

December 22, 2011

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201

Dear Secretary Sebelius:

On behalf of the undersigned organizations dedicated to the health and wellness of America's infants, children, and adults, we acknowledge the December 16 bulletin issued by the Department of Health and Human Services (HHS) which describes the planned regulatory approach to defining essential health benefits as required under §1302 of the Patient Protection and Affordable Care Act (P.L. 111-148). However, we encourage the Department to recognize the critical nature of medical foods to millions of Americans by requiring that they be included as an essential health benefit in all states.

Medical foods are foods or dietary supplements that are specially formulated and processed (as opposed to a naturally occurring food used in its natural state) for a patient who requires the food as a major treatment modality. The Orphan Drug Amendments of 1988 (21 USC 360ee (b)(3)), defines a medical food as:

“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.”

The Food and Drug Administration (FDA) distinguishes medical foods from the broader category of foods for special dietary use and from foods that make health claims by requiring that medical foods meet the distinctive nutritional requirements of a disease or condition. Medical foods are distinguished from over-the-counter vitamins and dietary supplements in that they are required to be consumed or administered under the supervision of a physician. It is important to note that medical foods do not include foods that are part of a regular diet given to patients, nor does the term describe foods or supplements that purport to improve health or function for otherwise healthy individuals.

Although the Advisory Committee on Heritable Disorders in Newborns and Children has recommended that medical foods be included as a covered by benefit by all private and public health insurance plans, no federal law exists to mandate consistent coverage and payment for medical foods. Thirty-seven states and the District of Columbia have laws mandating that health insurance cover medical foods for special dietary use, but these laws are inconsistent and variable. For many insured individuals, medical foods are an integral or essential component of their medical treatment; however, because they are not a covered benefit, patients incur the tremendous cost of medical foods or forgo their physician's recommended treatment, which in turn can lead to less favorable medical outcomes. HHS has the opportunity to help these individuals by including medical foods in the definition of essential health benefits. If medical

foods are not included as an essential benefit, state laws requiring coverage for medical foods could be undermined, resulting in a loss of the coverage of necessary medical care for thousands of people across the country.

There are a number of chronic diseases or conditions that require special dietary intervention, including inherited metabolic diseases and diseases of the digestive system. Medical foods are prescribed by physicians in some cases to prevent serious disability and even death, and, in other cases, to foster normal growth and development. Specifically:

**Inherited Metabolic Diseases:** For almost 50 years, neonatologists and pediatricians have conducted newborn screenings to identify a variety of genetic disorders shortly after a child is born in order to immediately begin treatment and habilitation for these infants. Unfortunately, while newborn screening to identify life threatening genetic disorders is covered under both public and private insurance plans, the expensive medical foods necessary to treat inborn errors of metabolism and ensure children are able to grow, develop and function normally are not uniformly considered reimbursable expenses.

**Diseases of the Digestive System:** For many diseases of the digestive system, medical foods constitute the prescribed medical treatment and may be essential to survival, yet are not covered benefits. These include chronic gastrointestinal diseases, complicated by malabsorption and malnutrition (e.g. short bowel syndrome/intestinal failure, Crohn's disease, chronic pancreatitis); chronic serious liver disease (e.g. biliary atresia, genetic cholestatic syndromes); and chronic allergic syndromes (e.g. eosinophilic esophagitis, gastroenteritis). Medical foods, including expensive vitamin formulations, used to treat these disorders are essential and, in a majority of cases, the only route of safe and effective therapy available. Oftentimes, insurers will cover a medical food, such as a special formula, only if it is administered enterally via nasogastric feedings or a gastrostomy, even though the patient is fully capable of oral consumption. This practice is not only more costly to the health care system, but it is fundamentally unfair to the patient. Enteral administration of medical foods by tube feeding should only be used in situations where the child is unable to consume sufficient quantities of needed foods orally. Enteral administration through devices can be not only associated with its own potential complications, but it is also cumbersome to the family and the patient. For example, a gastrostomy tube can leak, cause ulcerations or, in severe cases, cause a perforation in the intestinal tract.

The essential health benefits package will have a lasting impact on the health and well-being of millions of infants, children, and families, and, as a result, future U.S. health care costs. Our organizations encourage you to include medical foods—including all medically necessary foods, medical equipment, and supplies to address chronic diseases or other conditions requiring special dietary interventions—in the definition of essential health benefits. Including medical foods as an essential health benefit will require that medically necessary foods, vitamins, and amino acids prescribed by a medical provider are covered under private insurance plans and ensure individuals can afford the medical interventions they need to thrive and, in some cases, survive.

Our organizations appreciate this opportunity to share our recommendation that medical foods be included in the essential health benefits package. The Department's decision on these issues will have a profound impact on the health of infants, children and adults for the foreseeable future. We would

welcome an opportunity to meet with you to discuss this issue further. Should you have any questions or wish to schedule a meeting, please contact Camille Bonta with the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition at (202) 320-3658.

Sincerely,

American Academy of Pediatrics  
American College of Gastroenterology  
American Gastroenterological Association  
American Partnership for Eosinophilic Disorders  
American Society for Gastrointestinal Endoscopy  
American Society for Parenteral and Enteral Nutrition  
Celiac Sprue Association  
Digestive Disease National Coalition  
March of Dimes  
National Foundation for Celiac Awareness  
New York Society for Gastrointestinal Endoscopy  
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition  
Society of Gastroenterology Nurses and Associates  
United Ostomy Associations of America, Inc.