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S. 3657

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, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 7, 2020

Mr. CASEY (for himself and Ms. ERNST) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Nutrition Equity Act of 2020''.

SEC. 2. FINDINGS.

Congress finds the following:

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

(2) Without medically necessary food, these patients risk malnutrition, surgery, and repeated hospitalizations. They may suffer intellectual disability or even death. Risks in pediatric populations are particularly profound and often severe and also include inadequate growth, abnormal development, cognitive impairment, and behavioral disorders. Specialized medically necessary food is standard-of-care therapy for these patients and is essential to preventing such outcomes.

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

(4) Insurance companies will typically cover pharmaceuticals or biologics for treatment of some

of these conditions. However, these types of treatments may not be the first-line therapy a physician would recommend, do not work for all patients, and can have undesirable risks, such as cancer or suppression of the immune system, which can increase a patient's risk of infection.

(5) Even when an insurance company does cover medically necessary food, it often comes with the stipulation that the formula be administered through a feeding tube, which requires expensive surgery and carries additional risks for the patient.

(6) Testing for select inborn errors of metabolism is required in all States, and more than 7,000 babies per year are diagnosed with an inherited metabolic disorder. Yet, policies on medically necessary food vary significantly and do not always make it possible for families to get sufficient nutrition for their affected children.

SEC. 3. COVERAGE OF MEDICALLY NECESSARY FOOD, VITAMINS, AND INDIVIDUAL AMINO ACIDS FOR DIGESTIVE AND INHERITED METABOLIC DISORDERS UNDER FEDERAL HEALTH PROGRAMS AND PRIVATE HEALTH INSURANCE.

(a) COVERAGE UNDER THE MEDICARE PROGRAM.—

(1) MEDICALLY NECESSARY FOOD.—

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

(i) in subparagraph (GG), by striking ''and'' at the end;

(ii) in subparagraph (HH), by striking the period and inserting ''and''; and

(iii) by adding at the end the following new subparagraph:

''(II) medically necessary food (as defined in subsection (kkk)) and the medical equipment and supplies necessary to administer such food (other than medical equipment and supplies described in subsection (n));''.

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

''Medically Necessary Food

''(kkk)(1) Subject to paragraph (2), the term 'medically necessary food' means food, including a low protein modified food product, an amino acid preparation product, a modified fat preparation product, or a nutritional formula (including such a formula that does not require a prescription), that is—

''(A) furnished pursuant to the prescription, order, or recommendation (as applicable) of a physician or other health care professional qualified to make such prescription, order, or recommendation, for the dietary management of a covered disease or condition;

''(B) a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of an individual by means of oral intake or enteral feeding by tube;

''(C) intended for the dietary management of an individual who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

''(D) intended to be used under medical supervision, which may include in a home setting; and

''(E) intended only for an individual receiving active and ongoing medical supervision wherein the individual requires medical care on a recurring basis

for, among other things, instructions on the use of the food.

''(2) For purposes of paragraph (1), the term 'medically necessary food' does not include the following:

''(A) Foods taken as part of an overall diet designed to reduce the risk of a disease or medical condition or as weight loss products, even if they are recommended by a physician or other health professional.

''(B) Foods marketed as gluten-free for the management of celiac disease or non-celiac gluten sensitivity.

''(C) Foods marketed for the management of diabetes.

''(D) Other products determined appropriate by the Secretary.

''(3) In this subsection, the term 'covered disease or condition' means the following diseases or conditions:

''(A) Inherited metabolic disorders, including the following:

''(i) Disorders classified as metabolic disorders on the Recommended Uniform Screening Panel Core Conditions list of the Secretary of Health and Human Services' Advisory Com-

mittee on Heritable Disorders in Newborns and Children.

''(ii) N-acetyl glutamate synthase deficiency.

''(iii) Ornithine transcarbamlyase deficiency.

''(iv) Carbamoyl phosphate synthestase deficiency.

''(v) Inherited disorders of mitochondrial functioning.

''(B) Medical and surgical conditions of malabsorption, including the following:

''(i) Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract, including short bowel syndrome and chronic intestinal pseudo-obstruction.

''(ii) Malabsorption due to liver or pancreatic disease.

''(C) Immunoglobulin E and non-Immunoglobulin E-mediated allergies to food proteins, including the following:

''(i) Immunoglobulin E and non-Immunoglobulin E-mediated allergies to food proteins.

''(ii) Food protein-induced enterocolitis syndrome.

''(iii) Eosinophilic disorders, including eosinophilic esophagitis, eosinophilic gastroenteritis, eosinophilic colitis, and post-transplant eosinophilic disorders.

''(D) Inflammatory or immune mediated conditions of the alimentary tract, including the following:

''(i) Inflammatory bowel disease, including Crohn's disease, ulcerative colitis, and indeterminate colitis.

''(ii) Gastroesophageal reflux disease that is nonresponsive to standard medical therapies.

''(E) Any other disease or condition determined appropriate by the Secretary.

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

''(B) Such term does not include foods that are naturally low in protein, such as some fruits or vegetables.''.

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

(i) by striking ''and'' before ''(DD)''; and

(ii) by inserting before the semicolon at the end the following: ''and (EE) with respect to medically necessary food (as defined in section 1861(kkk)), the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph.''.

(D) EFFECTIVE DATE.—The amendments made by this subsection shall apply to items and services furnished on or after the date that is 1 year after the date of the enactment of this Act.

