

119TH CONGRESS
1ST SESSION

S. 3304

To provide for the coverage of medical food and vitamins and individual amino acids for digestive and inherited metabolic disorders under Federal health programs, to ensure State and Federal protection for existing coverage, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 2, 2025

Mr. WICKER (for himself, Ms. KLOBUCHAR, Mr. GRASSLEY, and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To provide for the coverage of medical food and vitamins and individual amino acids for digestive and inherited metabolic disorders under Federal health programs, to ensure State and Federal protection for existing coverage, 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 and
5 Formulas Access Act of 2025”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Each year, thousands of children and adults
2 in the United States are diagnosed with certain di-
3 gestive or inherited metabolic disorders that prevent
4 their bodies from digesting or metabolizing the food
5 they need to survive. For them, medically necessary
6 food, which can often be administered as an orally
7 consumed formula, is their treatment.

8 (2) Without medically necessary food, these pa-
9 tients risk malnutrition, surgery, and repeated hos-
10 pitalizations. They may suffer intellectual disability
11 or even death. Risks in pediatric populations are
12 particularly profound and often severe and also in-
13 clude inadequate growth, abnormal development,
14 cognitive impairment, and behavioral disorders. Spe-
15 cialized medically necessary food is standard-of-care
16 therapy for these patients and is essential to pre-
17 venting such outcomes.

18 (3) While not every person diagnosed with these
19 conditions needs to be treated with medically nec-
20 essary food for a prolonged period, it is critical that
21 patients and their physicians be able to consider the
22 full range of options and select the treatment that
23 will be most effective for each patient.

24 (4) Insurance will typically cover pharma-
25 ceuticals or biologics for treatment of many of these

1 conditions, if there is a therapy approved by the
2 Food and Drug Administration. However, these
3 types of treatments may not be the first-line therapy
4 a physician would recommend, do not work for all
5 patients, and can have undesirable risks, such as
6 certain cancers or suppression of the immune sys-
7 tem, which can increase a patient's risk of infection.

8 (5) Even when insurance does cover medically
9 necessary food, it can come with the stipulation the
10 formula be administered through a feeding tube,
11 placed through the nose into the stomach or sur-
12 gically placed directly into the stomach or jejunum,
13 even if a patient is capable of taking the formula
14 orally without these devices. Surgical placement of
15 feeding tubes unnecessarily results in increased risk
16 to the patient and increased cost to the health care
17 system.

18 (6) Vitamins are essential micronutrients that
19 play critical roles in metabolism, cellular function,
20 and overall health. Amino acids serve as the building
21 blocks of proteins and function as critical metabolic
22 intermediates. Both vitamins and amino acids re-
23 quire careful assessment and monitoring in patients
24 with GI and metabolic disorders, as their absorption,

1 metabolism, and utilization may be significantly im-
2 pacted by the underlying disease processes.

3 (7) Testing for select inherited metabolic dis-
4 orders is required in all States, and approximately
5 2,000 babies per year are diagnosed with one of
6 these disorders that requires treatment through
7 medically necessary food. Yet, policies on medically
8 necessary food vary significantly and do not always
9 make it possible for families to get sufficient nutri-
10 tion for their affected children which can lead to de-
11 layed development, brain damage, and even death.

12 (8) The 2022 formula shortage demonstrated
13 the essential nature of specialty formulas for those
14 with digestive and metabolic conditions and the dire
15 medical consequences that can result when these for-
16 mulas are inaccessible. During the shortage, patients
17 lacking access to their formulas faced medical con-
18 sequences such as feeding intolerance, weight loss,
19 rectal bleeding, rapid gastric emptying, acute kidney
20 injury, and electrolyte disturbances, all of which re-
21 sulted in increased physician and emergency depart-
22 ment visits. Children with metabolic disorders who
23 were hospitalized due to lack of formula faced simi-
24 lar challenges due to lack of formula supply and had
25 to be placed on IV nutrition.

1 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITA-**
 2 **MINS, AND INDIVIDUAL AMINO ACIDS FOR DI-**
 3 **GESTIVE AND INHERITED METABOLIC DIS-**
 4 **ORDERS UNDER FEDERAL HEALTH PRO-**
 5 **GRAMS.**

6 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

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

10 (A) in subparagraph (II), by striking
 11 “and” at the end;

12 (B) in subparagraph (JJ), by inserting
 13 “and” at the end; and

14 (C) by adding at the end the following new
 15 subparagraph:

16 “(KK) medically necessary food (as defined in
 17 subsection (nnn)) and, if required, the medical
 18 equipment and supplies necessary to administer such
 19 food, other than such food, equipment, and supplies
 20 furnished to an individual that would otherwise be
 21 covered for such individual under part B without ap-
 22 plication of this subparagraph;”.

