

**CENTER FOR HEALTH  
INFORMATION AND ANALYSIS**

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**MANDATED BENEFIT REVIEW OF HOUSE BILL 3488  
SUBMITTED TO THE 189TH GENERAL COURT:  
AN ACT PROVIDING FOR CERTAIN HEALTH  
INSURANCE COVERAGE**

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## **BENEFIT MANDATE OVERVIEW:**

### **H.B. 3488: AN ACT PROVIDING FOR CERTAIN HEALTH INSURANCE COVERAGE**

#### **HISTORY OF THE BILL**

The Joint Committee on Financial Services referred House Bill (H.B.) 3488, “An Act providing for certain health insurance coverage,” sponsored by Rep. Garballey of Arlington in the 189<sup>th</sup> General Court, to the Center for Health Information and Analysis (CHIA) for review.<sup>1</sup> Massachusetts General Laws, Chapter 3, Section 38C requires CHIA to review and evaluate the potential fiscal impact of a mandated benefit bill referred to the agency by a legislative committee.

#### **WHAT DOES THE BILL PROPOSE?**

H.B. 3488, as submitted in the 189<sup>th</sup> General Court, would amend and extend the current health insurance benefit mandate regarding nonprescription enteral formulas for home use<sup>2</sup> by expanding the list of conditions for which coverage is required to include eosinophilic gastrointestinal disorders, severe allergies, and others not specifically listed but for which such treatments have proven effective. The proposed mandate would require insurers to cover enteral formulas for home use, whether administered orally or via tube feeding, for which a physician has issued a written order. The bill does not require coverage for elective nutritional supplements.

#### **MEDICAL EFFICACY OF H.B. 3488**

Enteral formulas are FDA-classified medical foods used to replace or supplement the nutrition of patients unable to consume sufficient nutrients through a normal oral diet. Such formulas can be consumed via tube feeding, which carries the risk of serious side effects, or orally, which is preferred whenever possible. Formula selection is based upon the specific needs of the patient. Some formula products are designed for specific diseases or conditions, and may be medically necessary to maintain a patient’s health when modifying a normal diet is not sufficient.

The proposed mandate expands the set of medical conditions for which coverage for enteral formulas is required to include those for which enteral nutrition has been proven medically necessary to restore or maintain the health of affected patients. The mandate also explicitly requires coverage for formulas for patients who can consume them orally, which is often recommended to eliminate risks associated with enteral feeding. To the extent this mandate improves access to the formula and administration method best suited to treating each patient’s, the legislation will contribute to the improved health of individuals who meet the criteria described in the bill.

#### **CURRENT COVERAGE**

Current Massachusetts law requires insurance carriers to “provide coverage for nonprescription enteral formulas for home use for which a physician has issued a written order and are medically necessary...”<sup>3</sup> Required coverage is limited to those patients diagnosed with malabsorption caused by Crohn’s disease, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, inherited diseases of amino acids and organic acids, and ulcerative colitis.<sup>4</sup> In responses to a recent survey of Massachusetts insurance carriers, all note that the diagnoses outlined in the existing law are covered, with ten of eleven carriers covering enteral formulas for both oral and enteral administration, even though the current statute does not address route of administration. Several carriers, which cover approximately 40 percent of fully-insured Massachusetts members, already cover enteral nutrition for the expanded diagnostic list.

## **COST OF IMPLEMENTING THE BILL**

Requiring coverage for this benefit by fully-insured health plans would result in an average annual increase, over five years, to the typical member's monthly health premiums of between \$0.01 (0.002%) and \$0.07 (0.014%), with the most likely value at approximately \$0.02. The increase is driven largely by the expansion of covered diagnoses for patients whose insured coverage does not currently provide this expanded coverage.

The Massachusetts Division of Insurance and the Commonwealth Health Insurance Connector Authority are responsible for determining any potential state liability associated with the proposed mandate under Section 1311 of the Affordable Care Act (ACA).

## **PLANS AFFECTED BY THE PROPOSED BENEFIT MANDATE**

The proposed mandate applies to commercial fully-insured health plans issued pursuant to Massachusetts General Laws, including individual and group accident and sickness insurance policies, corporate group insurance policies, and HMO coverage, and to both fully- and self-insured plans operated by the Group Insurance Commission (GIC) for the benefit of public employees. The proposed mandate would apply to members covered under plans issued in the Commonwealth, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

## **PLANS NOT AFFECTED BY THE PROPOSED BENEFIT MANDATE**

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or insurance carrier only to provide administrative functions), except for those provided by the GIC, are not subject to state-level health benefit plan mandates. State health benefit plan mandates do not apply to Medicare and Medicare Advantage plans, the benefits of which are qualified by Medicare. This analysis excludes members of commercial fully-insured plans over 64 years of age. State mandates also do not apply to federally-funded plans including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employee's Health Benefit Plan. The proposed mandate does not address Medicaid/MassHealth plans. In addition, Massachusetts benefit plan mandates do not apply to Massachusetts residents covered by plans issued in other states.

## MEDICAL EFFICACY ASSESSMENT

Massachusetts House Bill (H.B.) 3488,<sup>5</sup> as submitted in the 189<sup>th</sup> General Court, would expand the current health benefit plan mandate for enteral formulas<sup>6</sup>. The current law directs insurance carriers to “provide coverage for nonprescription enteral formulas for home use for which a physician has issued a written order and are medically necessary...”<sup>7</sup> The proposed mandate expands on this language, and requires:

coverage for the cost of enteral formulas for home use, whether administered orally or via tube feeding, for which a physician has issued a written order. Such written order shall state that the enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regimen for those individuals who are or will become malnourished or suffer from disorders, which if left untreated, cause chronic physical or intellectual disability or death.

