

118TH CONGRESS  
1ST SESSION

# H. R. 6892

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

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 22, 2023

Mr. MCGOVERN (for himself and Mr. RUTHERFORD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Oversight and Accountability, 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

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## A BILL

To provide for the coverage of medically necessary food and vitamins and individual amino acids for digestive and inherited metabolic disorders under Federal health programs and private health insurance, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medical Nutrition Eq-  
3 uity Act of 2023”.

4 **SEC. 2. FINDINGS.**

5 Congress finds the following:

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

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

23 (3) While not every person diagnosed with these  
24 conditions needs to be treated with medically nec-  
25 essary food for a prolonged period, it is critical that  
26 patients and their physicians be able to consider the

1 full range of options and select the treatment that  
2 will be most effective for each patient.

3 (4) Insurance companies will typically cover  
4 pharmaceuticals or biologics for treatment of many  
5 of these conditions, if there is a therapy approved by  
6 the Food and Drug Administration. However, these  
7 types of treatments may not be the first-line therapy  
8 a physician would recommend, do not work for all  
9 patients, and can have undesirable risks, such as  
10 certain cancers or suppression of the immune sys-  
11 tem, which can increase a patient's risk of infection.

12 (5) Even when an insurance company does  
13 cover medically necessary food, it can come with the  
14 stipulation the formula be administered through a  
15 feeding tube, placed through the nose into the stom-  
16 ach or surgically placed directly into the stomach or  
17 jejunum, even if a patient is capable of taking the  
18 formula orally without these devices. Surgical place-  
19 ment of feeding tubes unnecessarily results in in-  
20 creased risk to the patient and increased cost to the  
21 health care system.

22 (6) Testing for select inherited metabolic dis-  
23 orders is required in all States, and approximately  
24 2,000 babies per year are diagnosed with one of  
25 these disorders that requires treatment through

1 medically necessary food. Yet, policies on medically  
2 necessary food vary significantly and do not always  
3 make it possible for families to get sufficient nutri-  
4 tion for their affected children which can lead to de-  
5 layed development, brain damage, and even death.

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

20 **SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITA-**  
21 **MINS, AND INDIVIDUAL AMINO ACIDS FOR DI-**  
22 **GESTIVE AND INHERITED METABOLIC DIS-**  
23 **ORDERS UNDER FEDERAL HEALTH PRO-**  
24 **GRAMS AND PRIVATE HEALTH INSURANCE.**

25 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

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

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

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

8                   (C) by adding at the end the following new  
9           subparagraph:

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

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

20                   “Medically Necessary Food

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

1           “(A) furnished pursuant to the prescription or  
2 order of a physician, physician assistant, nurse prac-  
3 titioner, or other health care practitioner acting  
4 within the practitioner’s scope of practice, for the di-  
5 etary management of a covered disease or condition;

6           “(B) a specially formulated and processed prod-  
7 uct (as opposed to a naturally occurring foodstuff  
8 used in its natural state) for the partial or exclusive  
9 feeding of an individual by means of oral intake or  
10 enteral feeding by tube;

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

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

21           “(E) intended only for an individual receiving  
22 active or ongoing medical care under the supervision  
23 of a physician, physician assistant, or nurse practi-  
24 tioner.

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

3           “(A) Foods taken as part of an overall diet de-  
4 signed to reduce the risk of a disease or medical con-  
5 dition or as weight loss products, even if they are  
6 recommended by a physician or other health profes-  
7 sional.

8           “(B) Foods marketed as gluten-free for the  
9 management of celiac disease or non-celiac gluten  
10 sensitivity.

11           “(C) Foods marketed for the management of  
12 diabetes.

13           “(D) Other products determined appropriate by  
14 the Secretary.

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

17           “(A) Inherited metabolic disorders, including  
18 the following:

19           “(i) Disorders classified as metabolic dis-  
20 orders on the Recommended Uniform Screening  
21 Panel Conditions list of the Secretary of Health  
22 and Human Services’ Advisory Committee on  
23 Heritable Disorders in Newborns and Children.

24           “(ii) N-acetyl glutamate synthase defi-  
25 ciency.

1           “(iii) Ornithine transcarbamylase defi-  
2           ciency.

3           “(iv) Carbamoyl phosphate synthetase de-  
4           ficiency.

5           “(v) Inherited disorders of mitochondrial  
6           functioning.

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

9           “(i) Impaired absorption of nutrients  
10           caused by disorders affecting the absorptive  
11           surface, functional length, and motility of the  
12           gastrointestinal tract, including short bowel  
13           syndrome and chronic intestinal pseudo-obstruc-  
14           tion.

15           “(ii) Malabsorption due to liver or pan-  
16           creatic disease.

17           “(C) Immunoglobulin E and non-  
18           Immunoglobulin E-mediated allergies to food pro-  
19           teins, including the following:

20           “(i) Immunoglobulin E and non-  
21           Immunoglobulin E-mediated allergies to food  
22           proteins.