23 (2) DEFINITION.—Section 1861 of the Social
 24 Security Act (42 U.S.C. 1395x) is amended by add-
 25 ing at the end the following new subsection:

1 “Medically Necessary Food

2 “(nnn)(1) Subject to paragraph (2), the term ‘medi-
3 cally necessary food’ means food, including a low protein
4 modified food product, an amino acid preparation product,
5 a modified fat preparation product, a nutritional formula,
6 a vitamin, or an individual amino acid, that is—

7 “(A) furnished pursuant to the prescription or
8 order of a physician, physician assistant, nurse prac-
9 titioner, or other health care practitioner acting
10 within the practitioner’s scope of practice, for the di-
11 etary management of a covered disease or condition;

12 “(B) a specially formulated and processed prod-
13 uct (as opposed to a naturally occurring foodstuff
14 used in its natural state) for the partial or exclusive
15 feeding of an individual by means of oral intake or
16 enteral feeding by tube;

17 “(C) intended for the dietary management of
18 an individual who, because of a specified disease or
19 condition, has limited or impaired capacity to ingest,
20 digest, absorb, or metabolize ordinary foodstuffs or
21 certain nutrients, or who has other special medically
22 determined nutrient requirements, the dietary man-
23 agement of which cannot be achieved by the modi-
24 fication of the normal diet alone;

1 “(D) intended to be used under medical direc-
2 tion, which may include in a home setting; and

3 “(E) intended only for an individual receiving
4 active or ongoing medical care under the supervision
5 of a physician, physician assistant, or nurse practi-
6 tioner.

7 “(2) For purposes of paragraph (1), the term ‘medi-
8 cally necessary food’ does not include the following:

9 “(A) Foods, including vitamins and amino
10 acids, taken as part of an overall diet designed to re-
11 duce the risk of a disease or medical condition or as
12 weight loss products, even if they are recommended
13 by a physician or other health professional.

14 “(B) Foods marketed as gluten-free for the
15 management of celiac disease or non-celiac gluten
16 sensitivity.

17 “(C) Foods marketed for the management of
18 diabetes.

19 “(D) Other products determined appropriate by
20 the Secretary.

21 “(3) In this subsection, the term ‘covered disease or
22 condition’ means the following diseases or conditions:

23 “(A) Inherited metabolic disorders, including
24 the following:

1 “(i) Conditions included on the Rec-
2 ommended Uniform Screening Panel Conditions
3 list of the Department of Health and Human
4 Services.

5 “(ii) Organic acid conditions.

6 “(iii) Fatty acid oxidation disorders.

7 “(iv) Amino acid disorders.

8 “(v) Urea cycle disorders.

9 “(vi) Glycogen storage disorders.

10 “(vii) Biotinidase deficiency.

11 “(viii) Guanidinoacetate methyltransferase
12 deficiency.

13 “(ix) Inherited disorders of mitochondrial
14 functioning.

15 “(B) Medical and surgical conditions of mal-
16 absorption, including the following:

17 “(i) Impaired absorption of nutrients
18 caused by disorders affecting the absorptive
19 surface, functional length, and motility of the
20 gastrointestinal tract, including short bowel
21 syndrome and chronic intestinal pseudo-obstruc-
22 tion.

23 “(ii) Malabsorption due to liver or pan-
24 creatic disease.

1 “(C) Immunoglobulin E and non-
2 Immunoglobulin E-mediated allergies to food pro-
3 teins, including the following:

4 “(i) Immunoglobulin E and non-
5 Immunoglobulin E-mediated allergies to food
6 proteins.

7 “(ii) Food protein-induced enterocolitis
8 syndrome.

9 “(iii) Eosinophilic disorders, including
10 eosinophilic esophagitis, eosinophilic
11 gastroenteritis, eosinophilic colitis, and post-
12 transplant eosinophilic disorders.

13 “(D) Inflammatory or immune mediated condi-
14 tions of the alimentary tract, including the following:

15 “(i) Inflammatory bowel disease, including
16 Crohn’s disease, ulcerative colitis, and indeter-
17 minate colitis.