(2) INCLUSION OF MEDICALLY NECESSARY VITAMINS AND INDIVIDUAL AMINO ACIDS AS A COVERED PART D DRUG.—

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

(i) in subparagraph (A), by striking ''or'' at the end;

(ii) in subparagraph (B), by striking the comma at the end and inserting ''; or''; and

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

''(C) medically necessary vitamins and individual amino acids used for the management of a covered disease or condition (as defined in section 1861(kkk)(3)) pursuant to the prescription, order, or recommendation (as applicable) of a physician or other health care professional qualified to make such prescription, order, or recommendation,''.

(B) EFFECTIVE DATE.—The amendments made by subparagraph (A) shall apply to plan years beginning on or after the date that is 1 year after the date of the enactment of this Act.

(b) COVERAGE UNDER THE MEDICAID PROGRAM.—

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

(A) in paragraph (29)—

(i) by adjusting the left margin so as to align with the left margin of paragraph (28); and

(ii) by striking ''and'' at the end;

(B) by redesignating paragraph (30) as paragraph (32); and

(C) by inserting after paragraph (29) the following new paragraphs:

''(30) medically necessary food (as defined in section 1861(kkk)) and the medical equipment and supplies necessary to administer such food;

''(31) medically necessary vitamins and individual amino acids used for the management of a covered disease or condition (as defined in section 1861(kkk)(3)) pursuant to the prescription, order, or recommendation (as applicable) of a physician or other health care professional qualified to make such prescription, order, or recommendation; and''.

(2) CONFORMING AMENDMENTS.—

(A) MANDATORY BENEFITS.—Section 1902(a)(10)(A) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)) is amended, in the matter preceding clause (i), by striking ''and (29)'' and inserting ''(29), (30), and (31)''.

(B) EXCEPTION TO COVERAGE RESTRICTION.—Section 1927(d)(2)(E) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)(E)) is amended by inserting ''and except for medically

necessary vitamins and individual amino acids described in section 1905(a)(31)'' before the period at the end.

(3) EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), the amendments made by this subsection shall take effect on the date that is 1 year after the date of the enactment of this Act.

(B) EXCEPTION TO EFFECTIVE DATE IF STATE LEGISLATION REQUIRED.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by this subsection, the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the pre-

vious sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(c) COVERAGE UNDER CHIP.—

(1) IN GENERAL.—Section 2103(c) of the Social Security Act (42 U.S.C. 1397cc(c)) is amended by adding at the end the following:

''(11) MEDICALLY NECESSARY FOOD.—The child health assistance provided to a targeted low-income child under the plan shall include coverage of medically necessary food (as defined in section 1861(kkk)) and the medical equipment and supplies necessary to administer such food.

''(12) CERTAIN VITAMINS AND INDIVIDUAL AMINO ACIDS.—The child health assistance provided to a targeted low-income child under the plan shall include coverage of medically necessary vitamins and individual amino acids used for the management of a covered disease or condition (as defined in section 1861(kkk)(3)) pursuant to the prescription, order, or recommendation (as applicable) of a physician or other health care professional qualified to make such prescription, order, or recommendation.''.

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

(3) EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), the amendments made by this subsection shall take effect on the date that is 1 year after the date of the enactment of this Act.

(B) EXCEPTION TO EFFECTIVE DATE IF STATE LEGISLATION REQUIRED.—In the case of a State child health plan for child health assistance under title XXI of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by this subsection, the State child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the

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

(d) MODIFICATION OF DEFINITION OF MEDICALLY NECESSARY FOOD AND COVERED DISEASE OR CONDITION UNDER THE TRICARE PROGRAM.—

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

(A) in paragraph (2)(A), in the matter preceding clause (i), by striking ''or an amino acid preparation product'' and inserting '', an amino acid preparation product, a modified fat preparation product, or a nutritional formula (including such a formula that does not require a prescription)''; and

(B) in paragraph (3)—

(i) in subparagraph (D), by striking ''and'' at the end;

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

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

''(E) Immunoglobulin E or non-Immunoglobulin E mediated allergies to food proteins; and''.

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

(e) COVERAGE UNDER FEHBP.—

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

''(p) A contract for a plan under this chapter shall require the carrier to provide coverage for—

''(1) medically necessary food (as defined in section 1861(kkk) of the Social Security Act) and the medical equipment and supplies necessary to administer such food; and

''(2) medically necessary vitamins and individual amino acids in the same manner provided for under section 1860D–2(e)(1)(C) of the Social Security Act.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to contract

years beginning on or after the date that is 1 year after the date of enactment of this Act.

(f) COVERAGE UNDER PRIVATE HEALTH INSURANCE.—

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

"SEC. 2729A. COVERAGE OF MEDICALLY NECESSARY FOOD, VITAMINS, AND INDIVIDUAL AMINO ACIDS.

''A health insurance issuer offering group or individual health insurance coverage shall provide coverage for—

''(1) medically necessary food (as defined in section 1861(kkk) of the Social Security Act) and the medical equipment and supplies necessary to administer such food; and

''(2) medically necessary vitamins and individual amino acids in the same manner provided for under section 1860D–2(e)(1)(C) of the Social Security Act.''.

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

(g) NONPREEMPTION OF STATE LAWS THAT PROVIDE GREATER COVERAGE.—Nothing in the provisions of, or the amendments made by, this section shall preempt a State law that requires coverage of medically necessary food and vitamins and individual amino acids for digestive and inherited metabolic disorders that exceeds the requirements for coverage under such provisions and amendments.

(h) MEDICALLY NECESSARY NUTRITION COVERAGE INCLUDES COMBINATIONS AND SUPPLIES.—Nothing in the provisions of, or the amendments made by, this section shall limit coverage of a medically necessary food (as defined in subsection (kkk) of section 1861 of the Social Security Act, as added by subsection (a)) or the medical equipment and supplies necessary to administer such food when prescribed, ordered, or recommended in combination with another medically necessary food (as so defined) or other necessary medical equipment and supplies.

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