

113TH CONGRESS
1ST SESSION

H. R. 3665

To provide for the coverage of medically necessary food under Federal health programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 5, 2013

Mr. DELANEY (for himself, Mr. GOODLATTE, Mr. POLIS, Mr. JOHNSON of Georgia, and Ms. MOORE) 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 Oversight and Government Reform, 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 for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Foods Equity
5 Act of 2013”.

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 CERTAIN FEDERAL HEALTH PRO-**
21 **GRAMS OF MEDICALLY NECESSARY FOOD**
22 **AND FOOD 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) by redesignating paragraph (29)
23 as paragraph (30); and

24 (iv) by inserting after paragraph (28)
25 the following new paragraph:

1 “(29) 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)(29), 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 (29)”.

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 determines requires State legis-
2 lation (other than legislation appropriating funds) in
3 order for the plan to meet the additional require-
4 ment imposed by the amendments made by this sub-
5 section, the State plan shall not be regarded as fail-
6 ing to comply with the requirements of such title
7 solely on the basis of its failure to meet this addi-
8 tional requirement before the first day of the first
9 calendar quarter beginning after the close of the
10 first regular session of the State legislature that be-
11 gins after the date of the enactment of this Act. For
12 purposes of the previous sentence, in the case of a
13 State that has a 2-year legislative session, each year
14 of such session shall be deemed to be a separate reg-
15 ular session of the State legislature.

16 (c) COVERAGE UNDER CHIP.—

17 (1) IN GENERAL.—

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

22 “(9) MEDICALLY NECESSARY FOOD.—

23 “(A) IN GENERAL.—The child health as-
24 sistance provided to a targeted low-income child
25 under the plan shall include coverage of medi-

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

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

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

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

22 “(II) includes nutritionally modi-
23 fied counterparts of traditional foods
24 and other forms of foods such as for-
25 mulas, pills, capsules, and bars, so

1 long as consumed or administered
2 enterally; and

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

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

23 (2) CONFORMING AMENDMENT.—Section
24 2103(a) of the Social Security Act (42 U.S.C.
25 1397cc(a)) is amended, in the matter preceding

1 paragraph (1), by striking “, and (7)” and inserting
2 “, (7), and (9)”.

3 (3) EXCEPTION TO EFFECTIVE DATE IF STATE
4 LEGISLATION REQUIRED.—In the case of a State
5 child health plan for child health assistance under
6 title XXI of the Social Security Act which the Sec-
7 retary of Health and Human Services determines re-
8 quires State legislation (other than legislation appro-
9 priating funds) in order for the plan to meet the ad-
10 ditional requirement imposed by the amendments
11 made by this subsection, the State child health plan
12 shall not be regarded as failing to comply with the
13 requirements of such title solely on the basis of its
14 failure to meet this additional requirement before
15 the first day of the first calendar quarter beginning
16 after the close of the first regular session of the
17 State legislature that begins after the date of the en-
18 actment of this Act. For purposes of the previous
19 sentence, in the case of a State that has a 2-year
20 legislative session, each year of such session shall be
21 deemed to be a separate regular session of the State
22 legislature.

23 (d) AVAILABILITY OF MEDICALLY NECESSARY FOOD,
24 FOOD MODIFIED TO BE LOW PROTEIN, AND RELATED

1 ITEMS UNDER THE TRICARE PROGRAM.—Section 1077
2 of title 10, United States Code, is amended—

3 (1) in subsection (a)(8), by striking “including”
4 and all that follows and inserting “including the fol-
5 lowing:

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

9 “(B) In accordance with subsection (g),
10 medically necessary food (as defined in section
11 1861(iii) of the Social Security Act) and food
12 modified to be low protein that is formulated to
13 be consumed or administered under the super-
14 vision of a qualified medical provider, for the
15 treatment of conditions as recommended by the
16 Advisory Committee on Heritable Disorders in
17 Newborns and Children, and the medical equip-
18 ment and supplies necessary to administer such
19 food.

20 “(C) In accordance with subsection (g),
21 pharmacological doses of vitamins and amino
22 acids used for the treatment of inborn errors of
23 metabolism and other conditions as rec-
24 ommended by the Advisory Committee on Heri-
25 table Disorders in Newborns and Children and

1 as prescribed by a qualified medical provider.”;

2 and

3 (2) by adding at the end the following new sub-
4 section:

5 “(g) Treatments described in subparagraphs (B) and
6 (C) of subsection (a)(8) may be provided under this sec-
7 tion to a patient regardless of the age of the patient.”.

8 (e) COVERAGE UNDER FEHBP.—

9 (1) IN GENERAL.—Section 8904 of title 5,
10 United States Code, is amended by adding at the
11 end the following new subsection:

12 “(c)(1) Any health benefits plan offered under this
13 chapter shall, in accordance with paragraph (2), include
14 benefits for—

15 “(A) medically necessary food (as defined in
16 section 1861(iii) of the Social Security Act) and food
17 modified to be low protein that is formulated to be
18 consumed or administered under the supervision of
19 a qualified medical provider, for the treatment of
20 conditions as recommended by the Advisory Com-
21 mittee on Heritable Disorders in Newborns and
22 Children, and the medical equipment and supplies
23 necessary to administer such food; and

24 “(B) pharmacological doses of vitamins and
25 amino acids used for the treatment of inborn errors

1 of metabolism, for the treatment of conditions as
2 recommended by the Advisory Committee on Heri-
3 table Disorders in Newborns and Children and as
4 prescribed by a qualified medical provider.

5 “(2) Benefits for treatments described in subpara-
6 graphs (A) and (B) of paragraph (1) shall be provided
7 under such a health benefits plan to an individual regard-
8 less of the age of the individual.”.

9 (2) EFFECTIVE DATE.—The amendment made
10 by paragraph (1) shall apply to contract years begin-
11 ning after the date that is 9 months after the date
12 of enactment of this Act.

13 **SEC. 4. EFFECTIVE DATE.**

14 Subject to subsections (b)(4) and (c)(3) of section
15 (3), the amendments made by section 3 (other than sub-
16 section (e) of such section) shall apply to plan years and
17 contract years beginning after the date that is 6 months
18 after the date of enactment of this Act.

○