The current law limits diagnoses for which enteral formulas must be covered; the proposed mandate expands the list of specific diagnoses, as outlined in the following pair of lists, and further states that the diseases for which enteral formulas have been proven effective are not limited to the items on the list.

### Current law

- Nonprescription enteral formulas for home use
- Malabsorption caused by Crohn’s disease
- Gastroesophageal reflux
- Gastrointestinal motility
- Chronic intestinal pseudo-obstruction
- Inherited diseases of amino acids and organic acids
- Ulcerative colitis

### Proposed mandate

- Enteral formulas for home use, whether administered orally or by tube feeding
- Crohn’s disease
- Gastroesophageal reflux with failure to thrive
- Gastrointestinal motility such as chronic intestinal pseudo-obstruction
- Amino acid or organic acid metabolism
- Eosinophilic gastrointestinal disorders
- Multiple, severe food allergies, which if left untreated will cause malnourishment, chronic physical or intellectual disability or death

The bill requires coverage for enteral formulas delivered by both oral and tube feeding methods. Finally, the bill excludes elective nutritional supplements from the coverage requirement, distinguishing them from the covered enteral formulas “which are medically necessary and taken under written order from a physician for the treatment of specific diseases...”

M.G.L. c. 3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

## NUTRITION SUPPORT THERAPY

When a patient cannot receive enough nutrition from the foods she/he eats, alternative means of feeding must be used.<sup>8</sup> Normally, a person consumes food orally, which is then digested through the stomach and bowel and absorbed through the bowel into the blood.<sup>9</sup> For some patients in need of nutrition without a functioning gastrointestinal (GI) tract, the stomach and small bowel are bypassed completely, and a nutritional formula is introduced through an intravenous catheter directly into the blood; this is known as parenteral nutrition (PN).<sup>10</sup>

For those patients with a functional GI tract, but who are unable to orally consume sufficient nutrients, enteral nutrition (EN) is used.<sup>11</sup> Through EN, or tube feeding, nutrition is introduced through a tube into the stomach or small bowel to allow for normal digestion.<sup>12</sup> A feeding tube may be passed through a patient's nose into the stomach (nasogastric) or small intestine (nasojejeunal), or through the skin directly into the stomach (gastrostomy) or small intestine (jejunostomy).<sup>13</sup> Such nutrition support therapies vary the amount, type, or route of nutrition according to patient needs to minimize infection and improve patient outcomes, including quality of life.<sup>14</sup> While patients may receive enteral feedings for short periods of time to address acute situations, such as during hospitalizations, some patients need enteral nutrition for longer-term issues.<sup>15</sup>

While use of EN is necessary for many patients, tube feeding carries a risk of serious harm and death.<sup>16</sup> Risks related to EN include:<sup>17,18,19</sup>

- Enteral misconnections
- Access device misplacement or displacement
- Mechanical tube complications
- Bronchopulmonary aspiration/ Aspiration pneumonia
- Irritation of the nose or throat
- Acute sinus infection
- Ulceration of the larynx or esophagus
- Wound infection
- Metabolic abnormalities
  - Improper absorption of nutrients
  - Electrolyte abnormalities
  - High blood sugar
  - Vitamin and mineral deficiencies
  - Decreased liver proteins
- Diarrhea
- Constipation
- Nausea
- Vomiting
- Dehydration
- Formula contamination
- Drug-nutrient interaction

Recognizing these documented risks of tube feeding, in its enteral nutrition recommendations, the American Society for Parenteral and Enteral Nutrition (ASPEN) states that “[t]he complexity of EN feedings cannot be underestimated.”<sup>20</sup> In general, “[n]utrition needs to be supplied to patients by the simplest and most cost-effective means acceptable. Unquestionably, the optimal method for delivering nutrition to a patient with a functioning gastrointestinal tract is by the oral route.”<sup>21</sup>

## ENTERAL FORMULAS

The term “enteral” can be used to describe the route of administration (“enteral nutrition”) or the food itself (“enteral formulas”). Enteral nutrition refers to the route of administration of nutrition via a tube into the GI tract, and may deliver human breast milk, as well as a variety of formulas.<sup>22</sup> Enteral formulas (EF) are the specialized mixtures of protein, carbohydrates, fats, vitamins, and minerals used to replace or supplement oral nutrition.<sup>23</sup> Types of enteral formulas include common blenderized, modular-component, or commercial-standardized formulas.<sup>24</sup> These standardized formulas include:<sup>25</sup>

- Polymeric (intact) feeds, suitable for patients with normal or near-normal functioning bowels and containing a wide variety of unaltered nutrients and, in some cases, fiber
- Elemental formulas or feeds, which are amino acid or predigested protein formulas that provide patients with oligopeptides and amino acids, and are most often used by patients with extensive gastrointestinal/digestive or absorptive impairments
- Disease-specific formulations

The U.S. Food and Drug Administration (FDA) classifies non-infant pediatric and adult EFs as medical food, defined in the U.S. Orphan Drug Act as “a food which is formulated to be [orally] 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.”<sup>26</sup> As opposed to parenteral products, EFs are not classified or regulated as drugs by the FDA, and unlike infant formulas, they are exempt from labeling laws regulating health and nutrient content claims.<sup>27</sup>

According to the FDA, a medical food 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. 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...”<sup>28</sup>

## ENTERAL FORMULAS IN THE TREATMENT OF SPECIFIC DISEASES

Nutrition support therapy using enteral formulas and medical foods plays an important role in treating a host of conditions, including those specifically listed in this legislation. Some of the conditions, such as gastroesophageal reflux disorders, are common,<sup>29</sup> while others, such as Crohn’s disease, are rarer,<sup>30</sup> but the portion of the affected populations for whom enteral nutrition plays a role in treatment varies substantially by condition.