23           “(ii) Food protein-induced enterocolitis  
24           syndrome.



1           “(iii) Eosinophilic disorders, including  
2           eosinophilic esophagitis, eosinophilic  
3           gastroenteritis, eosinophilic colitis, and post-  
4           transplant eosinophilic disorders.

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

7           “(i) Inflammatory bowel disease, including  
8           Crohn’s disease, ulcerative colitis, and indeter-  
9           minate colitis.

10          “(ii) Gastroesophageal reflux disease that  
11          is nonresponsive to standard medical therapies.

12          “(E) Any other disease or condition determined  
13          appropriate by the Secretary, in consultation with  
14          appropriate scientific entities, such as the Agency  
15          for Healthcare Research and Quality.

16          “(4)(A) In this subsection, the term ‘low protein  
17          modified food product’ means a type of medical food that  
18          is modified to be low in protein and formulated for oral  
19          consumption for individuals with inborn errors of protein  
20          metabolism.

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

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

1 (A) by striking “and” before “(GG)”; and

2 (B) by inserting before the semicolon at  
3 the end the following: “and (HH) with respect  
4 to medically necessary food (as defined in sec-  
5 tion 1861(nnn)), the amount paid shall be an  
6 amount equal to 80 percent of the lesser of the  
7 actual charge for the services or the amount de-  
8 termined under a fee schedule established by  
9 the Secretary for purposes of this subpara-  
10 graph.”.

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

15 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

19 (A) in paragraph (30), by striking “and”  
20 at the end;

21 (B) by redesignating paragraph (31) as  
22 paragraph (32); and

23 (C) by inserting after paragraph (30) the  
24 following new paragraph:

1 “(31) medically necessary food (which shall in-  
2 clude at least the items and services included in such  
3 term for purposes of section 1861(nnn)) and the  
4 medical equipment and supplies necessary to admin-  
5 ister such food; and”.

6 (2) CONFORMING AMENDMENTS.—

7 (A) MANDATORY BENEFITS.—Section  
8 1902(a)(10)(A) of the Social Security Act (42  
9 U.S.C. 1396a(a)(10)(A)) is amended, in the  
10 matter preceding clause (i), by striking “and  
11 (30)” and inserting “(30), and (31)”.

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

15 (i) by inserting “or for equipment and  
16 supplies described in section 1905(a)(31),”  
17 after “2018,”; and

18 (ii) by striking “such items” each  
19 place such phrase appears and inserting  
20 “such items, equipment, or supplies”.

21 (C) APPLICATION TO BENCHMARK AND  
22 BENCHMARK-EQUIVALENT COVERAGE.—Section  
23 1937(b) of the Social Security Act (42 U.S.C.  
24 1396u–7(b)) is amended by adding at the end  
25 the following new paragraph:

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

12           (3) EFFECTIVE DATE.—

13           (A) IN GENERAL.—Subject to subpara-  
14 graph (B), the amendments made by this sub-  
15 section shall take effect on the date that is 2  
16 years after the date of the enactment of this  
17 Act.

18           (B) EXCEPTION TO EFFECTIVE DATE IF  
19 STATE LEGISLATION REQUIRED.—In the case of  
20 a State plan for medical assistance under title  
21 XIX of the Social Security Act which the Sec-  
22 retary of Health and Human Services deter-  
23 mines requires State legislation (other than leg-  
24 islation appropriating funds) in order for the  
25 plan to meet the additional requirements im-

1           posed by the amendments made by this sub-  
2           section, the State plan shall not be regarded as  
3           failing to comply with the requirements of such  
4           title solely on the basis of its failure to meet  
5           this additional requirement before the first day  
6           of the first calendar quarter beginning after the  
7           close of the first regular session of the State  
8           legislature that begins after the date of the en-  
9           actment of this Act. For purposes of the pre-  
10          vious sentence, in the case of a State that has  
11          a 2-year legislative session, each year of such  
12          session shall be deemed to be a separate regular  
13          session of the State legislature.

14          (c) COVERAGE UNDER CHIP.—

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

18                    “(12) MEDICALLY NECESSARY FOOD.—The  
19                    child health assistance provided to a targeted low-in-  
20                    come child under the plan shall include coverage of  
21                    medically necessary food (which shall include at least  
22                    the items and services included in such term for pur-  
23                    poses of section 1861(nnn)) and the medical equip-  
24                    ment and supplies necessary to administer such  
25                    food.”.

1           (2) CONFORMING AMENDMENT.—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 (8)” and inserting  
5           “(8), and (12)”.

