

Overview of Medical Food Definitions

I. Definitions of “Medical Foods” in State Government

A. The Montana Medical Foods Bill (33-22-131):

...(3) For purposes of this section:

(a) "medical foods" means nutritional substances in any form that are:

(i) formulated to be consumed or administered enterally under supervision of a physician;

(ii) specifically processed or formulated to be distinct in one or more nutrients present in natural food;

(iii) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or certain nutrients contained in ordinary foodstuffs or who have other specific nutrient requirements as established by medical evaluation; and

(iv) essential to optimize growth, health, and metabolic homeostasis;

(b) "treatment" means licensed professional medical services under the supervision of a physician...

En. Sec. 1, Ch. 80, L. 1989; amd. Sec. 28, Ch. 451, L. 1993; amd. Sec. 56, Ch. 379, L. 1995; amd. Sec. 2, Ch. 434, L. 1999.

B. The Oregon Medical Foods Bill

72nd OREGON LEGISLATIVE ASSEMBLY--2003 Regular Session

Senate Bill 74 Ordered by the House May 9

Including Senate Amendments dated March 25 and House Amendments dated May 9

...(2) As used in this section, 'medical foods' means foods that are formulated to be consumed or administered enterally under the supervision of a physician, as defined in ORS 677.010, that are specifically processed or formulated to be deficient in one or more of the nutrients present in typical nutritional counterparts, that are for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or certain nutrients contained therein or have other specific nutrient requirements as established by medical evaluation and that are essential to optimize growth, health and metabolic homeostasis...

C. The Delaware Medical Foods Bill

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 33, Subchapter III, Title 18, by inserting therein a new section, designated as §3355, which shall read as follows:

...(2) a. “Low protein modified formula or food product” means a formula or food product that is:

(i) specially formulated to have less than one (1) gram of protein per serving; and is

(ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease.

b. “Low protein modified food product” does not include a natural food that is naturally low in protein.

(3) “Medical formula or food” means a formula or food that is:

- a. intended for the dietary treatment of an inherited metabolic disease for which nutritional requirements and restrictions have been established by medical research; and
- b. formulated to be consumed or administered enterally under the direction of a physician...

§3571

- ...(2) a. "Low protein modified formula or food product" means a formula or food product that is:
- (i) specially formulated to have less than one (1) gram of protein per serving; and is
 - (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease.
- b. "Low protein modified food product" does not include a natural food that is naturally low in protein.
- (3) "Medical formula or food" means a formula or food that is:
- a. intended for the dietary treatment of an inherited metabolic disease for which nutritional requirements and restrictions have been established by medical research; and
 - b. formulated to be consumed or administered enterally under the direction of a physician...

II. Definitions of "Medical Foods" in Federal Government

A. CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
TITLE 21--FOOD AND DRUGS
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION
[PART 101 -- FOOD LABELING](#)
Subpart A--General Provisions

Sec. 101.9 Nutrition labeling of food.

- (8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is 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. A food is subject to this exemption only if:
- (i) It is 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 a patient by means of oral intake or enteral feeding by tube;
 - (ii) It is intended for the dietary management of a patient 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;
 - (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
 - (iv) It is intended to be used under medical supervision; and
 - (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

B. Orphan Drug Act - Chapter 9 Subchapter 5 (21 U.S.C. 360ee(b)(3))

(3) The term “medical food” means 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.

III. Definitions of “Medical Foods” in Literature

A. Kathryn Camp et al.

“When initiated within the first weeks of life and maintained throughout life, an appropriately designed nutritional treatment regimen can enable individuals with PKU to achieve and maintain normal intellectual development.”

Formula and Low Protein Foods: “Nutritional products for IEM treatment include two different forms of medical foods—one containing protein without the offending amino acid(s) and the other consisting of foods that have been modified to be low in protein.”

Supplements: “For some IEM, single amino acids and amino acid mixtures, vitamins, and other compounds are used to replace conditionally essential nutrients or enhance enzyme activity.” (e.g. Tyrosine or Arginine supplementation)

“The products used to treat IEM can be broadly categorized by purpose as follows: 1) those that provide the bulk of nutritional intake for individuals with an IEM, specialized for a specific disorder, and include protein and a range of other nutrients but not the offending amino acid(s); 2) those that are modified to be low in protein; and 3) those that are single amino acids, amino acid mixtures, vitamins, or other compounds used to replace conditionally essential nutrients or to enhance enzyme activity.”