18 “(ii) Gastroesophageal reflux disease that
19 is nonresponsive to standard medical therapies.

20 “(E) Any other disease or condition determined
21 appropriate by the Secretary, in consultation with
22 appropriate scientific entities.

23 “(4)(A) In this subsection, the term ‘low protein
24 modified food product’ means a type of medical food that
25 is modified to be low in protein and formulated for oral

1 consumption for individuals with inborn errors of protein
2 metabolism.

3 “(B) Such term does not include foods that are natu-
4 rally low in protein, such as some fruits or vegetables.”.

5 (3) PAYMENT.—Section 1833(a)(1) of the So-
6 cial Security Act (42 U.S.C. 1395l(a)(1)) is amend-
7 ed—

8 (A) by striking “and” before “(HH)”; and

9 (B) by inserting before the semicolon at
10 the end the following: “and (II) with respect to
11 medically necessary food (as defined in section
12 1861(nnn)), the amount paid shall be an
13 amount equal to 80 percent of the lesser of the
14 actual charge for the services or the amount de-
15 termined under a fee schedule established by
16 the Secretary for purposes of this subpara-
17 graph.”.

18 (4) EFFECTIVE DATE.—The amendments made
19 by this subsection shall apply to items and services
20 furnished on or after the date that is 3 years after
21 the date of the enactment of this Act.

22 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

23 (1) IN GENERAL.—Section 1905(a) of the So-
24 cial Security Act (42 U.S.C. 1396d(a)) is amend-
25 ed—

1 (A) in paragraph (31), by striking “and”
 2 at the end;

3 (B) by redesignating paragraph (32) as
 4 paragraph (33); and

5 (C) by inserting after paragraph (31) the
 6 following new paragraph:

7 “(32) medically necessary food (which shall in-
 8 clude at least the items and services included in such
 9 term for purposes of section 1861(nnn)) and the
 10 medical equipment and supplies necessary to admin-
 11 ister such food; and”.

12 (2) CONFORMING AMENDMENTS.—

13 (A) MANDATORY BENEFITS.—Section
 14 1902(a)(10)(A) of the Social Security Act (42
 15 U.S.C. 1396a(a)(10)(A)) is amended, in the
 16 matter preceding clause (i), by striking “and
 17 (30)” and inserting “(30), and (32)”.

18 (B) APPLICATION OF COST LIMITS.—Sec-
 19 tion 1903(i)(27) of the Social Security Act (42
 20 U.S.C. 1396b(i)(27)) is amended—

21 (i) by inserting “or for equipment and
 22 supplies described in section 1905(a)(32),”
 23 after “2018,”; and

1 (ii) by striking “such items” each
 2 place such phrase appears and inserting
 3 “such items, equipment, or supplies”.

4 (C) APPLICATION TO BENCHMARK AND
 5 BENCHMARK-EQUIVALENT COVERAGE.—Section
 6 1937(b) of the Social Security Act (42 U.S.C.
 7 1396u–7(b)) is amended by adding at the end
 8 the following new paragraph:

9 “(9) MEDICALLY NECESSARY FOOD.—Notwith-
 10 standing the previous provisions of this section, a
 11 State may not provide for medical assistance
 12 through enrollment of an individual with benchmark
 13 coverage or benchmark-equivalent coverage under
 14 this section unless such coverage includes coverage
 15 of medically necessary food (which shall include at
 16 least the items and services included in such term
 17 for purposes of section 1861(nnn)) and the medical
 18 equipment and supplies necessary to administer such
 19 food.”.

20 (3) EFFECTIVE DATE.—

21 (A) IN GENERAL.—Subject to subpara-
 22 graph (B), the amendments made by this sub-
 23 section shall take effect on the date that is 2
 24 years after the date of the enactment of this
 25 Act.

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

22 (c) COVERAGE UNDER CHIP.—

23 (1) IN GENERAL.—Section 2103(c) of the So-
 24 cial Security Act (42 U.S.C. 1397cc(c)) is amended
 25 by adding at the end the following new paragraph:

1 “(13) MEDICALLY NECESSARY FOOD.—The
 2 child health assistance provided to a targeted low-in-
 3 come child under the plan shall include coverage of
 4 medically necessary food (which shall include at least
 5 the items and services included in such term for pur-
 6 poses of section 1861(nnn)) and the medical equip-
 7 ment and supplies necessary to administer such
 8 food.”.