### Crohn’s disease

Crohn’s disease is an incurable inflammatory bowel disease that results in chronic inflammation of the GI tract, and can lead to abdominal pain, severe diarrhea, fatigue, weight loss, malnutrition, or even to life-threatening complications.<sup>31,32</sup> Nutrition therapy is used to treat some patients.<sup>33</sup> The use of exclusive enteral nutrition (EEN) for children and adolescents with Crohn’s disease is a “very efficacious approach” that results in high rates of remission, mucosal healing, nutritional improvements, and enhanced bone health.<sup>34</sup> In contrast, a meta-analysis of the use of EEN for adults found that the rates of remission varied considerably across several studies, with half the studies citing as an issue poor compliance due to unpalatable formulas.<sup>35</sup> This research concluded that some evidence exists to support the use of EEN with adults motivated to adhere to an EEN regimen, as well as those who are newly diagnosed, and that more palatable formulas could increase compliance.<sup>36</sup>

## Chronic intestinal pseudo-obstruction

Disorders of gastrointestinal motility affect the contraction of the muscles in the GI tract, which includes the esophagus, stomach, and small and large intestines.<sup>37,38</sup> Each part of the GI tract performs a unique digestive function and has a distinct motility;<sup>39</sup> its muscles normally contract either in synchrony to move food in one direction in a process called peristalsis, or independently to mix contents.<sup>40</sup> Sphincters muscles regulate the movement of food between sections.<sup>41</sup> When the muscles in or between a section do not function properly, abnormal motility or sensitivity can occur, resulting in food sticking, pain, heartburn, bloating, diarrhea, constipation, fecal incontinence, nausea, vomiting, or intestinal obstructions.<sup>42,43</sup>

Chronic intestinal pseudo-obstruction (CIP) is a rare disorder of GI motility in which peristalsis becomes inefficient, with the intestines reacting as if a mechanical obstruction has occurred when none is present, and the nutritional needs of a patient are not met.<sup>44,45</sup> While CIP is more commonly a congenital condition found in children, it can be acquired at any age, such as after illness or surgery.<sup>46</sup> Symptoms include chronic abdominal pain, nausea, vomiting, diarrhea, abdominal distention, constipation, early satiety (feeling full), food aversion, weight loss, bacterial infections, malnutrition, and bladder disease.<sup>47</sup> The main treatment for CIP is nutritional support, including enteral formulas, to prevent malnutrition, and antibiotics for any bacterial infections.<sup>48</sup> Depending on symptom severity, patients may be unable or unwilling to eat to avoid symptoms, leading to severe malnutrition, and may require enteral or parenteral feeding, or surgery.<sup>49,50,51</sup>

## Gastroesophageal reflux disease

Gastroesophageal reflux disease (GERD) is another chronic digestive disease in which stomach acid or contents flow back into the esophagus and, in some cases, the mouth.<sup>52</sup> While the stomach mucosal lining protects it from acid injury, the esophagus, throat, nose, and lungs lack this protection; repeated exposures to the stomach acid can result in tissue edema, ulcerations, granulation, glottis scarring, and airway compromise.<sup>53</sup> For infants and children, the condition may result in “failure to thrive” in which a patient’s weight or rate of weight gain is significantly lower than that of others of similar age and gender, leading to abnormal growth and development, and to negative impacts on physical, mental, and social skills, and on secondary sexual characteristics.<sup>54</sup> For some patients, EN is a treatment option recommended under the guidelines of the North American Society for Pediatric Gastroenterology Hepatology and Nutrition, instead of or in addition to pharmacological or surgical treatments.<sup>55,56</sup>

## Eosinophilic gastrointestinal disorders

Eosinophilic gastrointestinal disorders (EGIDs) are rare chronic diseases in which white blood cells, known as eosinophils, infiltrate the GI tract and increase in number in the blood in reaction to food.<sup>57</sup> Depending on the specific disorder, EGIDs can cause nausea, vomiting, chronic abdominal or chest pain, diarrhea, poor growth/failure to thrive, weight loss or difficulty with weight gain, difficulty swallowing, esophageal food impaction, feeding refusal, food intolerances, poor appetite, fatigue, and sleep difficulties. Treatment varies by the type of EGID and can include elimination diets, enteral formulas, and use of topical or systemic steroids, as well as acid suppressors or immunosuppressives.<sup>58,59,60,61,62,63</sup> Consensus guidelines recommend dietary therapy as effective for all children and motivated adults diagnosed with eosinophilic esophagitis (EoE), as its use has been found to lead to “near-complete resolution of both clinical and histologic abnormalities.”<sup>64</sup> The use of elemental formulas specifically has been found to be the most effective dietary therapy for EoE.<sup>65</sup> For eosinophilic colitis, elemental diets and enteral formulas have been found to provide symptomatic relief for many patients, though poor palatability often diminishes compliance and therefore effectiveness.<sup>66</sup>