6           (3) EFFECTIVE DATE.—

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

11          (B) EXCEPTION TO EFFECTIVE DATE IF  
12          STATE LEGISLATION REQUIRED.—In the case of  
13          a State child health plan for child health assist-  
14          ance under title XXI of the Social Security Act  
15          which the Secretary of Health and Human  
16          Services determines requires State legislation  
17          (other than legislation appropriating funds) in  
18          order for the plan to meet the additional re-  
19          quirements imposed by the amendments made  
20          by this subsection, the State child health plan  
21          shall not be regarded as failing to comply with  
22          the requirements of such title solely on the  
23          basis of its failure to meet this additional re-  
24          quirement before the first day of the first cal-  
25          endar quarter beginning after the close of the

1 first regular session of the State legislature that  
2 begins after the date of the enactment of this  
3 Act. For purposes of the previous sentence, in  
4 the case of a State that has a 2-year legislative  
5 session, each year of such session shall be  
6 deemed to be a separate regular session of the  
7 State legislature.

8 (d) MODIFICATION OF DEFINITION OF MEDICALLY  
9 NECESSARY FOOD AND COVERED DISEASE OR CONDI-  
10 TION UNDER THE TRICARE PROGRAM.—

11 (1) IN GENERAL.—Section 1077(h) of title 10,  
12 United States Code, is amended—

13 (A) in paragraph (2)(A), in the matter  
14 preceding clause (i), by striking “or an amino  
15 acid preparation product” and inserting “, an  
16 amino acid preparation product, a modified fat  
17 preparation product, or a nutritional formula  
18 (including such a formula that does not require  
19 a prescription)”; and

20 (B) in paragraph (3)—

21 (i) in subparagraph (D), by striking  
22 “and” at the end;

23 (ii) by redesignating subparagraph  
24 (E) as subparagraph (F); and

1 (iii) by inserting after subparagraph  
2 (D) the following:

3 “(E) Immunoglobulin E or non-Immunoglobulin  
4 E mediated allergies to food proteins; and”.

5 (2) EFFECTIVE DATE.—The amendments made  
6 by paragraph (1) shall apply to health care provided  
7 under chapter 55 of title 10, United States Code, on  
8 or after the date that is one year after the date of  
9 the enactment of this Act.

10 (e) COVERAGE UNDER FEHBP.—

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

14 “(p) A contract for a plan under this chapter shall  
15 require the carrier to provide coverage for medically nec-  
16 essary food (as defined in section 1861(nnn) of the Social  
17 Security Act) and the medical equipment and supplies nec-  
18 essary to administer such food.”.

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

23 (f) COVERAGE UNDER PRIVATE HEALTH INSUR-  
24 ANCE.—



1           (1) IN GENERAL.—Subpart II of part A of title  
2           XXVII of the Public Health Service Act (42 U.S.C.  
3           300gg–11 et seq.) is amended by adding at the end  
4           the following new section:

5           **“SEC. 2729A. COVERAGE OF MEDICALLY NECESSARY FOOD,**  
6                                   **VITAMINS, AND INDIVIDUAL AMINO ACIDS.**

7           “A group health plan and a health insurance issuer  
8           offering group or individual health insurance coverage  
9           shall provide coverage for medically necessary food (as de-  
10          fined in section 1861(nnn) of the Social Security Act) and  
11          the medical equipment and supplies necessary to admin-  
12          ister such food.”.

13          (2) INCLUSION AS AN ESSENTIAL HEALTH BEN-  
14          EFIT.—Section 1302(b)(1) of the Patient Protection  
15          and Affordable Care Act (42 U.S.C. 18022(b)(1)) is  
16          amended by adding at the end the following new  
17          subparagraph:

18                           “(K) Medically necessary food (as defined  
19                           in section 1861(nnn) of the Social Security Act)  
20                           an the medical equipment and supplies nec-  
21                           essary to administer such food.”.

22          (3) EFFECTIVE DATE.—The amendments made  
23          by this subsection shall apply to plan years begin-  
24          ning on or after the date that is 1 year after the  
25          date of the enactment of this Act.

1 (g) NONPREEMPTION OF STATE LAWS THAT PRO-  
2 VIDE GREATER COVERAGE.—Nothing in the provisions of,  
3 or the amendments made by, this section shall preempt  
4 a State law that requires coverage of medically necessary  
5 food (as defined in subsection (lll) of section 1861 of the  
6 Social Security Act, as added by subsection (a)) that ex-  
7 ceeds the requirements for coverage under such provisions  
8 and amendments.

9 (h) MEDICALLY NECESSARY NUTRITION COVERAGE  
10 INCLUDES COMBINATIONS AND SUPPLIES.—Nothing in  
11 the provisions of, or the amendments made by, this section  
12 shall limit coverage of a medically necessary food (as de-  
13 fined in subsection (lll) of section 1861 of the Social Secu-  
14 rity Act, as added by subsection (a)) or the medical equip-  
15 ment and supplies necessary to administer such food when  
16 prescribed, ordered, or recommended in combination with  
17 another medically necessary food (as so defined) or other  
18 necessary medical equipment and supplies.

○