplies necessary to administer
2 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 (B) CONFORMING AMENDMENT.—The
17 table of sections for subchapter B of chapter
18 100 of such Code is amended by inserting after
19 the item relating to section 9813 the following
20 new item:

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

21 (b) INDIVIDUAL MARKET.—Subpart 3 of part B of
22 title XXVII of the Public Health Service Act (42 U.S.C.
23 300gg–51 et seq.) is amended by adding at the end the
24 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.

○