## Amino acid and organic acid metabolism disorders

Amino acid and organic acid metabolism disorders are genetic diseases that affect a body's metabolism, or ability to change food into energy.<sup>67,68</sup> These disorders result from the body's inability to break down or use specific amino acids, ketones, proteins, vitamins, or carbohydrates, leading to a buildup of (often) toxic chemicals and a shortage of other vital chemicals essential to normal body functioning.<sup>69</sup> Untreated, these disorders may lead to brain, heart, liver or kidney damage, eye problems or vision loss, osteoporosis, intellectual or developmental disabilities, coma, seizures, or death.<sup>70,71</sup> Infants are most often diagnosed with these disorders through newborn screenings; early diagnosis is essential to prevent damage caused by these disorders, and most patients will require lifelong management of their condition.<sup>72</sup> Patients must eliminate and avoid certain foods, often including those high in protein, and many rely on enteral elemental or disease-specific formulas to meet their nutritional needs.<sup>73,74,75</sup>

## Food allergies

A food allergy is the body's response to a food in which the immune system creates antibodies and the body reacts as if the food is a threat.<sup>76</sup> Reactions range from mild to severe, and may include swelling or itching in the mouth, GI symptoms including vomiting, diarrhea, cramps, and abdominal pain, hives or eczema, trouble breathing, a drop in blood pressure, or life-threatening anaphylaxis.<sup>77</sup> It is estimated that eight foods – milk, egg, wheat, peanuts, soy, tree nuts, fish, and shellfish – cause 90 percent of food allergies.<sup>78</sup> Treatment of food allergies includes eliminating the triggering food(s), which may severely restrict a patient's diet if multiple foods are involved, and can eventually result in failure to thrive and other growth and development problems associated with an inadequate diet.<sup>79,80,81</sup> It is recommended that patients with certain food allergies use protein hydrolysates and/or amino acid-based elemental formulas to ensure proper protein intake which can alleviate residual symptoms and prevent problems with growth and development.<sup>82</sup> For other patients, "[c]ontinued use of commercially prepared complete formulas beyond infancy is sometimes recommended for [those] with multiple food allergies on very limited diets" to ensure consumption of appropriate levels of protein and other nutrients.<sup>83</sup>

## CONCLUSION

Enteral formulas are FDA-classified medical foods used to replace or supplement the nutrition of patients unable to consume sufficient nutrients through a normal oral diet. Such formulas can be consumed via tube feeding, which carries the risk of serious side effects, or orally, which is preferred whenever possible. Formulas vary according to the needs of the patient for the dietary management of specific diseases or conditions, and may be medically necessary to maintain a patient's health when simply modifying a normal diet is not sufficient. Such patients are unable to ingest, digest, absorb, or metabolize food safely, efficiently, or effectively, and are therefore at risk of malnutrition and/or prolonging or exacerbating their disease.

The proposed mandate expands the set of medical conditions for which coverage for enteral formulas is required to include those for which enteral nutrition has been proven medically necessary to restore or maintain the health of affected patients. The mandate also explicitly requires coverage for formulas for patients who can consume them orally, which is often recommended to eliminate risks associated with enteral feeding. To the extent this mandate improves access to the formula and administration method best suited to treating each patient's condition, the legislation will contribute to the improved health of individuals who meet the criteria described in the bill.

