RE: HNC Support for New York Assembly Bill 10576 (Senate Bill 3345)

Dear Chairman Cahill,

The Healthcare Nutrition Council (HNC), representing the manufacturers of enteral and parenteral nutrition formulas, solutions, supplies, and equipment, is writing to express our strong support for New York Assembly Bill 10576, which would provide health insurance coverage for enteral infant and baby formulas for home use, whether administered orally or via tube feeding. HNC supports this bill because it will ensure that infants and babies have access to enteral formulas for home use when deemed medically necessary for the management of specific diseases and disorders, including but not limited to, inherited diseases of amino acid or organic acid metabolism, Crohn's Disease, gastroesophageal reflux, and multiple, severe food allergies.

Patients, particularly infants and babies, with chronic diseases, gastrointestinal (GI) medical conditions, multiple, severe food allergies, often suffer from malnutrition or other medical complications. Many of the younger patients' anatomies require a specially formulated or specialized diet that is referred to as an elemental amino acid-based diet. Such diets are specifically designed to help them properly digest essential nutrients, stay healthy, and to support growth and development in infants. Malnutrition and other complications can arise in these vulnerable patients as a result of their underlying conditions that may impair their ability to absorb nutrients. When infants and babies become malnourished, they are at a significantly higher risk for negative complications, including mortality.\(^1\)

Despite these potential complications and the clear benefits such specialized enteral products provide to patients, many families lack access to amino acid-based elemental enteral formulas.\(^6\) HNC supports the increased access to these products for home use when medically indicated because enteral formulas contribute to the intervention of malnutrition and may help manage GI disorders and conditions at home. To help ensure infants and babies with complex GI conditions receive access to these formulas, HNC encourages the Committee on Insurance to consider Assembly Bill 10576, pass this legislation, and ensure this important bill is signed into New York State law. Enactment of this legislation will directly benefit young patients and their families while also preemptively addressing the complications and added medical expenses associated with the management of these conditions.

Importance of Enteral Formulas for Home Use

Interventions recommended by healthcare providers for patients with impaired or compromised GI function typically include some type of specialized nutritional support.\(^11\) Enteral formulas for home use are deemed necessary by many health care providers for those patients who cannot tolerate hydrolyzed protein or need an amino acid-based medical food.\(^9\) Without these specialized formulas, which include elemental formulas for various life stages, infants and babies can suffer adverse health consequences, including hospitalization, inadequate growth, nutrient deficiencies, or even death.\(^7\) Because of how they are formulated, these products require minimal digestive function to be broken down and absorbed, making it easy to digest for patients in a malabsorptive state.\(^6\) Many patients rely on enteral formulas to help intervene with and manage chronic medical conditions, complications and comorbidities related to...
the poor absorption of nutrients because such nutrients would be otherwise unavailable to them through breastfeeding, over-the-counter formulas or a conventional diet.

Depending on the infant or baby’s disease state and other underlying medical conditions, enteral formulas may be fed directly into the GI tract through a nasogastric, gastrostomy, jejunostomy or other type of feeding tube. Enteral formulas may also be administered orally as oral nutrition supplements (ONS) for patients who are able to swallow normally. For example, enteral formulas provide infants with short bowel syndrome, who often cannot absorb protein unless it is broken down into its component amino acids, with essential nutrients as a specialized nutritional formula. Similarly, almost all infants suffering from severe food allergies can tolerate hypoallergenic enteral formulas, while some infants with milk protein allergies cannot properly digest alternative formula options, such as hydrolyzed formulas. Consuming these elemental formulas orally or by tube feeding is essential to patients suffering from specified digestive and inherited metabolic disorders as a therapeutic treatment and should be covered by health insurance. . If these infant and pediatric populations do not receive treatment with enteral formulas as a result of lack of access, malnutrition and associated severe medical complications can occur, which can be life-threatening. Additionally, the growth and development of infants and children can be compromised. Additionally, it is more beneficial and cost-effective for patients who require enteral formulas to be treated at home instead of in a hospital or alternative healthcare setting. These enteral formulas are not optional to the patients that receive them and they must be administered regardless of where the patient accesses the formulas. If there is a lack of access to these products, a patient is at risk for becoming malnourished. The economic burden of malnutrition across care settings in the United States was estimated at $157 billion in 2014. It would be more economically feasible for patients to have access to these enteral formulas for use at home, so they can remain well-nourished and avoid subsequent readmissions into hospitals or other healthcare settings. Due to the critical nutrition that enteral formulas for home use provides patients, HNC believes that these products should be made available to all infants and babies, including those receiving care at home, if they have a diagnoses or condition for which such products are clinically indicated.

**Conclusion**

Given the importance of enteral, infant and baby, formulas for home use, HNC supports New York Assembly Bill 10576 and encourages the Committee on Insurance to consider this legislation. We commend the New York State Legislature for recognizing the gap in insurance coverage for these important infant and baby enteral formulas for home that are needed for malnutrition intervention and the management of many chronic medical conditions, complications, and comorbidities. We believe that by passing this legislation and supporting access to these enteral formulas for the infants and babies of New York who need them, there will be an immediate and meaningful impact on patient health outcomes. HNC welcomes the opportunity to work with the Assembly Committee on Insurance, relevant stakeholders, doctors, and patient groups to identify additional types of enteral formulas and additional disease states that would be deemed clinically necessary by a health care professional for use as a treatment method.

Thank you for the opportunity to comment on this bill. If you have any questions or would like additional information, please contact me at ncayce@kellencompany.com or 202-207-1126.

Sincerely,

Nadia Cayce
Executive Director
Healthcare Nutrition Council
**About HNC:** The Healthcare Nutrition Council (HNC) is an organization representing the manufacturers of enteral nutrition formulas, parenteral nutrition solutions, supplies and equipment. HNC member companies are Abbott Nutrition, B. Braun Medical, Nestlé Health Science and Nutricia North America. We are committed to improving health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. This includes promoting nutritional screenings, diagnoses, assessments and appropriate and timely nutrition clinical interventions while protecting patients’ access to specialized nutrition support products and services throughout the continuum of care. For more information on HNC, please visit [https://healthcarenutrition.org](https://healthcarenutrition.org)

References

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iii Id.


vi Id.