“Further information on the definition of a medical food is available in FDA's *Compliance Program Guidance Manual*, which includes the following expanded definition [17]: Generally, to be considered a medical food, a product must, at a minimum, meet the following criteria:

- a) The product is a food for oral or tube feeding;
- b) The product is labeled for the dietary management of a medical disorder, disease, or condition; and
- c) The product is labeled to be used under medical supervision, and is primarily obtained through hospitals, clinics, and other medical and long term care facilities.”

Camp et al.'s reference: U.S. Food and Drug Administration, Compliance program guidance manual, chapter 21, Food Composition, Standards, Labeling and Economics, 2006.

“Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods are to be used under medical supervision. The term “medical foods” does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality.”

Overall Reference:

K.M. Camp, M.A. Lloyd-Puryear, K.L. Huntington. Nutritional treatment for inborn errors of metabolism: Indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Molecular Genetics and Metabolism*. 107 (2012) 3–9.

B. Neil R. M. Buist, et al.

“Medical nutritional therapy is based on the principle that abnormal levels of metabolites in the blood cause serious or lethal complications that can be prevented by normalizing the blood biochemistry through manipulation of specific nutrients in the diet.”

“Medical foods come in three basic formats:

1. **Infant formulas:** For over 50 years the main products have used elemental forms of nutrients to make ersatz milk formula substitutes based on the composition of regular milk but lacking the “toxic” ingredients. Such products are ideal for use during infancy. However, a diet exclusively of milk is not feasible for normal adults and such products cannot provide a majority of the nutritional needs of older patients. An additional array of products for older children and adults is essential. These “milks” have been the main constituent in most metabolic diets and some people appear to consider them as the only legitimate form of medical food. This is clearly not the case.

2. **Alternate protein products:** As patients grow, infant formulas alone cannot to provide normal nutrition or any semblance of a normal existence. As a result novel formulations have emerged to provide the same essential protein and energy needs for older patients as the formulas do for infants. These include solid and powder forms of critical nutrients, amino acids in a variety of forms and protein free beverage powders that can be compounded into tailor-made diets that are somewhat more acceptable to older children, adolescents and adults. These products also exclude the specific nutrients that are harmful because of the primary diagnosis.

3. **Low protein energy sources and alternate energy products:** The above products are, by far, the most costly to manufacture. However, except for infants they still do not provide adequate amounts of energy. They are designed as the main alternative to natural protein and thus are not suited to provide the total energy requirements. Adequate energy intake is just as important to a balanced diet as the control of the primary underlying metabolic defect. Inadequate energy intake can cause metabolic decompensation that can result in neurological damage just as severe as if treatment had never been started. Low protein substitute products come in the form of baking mixes, pastas, rice, sauces and pre-made items that are designed to be as similar to their normal counterparts as possible but yet supply negligible protein. They become essential sources of energy, satiety and organoleptic satisfaction and markedly increase the chances of patient acceptance and compliance.”

Overall reference: N.R.M. Buist, K. Huntington, S.C. Winter. Healthcare coverage for medical food treatment of inborn errors of metabolism. June 23, 2009.

IV. Take-Home Definition of “Medical Foods”

- A. Any nutrient-containing product labeled for a specific medical condition known to disrupt the metabolism of proteins, carbohydrates and/or lipids and is determined by a state-licensed medical care provider to be vital for treatment of the affected individual.
- B. Other useful terms for “Medical Food” without the connotation of “food” or “diet.”
 - a. Nutritional therapy/treatment
 - b. Nutritional product
- C. Three prongs of nutritional therapy for patients with inborn errors of metabolism
 - a. Formulas and amino acid mixtures
 - Essential nutrient replacement
 - b. Low-protein modified foods
 - Energy source without damaging effects
 - c. Single compound supplementation
 - Vitamin, amino acid, mineral, etc. not utilized or produced in the body of the affected individual