## ENDNOTES

- 1 The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill 3488, “An Act providing for certain health insurance coverage.” Accessed 29 February 2016: <https://malegislature.gov/Bills/189/House/H3488>.
- 2 M.G.L. c.32A §17A, c.175 §47I, c.176A §8L, c.176B §4K, c.176G §4D.
- 3 M.G.L. c.175 §47W, c.176A §8W, c.176B §4W, c.176G §4O.
- 4 M.G.L. c.175 §47W, c.176A §8W, c.176B §4W, c.176G §4O.
- 5 *Op. cit. The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill 3488, “An Act providing for certain health care coverage.”*
- 6 M.G.L. c.175 §47W, c.176A §8W, c.176B §4W, c.176G §4O.
- 7 M.G.L. c.175 §47W, c.176A §8W, c.176B §4W, c.176G §4O.
- 8 American Society for Parenteral and Enteral Nutrition (ASPEN). What Is Nutrition Support Therapy. Accessed 29 February 2016: [https://www.nutritioncare.org/About\\_Clinical\\_Nutrition/What\\_is\\_Nutrition\\_Support\\_Therapy/](https://www.nutritioncare.org/About_Clinical_Nutrition/What_is_Nutrition_Support_Therapy/).
- 9 ASPEN: What Is Parenteral Nutrition. Accessed 29 February 2016: [https://www.nutritioncare.org/About\\_Clinical\\_Nutrition/What\\_is\\_Parenteral\\_Nutrition/](https://www.nutritioncare.org/About_Clinical_Nutrition/What_is_Parenteral_Nutrition/).
- 10 *Op. cit. ASPEN: What Is Parenteral Nutrition.*
- 11 Bankhead R, Boullata J, Brantley S, Corkins, et. al.; A.S.P.E.N. Board of Directors. Enteral nutrition practice recommendations. JPEN J Parenter Enteral Nutr. 2009 Mar-Apr;33(2):122-67. Accessed 3 March 2016: <http://pen.sagepub.com/content/early/2009/01/27/0148607108330314.full.pdf+html>.
- 12 ASPEN: What Is Enteral Nutrition. Accessed 29 February 2016: [https://www.nutritioncare.org/About\\_Clinical\\_Nutrition/What\\_is\\_Enteral\\_Nutrition/](https://www.nutritioncare.org/About_Clinical_Nutrition/What_is_Enteral_Nutrition/).
- 13 Mayo Clinic. Tests and Procedures, Home enteral nutrition: Definition. Updated 9 December 2014. Accessed 4 March 2016: <http://www.mayoclinic.org/tests-procedures/home-enteral-nutrition/basics/definition/prc-20012832>.
- 14 *Op. cit. ASPEN: What Is Nutrition Support Therapy.*
- 15 Pearce CB, Duncan HD. Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations. Postgrad Med J. 2002 Apr;78(918):198-204. Accessed 3 March 2016: <http://pmj.bmj.com/content/78/918/198.full>.
- 16 *Op. cit. Bankhead R, Boullata J, Brantley S, Corkins, et. al.; A.S.P.E.N. Board of Directors.*
- 17 *Op. cit. Bankhead R, Boullata J, Brantley S, Corkins, et. al.; A.S.P.E.N. Board of Directors.*
- 18 Kattelmann KK, Hise M, Russell M, et. al. Preliminary evidence for a medical nutrition therapy protocol: enteral feedings for critically ill patients. J Am Diet Assoc. 2006 Aug;106(8):1226-41. Accessed 4 March 2016: <http://www.ncbi.nlm.nih.gov/pubmed/16863719>.
- 19 American College of Gastroenterology (ACG). Patient Education and Resource Center: Enteral and Parenteral Nutrition. Published September 2011; accessed 4 March 2016: <http://patients.gi.org/topics/enteral-and-parenteral-nutrition/>.
- 20 *Op. cit. Bankhead R, Boullata J, Brantley S, Corkins, et. al.; A.S.P.E.N. Board of Directors.*
- 21 Lloyd DA, Powell-Tuck J. Artificial nutrition: principles and practice of enteral feeding. Clin Colon Rectal Surg. 2004 May;17(2):107-18. Accessed 4 March 2016: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2780045/>.
- 22 *Op. cit. Bankhead R, Boullata J, Brantley S, Corkins, et. al.; A.S.P.E.N. Board of Directors.*
- 23 *Op. cit. ASPEN: What Is Enteral Nutrition.*
- 24 *Op. cit. Bankhead R, Boullata J, Brantley S, Corkins, et. al.; A.S.P.E.N. Board of Directors.*
- 25 *Op. cit. Pearce CB, Duncan HD.*
- 26 U.S. Food and Drug Administration (FDA). Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition. May 1997; May 2007; Revised August 2013. Accessed 3 March 2016: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm>.

FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. 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 be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition’s specific dietary management.

- 27 *Op. cit. FDA: Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition.*  
 A food is a medical food and is exempt from the nutrition labeling requirements ... only if:  
 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;  
 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;  
 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;  
 It is intended to be used under medical supervision; and  
 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.
- 28 *Op. cit. FDA: Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition.*
- 29 See, for example: El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut*. 2014 Jun;63(6):871-80. Accessed 22 April 2016: <http://www.ncbi.nlm.nih.gov/pubmed/23853213>.
- 30 See, for example: CDC. Epidemiology of the IBD. Accessed 22 April 2016: <http://www.cdc.gov/ibd/ibd-epidemiology.htm>.
- 31 Mayo Clinic. Disease and Conditions, Crohn's Disease: Definition. Updated 13 August 2014; accessed 4 March 2016: <http://www.mayoclinic.org/diseases-conditions/crohns-disease/basics/definition/con-20032061>.
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- 33 Mayo Clinic. Disease and Conditions, Crohn's Disease: Treatments and drugs. Accessed 4 March 2016: <http://www.mayoclinic.org/diseases-conditions/crohns-disease/basics/treatment/con-20032061>.
- 34 Day AS, Lopez RN. Exclusive enteral nutrition in children with Crohn's disease. *World J Gastroenterol*. 2015 Jun 14; 21(22): 6809–6816. Accessed 4 March 2016: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4462720/>.
- 35 Wall CL, Day AS, Geary RB. Use of exclusive enteral nutrition in adults with Crohn's disease: A review. *World J Gastroenterol*. 2013 Nov 21; 19(43): 7652–7660. Accessed 4 March 2016: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837264/>.
- 36 *Op. cit. Wall CL, Day AS, Geary RB.*
- 37 International Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders. Accessed 7 March 2016: <http://www.iffgd.org/gi-disorders/motility-disorders.html>.
- 38 *Op Cit. International Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders.*
- 39 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders.*
- 40 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders.*
- 41 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders.*
- 42 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders.*
- 43 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Motility Disorders.*
- 44 Medline Plus. Intestinal pseudo-obstruction. National Institutes of Health, National Library of Medicine. Updated 11 August 2014; accessed 7 March 2016: <https://www.nlm.nih.gov/medlineplus/ency/article/000253.htm>.
- 45 International Foundation for Functional Gastrointestinal Disorders (iffgd). Intestinal Pseudo-Obstruction. Reviewed 1 October 2010; accessed 7 March 2016: <http://aboutgimotility.org/disorders-of-the-small-intestine/intestinal-pseudo-obstruction.html>.
- 46 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Intestinal Pseudo-Obstruction.*
- 47 *Op. cit. Foundation for Functional Gastrointestinal Disorders (iffgd). Intestinal Pseudo-Obstruction.*
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**Actuarial Assessment of  
House Bill 3488  
Submitted to the 189<sup>th</sup> General Court:  
“An act providing for certain health insurance coverage”**

Prepared for  
Commonwealth of Massachusetts  
Center for Health Information and Analysis

July 2016

Prepared by  
Compass Health Analytics, Inc.



