

Medical Foods Equity Act of 2009

Outline of Legislation

Section 1: Short Title; Table of Contents

- (a) Short Title: This Act may be cited as the “Medical Foods Equity Act of 2009”.
- (b) Table of Contents

Section 2: Findings

- (1) Newborns are screened for inborn errors of metabolism but treatment for such conditions is not uniformly covered
- (2) Each year approximately 2,550 children in the United States are diagnosed with an inborn error of metabolism disorder, requiring foods modified to be void of the nutrient or nutrients the child’s body is incapable of processing and/or requiring supplementation with vitamins and/or amino acids
- (3) Over 30 states have passed laws to at least partially address the inequity in coverage for medically necessary foods, critical treatment for such disorders
- (4) The cost associated with providing medically necessary foods presents a large financial burden for many families
- (5) There is no current cure for inborn errors of metabolism disorders and treatment is necessary during the entire lifespan of the individual

Section 3: Definitions

- (1) The term “medically necessary foods” refers to the Food and Drug Administration’s definition:
“... a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”(section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))) In addition to nutritionally modified counterparts of traditional foods, medical foods are recognized for purposes of this Act to include, but not be limited to, other forms of foods such as formulas, pills, capsules and bars, so long as consumed or administered enterally.
- (2) The term “enterally” refers to consumption or administration through the gastrointestinal tract, whether orally or by tube.

Section 4: Coverage of medically necessary foods and foods modified to be low protein under Federal insurance plans

- (1) Medically necessary foods and foods modified to be low protein, formulated to be consumed or administered under the supervision of a qualified medical provider, for conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), along with the medical equipment and supplies necessary to administer such foods, , shall be covered as medical benefits under Federal insurance plans, including: Children’s Health Insurance Program, Tricare, Medicaid, and Medicare.
- (2) Pharmacological doses of vitamins and amino acids used specifically for the treatment of inborn errors of metabolism, for conditions recommended by the

Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and as prescribed by a qualified medical provider, shall be covered to the same extent as prescription drugs under Federal insurance plans, including: Children's Health Insurance Program, Tricare, Medicaid, and Medicare.

Section 5: Coverage of medically necessary foods and foods modified to be low protein under health insurance plans governed by the Employment Retirement Income Security Act (ERISA)

- (1) Medically necessary foods and foods modified to be low protein, formulated to be consumed or administered under the supervision of a qualified medical provider, for conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), along with the medical equipment and supplies necessary to administer such foods, shall be covered as medical benefits under plans governed by ERISA, and will not be subject to state exclusions.
- (2) Pharmacological doses of vitamins and amino acids used specifically for the treatment of inborn errors of metabolism, for conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and as prescribed by a qualified medical provider, shall be covered to the same extent as prescription drugs under plans governed by ERISA, and will not be subject to state exclusions.

Section 6: Coverage of medically necessary foods under health insurance plans on the individual and group markets

- (1) Medically necessary foods and foods modified to be low protein, formulated to be consumed or administered under the supervision of a qualified medical provider, for conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), along with the medical equipment and supplies necessary to administer such foods, shall be covered as medical benefits under all health plans on the individual and group markets.
- (2) Pharmacological doses of vitamins and amino acids used specifically for the treatment of inborn errors of metabolism, for conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and as prescribed by a qualified medical provider, shall be covered to the same extent as prescription drugs under all health plans on the individual and group markets.

Section 7: Determination of minimum yearly coverage

- (1) The Secretary of Health and Human Services (HHS) shall determine, prior to the implementation of this Act, the minimum yearly coverage for all health insurance plans. The minimum yearly coverage applies to individuals across their entire lifespan for as long as deemed medically necessary. The Secretary shall have the authority to set age-specific minimum levels of coverage and periodically update these levels based on a standard cost of living index, the actual cost of treatment, and other appropriate measures as determined by the Secretary. Federal minimum standards shall not pre-empt state standards that require a higher minimum yearly coverage level.