9 (2) CONFORMING AMENDMENT.—Section
 10 2103(a) of the Social Security Act (42 U.S.C.
 11 1397cc(a)) is amended, in the matter preceding
 12 paragraph (1), by striking “and (8)” and inserting
 13 “(8), and (13)”.

14 (3) EFFECTIVE DATE.—

15 (A) IN GENERAL.—Subject to subpara-
 16 graph (B), the amendments made by this sub-
 17 section shall take effect on the date that is 1
 18 year after the date of the enactment of this Act.

19 (B) EXCEPTION TO EFFECTIVE DATE IF
 20 STATE LEGISLATION REQUIRED.—In the case of
 21 a State child health plan for child health assist-
 22 ance under title XXI of the Social Security Act
 23 which the Secretary of Health and Human
 24 Services determines requires State legislation
 25 (other than legislation appropriating funds) in

1 order for the plan to meet the additional re-
2 quirements imposed by the amendments made
3 by this subsection, the State child health plan
4 shall not be regarded as failing to comply with
5 the requirements of such title solely on the
6 basis of its failure to meet this additional re-
7 quirement before the first day of the first cal-
8 endar quarter beginning after the close of the
9 first regular session of the State legislature that
10 begins after the date of the enactment of this
11 Act. For purposes of the previous sentence, in
12 the case of a State that has a 2-year legislative
13 session, each year of such session shall be
14 deemed to be a separate regular session of the
15 State legislature.

16 (d) COVERAGE UNDER FEHBP.—

17 (1) IN GENERAL.—Section 8902 of title 5,
18 United States Code, is amended by adding at the
19 end the following:

20 “(q) A contract for a plan under this chapter shall
21 require the carrier to provide coverage for medically nec-
22 essary food (as defined in section 1861(nnn) of the Social
23 Security Act) and the medical equipment and supplies nec-
24 essary to administer such food.”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by paragraph (1) shall apply with respect to contract
3 years beginning on or after the date that is 1 year
4 after the date of enactment of this Act.

5 (e) SENSE OF CONGRESS REGARDING COVERAGE
6 UNDER PRIVATE HEALTH INSURANCE.—It is the sense
7 of Congress that—

8 (1) medically necessary food (as defined in sub-
9 section (nnn) of section 1861 of the Social Security
10 Act (42 U.S.C. 1395x), as added by subsection
11 (a)(2)) can be life sustaining and life saving; and

12 (2) all health plans, including private health
13 plans offered by health insurance issuers, should
14 provide coverage of, and access to, medically nec-
15 essary food (as so defined) for individuals with cer-
16 tain digestive and metabolic disorders and condi-
17 tions, when prescribed or ordered by a physician,
18 physician assistant, nurse practitioner, or other
19 health care practitioner, in a manner similar to the
20 required coverage of medically necessary food for
21 such individuals under the Medicare program under
22 title XVIII of the Social Security Act (42 U.S.C.
23 1395 et seq.), the Medicaid program under title XIX
24 of the Social Security Act (42 U.S.C. 1396 et seq.),
25 the State Children’s Health Insurance Program

1 under title XXI of the Social Security Act (42
 2 U.S.C. 1397aa et seq.), and chapter 89 or title 5,
 3 United States Code, as amended by subsections (a),
 4 (b), (c), and (d), respectively.

5 (f) NONPREEMPTION OF STATE LAWS THAT PRO-
 6 VIDE GREATER COVERAGE.—Nothing in the provisions of,
 7 or the amendments made by, this section shall preempt
 8 a State law that requires coverage of medically necessary
 9 food (as defined in subsection (nnn) of section 1861 of
 10 the Social Security Act, as added by subsection (a)) that
 11 exceeds the requirements for coverage under such provi-
 12 sions and amendments.

13 (g) MEDICALLY NECESSARY NUTRITION COVERAGE
 14 INCLUDES COMBINATIONS AND SUPPLIES.—Nothing in
 15 the provisions of, or the amendments made by, this section
 16 shall limit coverage of a medically necessary food (as de-
 17 fined in subsection (nnn) of section 1861 of the Social Se-
 18 curity Act, as added by subsection (a)) or the medical
 19 equipment and supplies necessary to administer such food
 20 when prescribed, ordered, or recommended in combination
 21 with another medically necessary food (as so defined) or
 22 other necessary medical equipment and supplies.

○