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**Actuarial Assessment of House Bill 3488**  
**Submitted to the 189<sup>th</sup> General Court:**  
**“An act providing for certain health insurance coverage”**

## **Executive Summary**

Massachusetts House Bill (H.B.) 3488,<sup>1</sup> as submitted in the 189<sup>th</sup> General Court, would amend and extend the current health insurance benefit mandate regarding nonprescription enteral formulas for home use,<sup>2</sup> expanding the list of conditions for which coverage is required to include eosinophilic gastrointestinal disorders, severe food allergies, and others not specifically listed but which have proven to be effective. The proposed mandate would require insurers to cover enteral formulas for home use, whether administered orally or via tube feeding, for which a physician has issued a written order. Elective nutritional supplements are excluded from coverage.

Massachusetts General Laws (M.G.L.) c.3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. (Compass) to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health insurance in Massachusetts.

### Background

Current Massachusetts law directs insurers to “provide coverage for nonprescription enteral formulas for home use for which a physician has issued a written order and are medically necessary...”<sup>3</sup> The current law limits diagnoses for which enteral formulas must be covered; the proposed mandate expands the list of specific diagnoses to additionally include eosinophilic gastrointestinal disorders and multiple, severe food allergies. The proposed mandate further states that the diseases for which enteral formulas have been proven effective are not limited to the diagnoses on the list, and must be covered whether delivered by oral or tube feeding methods “when clearly medically necessary and...proven effective as a disease-specific regimen for [malnourishment or those] disorders, which if left untreated, cause chronic physical or intellectual disability or death.” Finally, the bill excludes elective nutritional supplements from the coverage requirement.

### Enteral formulas

Enteral formulas are FDA-classified medical foods used to replace or supplement the nutrition of patients unable to consume sufficient nutrients through a normal oral diet. Such formulas can be consumed via tube feeding, which carries the risk of serious side effects, or orally, which is preferred whenever possible. Formulas vary according to the needs of the patient for the dietary management of specific diseases or conditions, and may be medically necessary to maintain a patient’s health when simply modifying a normal diet is not sufficient. Such patients are unable to

ingest, digest, absorb, or metabolize food safely, efficiently, or effectively, and are therefore at risk of malnutrition and/or prolonging or exacerbating their disease.

### Existing laws regarding enteral formulas

Under current Massachusetts statutes, plans must cover “nonprescription enteral formulas for home use for which a physician has issued a written order and which are medically necessary for the treatment of malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids.”<sup>4</sup> Other laws require coverage for special medical formulas which are medically necessary for treatment of certain inherited diseases of amino acids and organic acids for infants, children, and pregnant women.<sup>5</sup> Because carriers must already cover these conditions, the cost of treating them is not included in the projection of the marginal cost of the proposed mandate.

### Analysis

Compass estimated the impact of H.B. 3488 by analyzing:

- The prevalence of each diagnosis in the proposed mandate not present in the existing statute
- The number of diagnosed patients for whom enteral formulas will be medically necessary
- The percent of those patients without existing coverage
- The treatment profile of various patients to determine the number of cans of enteral formula to be consumed monthly and for how long
- The cost per can of enteral formula

Compass then aggregated these components and projected them forward over the next five years (2017 to 2021) for the fully-insured Massachusetts population under age 65, forecasting medical inflation and adding insurer retention (administrative cost and profit) to arrive at an estimate of the bill's effect on premiums.

This analysis relies on estimates of the prevalence of the relevant diagnoses, the number of patients for whom enteral formulas are medically necessary, and estimates of enteral formula costs paid by carriers. These uncertainties are addressed by modeling a range of assumptions within reasonable judgment-based limits, and producing a range of incremental impact estimates based on varying these parameters.

### Summary results

Table ES-1 summarizes the estimated effect of H.B. 3488 on premiums for fully-insured plans over five years. This analysis estimates that the mandate, if enacted as drafted for the 189<sup>th</sup> General Court, would increase fully-insured premiums by as much as 0.014 percent on average over the

next five years; a more likely increase is in the range of 0.005 percent, equivalent to an average annual expenditure of \$706 thousand over the period 2017 to 2021.

The impact on premiums is driven by the estimates of the number of patients diagnosed with the newly-included conditions, the number of these who will need enteral formula treatment, the number of cans each will require in a month, the number of months per year that each will need treatment, and the cost per can of enteral formula under commercial coverage.

The impact of the bill on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides and on how those benefits would change under the proposed mandate.

**Table ES-1:  
Summary Results**

	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>Weighted Average</b>	<b>5 Yr Total</b>
Members (000s)	2,433	2,407	2,381	2,354	2,327		
Medical Expense Low (\$000s)	\$136	\$198	\$206	\$214	\$223	\$207	\$975
Medical Expense Mid (\$000s)	\$411	\$600	\$624	\$648	\$676	\$629	\$2,959
Medical Expense High (\$000s)	\$1,098	\$1,601	\$1,664	\$1,731	\$1,803	\$1,678	\$7,897
Premium Low (\$000s)	\$152	\$222	\$231	\$240	\$250	\$233	\$1,096
Premium Mid (\$000s)	\$462	\$674	\$700	\$728	\$759	\$706	\$3,324
Premium High (\$000s)	\$1,233	\$1,798	\$1,870	\$1,944	\$2,026	\$1,885	\$8,871
PMPM Low	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
PMPM Mid	\$0.02	\$0.02	\$0.02	\$0.03	\$0.03	\$0.02	\$0.02
PMPM High	\$0.06	\$0.06	\$0.07	\$0.07	\$0.07	\$0.07	\$0.07
Estimated Monthly Premium	\$463	\$473	\$483	\$493	\$503	\$483	\$483
Premium % Rise Low	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%
Premium % Rise Mid	0.005%	0.005%	0.005%	0.005%	0.005%	0.005%	0.005%
Premium % Rise High	0.013%	0.013%	0.014%	0.014%	0.014%	0.014%	0.014%

## Executive Summary Endnotes

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<sup>1</sup> The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill 3488, “An Act providing for certain health insurance coverage.” Accessed 26 April 2016: <https://malegislature.gov/Bills/189/House/H3488>.

