

173-4-05.4

Medical food and food for special dietary use.

A provider shall only provide medical food or food for special dietary use if the food complies with rule 173-4-05 of the Administrative Code and the additional requirements under this rule.

(A) Medical food:

- (1) The AAA shall determine the need, feasibility, and cost-effectiveness of establishing a service for implementing medical food by using the expertise of a LD.
- (2) Under the "Orphan Drug Amendment of 1988," Public Law 100-290, medical food is formulated to be consumed or administered internally under the direction of a physician and 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.
- (3) Medical food is not intended for the general public.
- (4) Examples are enteral products that treat:
 - (a) Kidney disease (dialyzed patients with chronic or acute renal failure);
 - (b) Liver disease (liver dysfunction, and encephalopathy);
 - (c) Hypermetabolic states (severe burns, trauma, or infection); or,
 - (d) Lung disease (chronic obstructive pulmonary disease, and acute respiratory distress syndrome).

(B) Food for special dietary use:

- (1) The provider shall determine the need, feasibility, and cost-effectiveness of establishing a service for implementing food for special dietary use by using the knowledge and expertise of a LD.
- (2) Under the "Food, Drug, and Cosmetics Act," 21 U.S.C. 350 (c)(3), food for special dietary use means a particular use for which a food purports or is represented to be used, including, but not limited to:
 - (a) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including, but not limited to, the condition of disease, convalescence, allergic hypersensitivity to food, being underweight, being overweight, or the need to control the intake of sodium or simple sugars; or,
 - (b) Supplying a dietary need by a food for special dietary use as the sole item

of the consumer's diet.

(3) Food for special dietary use is intended for the general public and may be used as a supplement to a normal diet or as a meal replacement.

(4) Examples of food for special dietary are:

(a) Thickened liquids used for dysphasia;

(b) Gluten-free products for those with celiac sprue;

(c) Meal-replacement liquids;

(d) High-calorie liquid supplements;

(e) High-calorie, high-protein liquid supplements for those with fluid restrictions;

(f) High-calorie puddings; or,

(g) A meal replacement with additional calcium for those at risk of fractures or recovering from fractures.

(5) Providers offering medical food or food for special dietary use shall:

(a) Only offer a consumer medical food or food for special dietary use if a physician, or healthcare professional with prescriptive authority, has prescribed the food for the consumer no more than ninety calendar days ago;

(b) Keep any prescription for the food on file with the provider or the AAA;

(c) Ask the physician, or healthcare professional with prescriptive authority, who has written a prescription for the food to review and update the prescription every ninety calendar days; and,

(d) Rely upon LDs for oversight for consumers who receive medical food or food for special dietary use, who may use the food in the following ways:

(i) It may replace a meal for a consumer if it is ordered by a physician or healthcare professional with prescriptive authority and meets one-third of the DRI, except in cases where the consumer's nutrition care plan dictates otherwise; or,

(ii) It may be needed as an addition to a complete meal, or to replace one item in the menu pattern. The combined meal plus the

medical food or food for special dietary use shall meet one-third of the DRI, except in cases where the consumer's nutrition care plan dictates otherwise.

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Certification

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