<sup>2</sup> M.G.L. c.32A §17A, c.175 §47I, c.176A §8L, c.176B §4K, c.176G §4D.

<sup>3</sup> M.G.L. c.175 §47W, c.176A §8W, c.176B §4W, c.176G §4O.

<sup>4</sup> M.G.L. c.175 §47W, c.176A §8W, c.176B §4W, c.176G §4O.

<sup>5</sup> M.G.L. c.175 §47C, c.176A §8B, c.176B §4C, c.176G §4.

# **Actuarial Assessment of House Bill 3488 Submitted to the 189<sup>th</sup> General Court: “An act providing for certain health insurance coverage”**

## **1. Introduction**

Massachusetts House Bill (H.B.) 3488,<sup>1</sup> as submitted in the 189<sup>th</sup> General Court, would amend and extend the current health insurance benefit mandate regarding nonprescription enteral formulas for home use,<sup>2</sup> expanding the list of conditions for which coverage is required to include eosinophilic gastrointestinal disorders, severe allergies, and others not specifically listed but which have proven to be effective. The proposed mandate would require insurers to cover enteral formulas for home use, whether administered orally or via tube feeding, for which a physician has issued a written order. Elective nutritional supplements are excluded from coverage.

Massachusetts General Laws (M.G.L.) c.3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. (Compass) to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health insurance in Massachusetts.

Assessing the impact of the proposed mandate on premiums entails analyzing its incremental effect on spending by insurance plans. This in turn requires comparing spending under the provisions of the bill to spending under current statutes and current benefit plans for the relevant services.

Section 2 of this analysis outlines the provisions of the bill. Section 3 summarizes the methodology used for the estimate. Section 4 discusses important considerations in translating the bill’s language into estimates of its incremental impact on health care costs and steps through the calculations. Section 5 summarizes the results.

## **2. Interpretation of H.B. 3488**

Current Massachusetts law directs insurers to “provide coverage for nonprescription enteral formulas for home use for which a physician has issued a written order and are medically necessary...”<sup>3</sup> The proposed mandate expands on this language, and requires:

coverage for the cost of enteral formulas for home use, whether administered orally or via tube feeding, for which a physician has issued a written order. Such written order shall state that the enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regimen for those individuals who are or will become malnourished or suffer from disorders, which if left untreated, cause chronic physical or intellectual disability or death.

## 2.1. Plans affected by the proposed mandate

The bill amends statutes that regulate health care insurers in Massachusetts. It includes five sections, each of which addresses statutes dealing with a particular type of health insurance policy:

- Section 1: Group Insurance Commission (GIC) (amending M.G.L. c. 32A, §17A)
- Section 2: Accident and sickness insurance policies (amending M.G.L. c. 175, §47I)
- Section 3: Contracts with non-profit hospital service corporations (amending M.G.L. c. 176A, §8L)
- Section 4: Certificates under medical service agreements (amending M.G.L. c. 176B, §4K)
- Section 5: Health maintenance contracts (amending M.G.L. 176G, § 4D)

The bill requires coverage for members under the relevant Massachusetts-licensed plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, the benefits of which are qualified by Medicare; this analysis excludes members of fully-insured commercial plans over 64 years of age and does not address any potential effect on Medicare supplement plans even to the extent they are regulated by state law. This analysis does not apply to Medicaid/MassHealth.

## 2.2. Covered services

Enteral formulas are FDA-classified medical foods used to replace or supplement the nutrition of patients unable to consume sufficient nutrients through a normal oral diet. Such formulas can be consumed via tube feeding, which carries the risk of serious side effects, or orally, which is preferred whenever possible. Formulas vary according to the needs of the patient for the dietary management of specific diseases or conditions, and may be medically necessary to maintain a patient's health when simply modifying a normal diet is not sufficient. Such patients are unable to ingest, digest, absorb, or metabolize food safely, efficiently, or effectively, and are therefore at risk of malnutrition and/or prolonging or exacerbating their disease.

The current law limits diagnoses for which insurers must cover enteral formulas; the proposed mandate requires coverage for enteral nutrition for conditions for which it has been proven medically necessary to restore or maintain the health of affected patients. It expands the list of specific diagnoses as outlined in the following pair of lists, and further states that the diseases for which enteral formulas have been proven effective are not limited to the diagnoses on the list. Note that the conditions specifically included in the proposed mandate, but not in the existing statute, are eosinophilic gastrointestinal disorders and severe food allergies.

#### Current statute

- Nonprescription enteral formulas for home use
- Malabsorption caused by Crohn’s disease
- Gastroesophageal reflux
- Gastrointestinal motility
- Chronic intestinal pseudo-obstruction
- Inherited diseases of amino acids and organic acids
- Ulcerative colitis

#### Proposed mandate

- Enteral formulas for home use, whether administered orally or by tube feeding
- Crohn’s disease
- Gastroesophageal reflux with failure to thrive
- Gastrointestinal motility such as chronic intestinal pseudo-obstruction
- Amino acid or organic acid metabolism
- Eosinophilic gastrointestinal disorders
- Multiple, severe food allergies, which if left untreated will cause malnourishment, chronic physical or intellectual disability or death

The proposed mandate explicitly requires coverage for formulas for patients who can consume them orally, which is often recommended to eliminate risks associated with enteral feeding. In addition, the bill excludes elective nutritional supplements from the coverage requirement, distinguishing them from the covered enteral formulas “which are medically necessary and taken under written order from a physician for the treatment of specific diseases...” The bill leaves untouched existing language providing “Coverage for inherited diseases of amino acids and organic acids shall include food products modified to be low protein in an amount not to exceed \$5,000 annually for any insured individual.”

The proposed mandate specifies that diseases for which enteral formulas have proven effective “shall include, but are not limited to” the list above, meaning it might reach other conditions. It does require the prescriber to document that the treatment has been “proven effective as a disease-specific treatment regimen for those individuals who are or will become malnourished or suffer from disorders, which if left untreated, cause chronic physical or intellectual disability or death.” To set some limits on this potentially open-ended set of conditions, this analysis examined claims in the Massachusetts All Payer Claim Database (APCD) for fully-insured plans, which showed that other conditions not in the bill’s list (or on the list in the existing statute) and currently treated with enteral formulas are already paid for by all major carriers in Massachusetts. In fact these other conditions, not subject to the current mandate, make up the majority of the enteral formula claims paid. Because these other conditions were not explicitly listed in the mandate and because evidence exists that carriers currently cover them, it is unlikely that other (currently known) conditions will contribute significantly to the incremental cost of the mandate. Beyond that, the analysis produces a range of estimates with a high end that accommodates additional utilization, and in any case the expected costs for this mandate are small.

### **2.3. Existing laws affecting the cost of H.B. 3488**

This analysis must estimate the incremental effect of H.B. 3488, given existing statutes. As noted, under existing Massachusetts statutes the proposed mandate amends, plans must already cover enteral formulas for some of the conditions in the proposed mandate.<sup>4</sup> Other Massachusetts statutes require coverage for special medical formulas necessary for treating certain inherited diseases of amino acids and organic acids for infants, children, and pregnant women.<sup>5</sup> Because

carriers must already cover these conditions, the cost of treating them is not included in the projection of the marginal cost of the proposed mandate.

No current federal mandates related to the specific subject matter of this bill have been identified.

## 2.4. Current coverage

In a recent survey of the largest insurance carriers in Massachusetts, all note that the diagnoses outlined in the existing law are covered, with ten of eleven carriers covering enteral formulas for both oral and enteral administration, even though the current statute does not address route of administration. Further, several carriers, which currently cover approximately 40 percent of fully-insured Massachusetts members, already cover enteral nutrition for the expanded diagnostic list, in both orally- and tube-administered forms.

This analysis estimates the incremental cost to the Massachusetts fully-insured commercial health care market for coverage of the added diagnoses listed in H.B.267 when the requirement to provide such coverage is expanded to include plans which currently do not cover these conditions.

## 3. Methodology

### 3.1. Overview

Estimating H.B. 3488's impact on premiums requires assessing the cost of covering enteral formulas not currently covered, and estimating the costs for patients with the newly-included diagnoses who will need these formulas in both the short- and long-terms. Combining these components, and accounting for carrier retention, results in a baseline estimate of the proposed mandate's incremental effect on premiums, which is then projected over the five years following the assumed January 1, 2017 implementation date of the law.

### 3.2. Data sources

The primary data sources used in the analysis were:

- Information, including descriptions of current coverage, from responses to a survey of commercial health insurance carriers in Massachusetts
- Academic literature, published reports, and population data, cited as appropriate
- Information from clinical providers
- Massachusetts insurer claim data from the Massachusetts All Payer Claim Database (APCD) for calendar year 2014, for plans covering the majority of the under-65 fully-insured population subject to the mandate

### 3.3. Steps in the analysis

The analysis was executed in the following steps.

#### *Analyze cost of enteral formulas not currently covered*

- Obtain prevalence rates for the newly-included conditions requiring coverage of enteral formulas under the proposed mandate using available literature.
- Determine a treatment profile based on input from a clinical expert. The profile includes the portion of patients with the newly-mandated conditions who will be treated using enteral formulas under three medically-necessary scenarios: full feeding replacement in the long-term, partial feeding replacement (supplementation) in the long-term, and full feeding replacement in the short-term.
- Calculate the number of users of enteral formulas for the newly-mandated conditions by applying the prevalence rate and the treatment profile percentages to the total 2014 fully-insured commercial membership, obtained from the APCD.
- Reduce the number of users to include only those without current coverage for treatment with enteral formulas for the newly-mandated conditions based on surveys of Massachusetts carriers.
- Develop an estimated range of the unit cost per single can of enteral formulas using the APCD for those carriers with current coverage in alignment with the mandate.
- Estimate the number of cans of enteral formula used per month per patient based on input from a clinical expert.
- Calculate the annual incremental cost of the mandate by multiplying the relevant factors, including the monthly number of incremental users, the cost per can, the number of cans per month, and the number of months in use per year.

#### *Calculate insurance premium impact of projected spending*

- Divide the annual incremental cost by the corresponding membership to calculate baseline per member per month (PMPM) costs.
- Project PMPM cost forward over the five-year analysis period using an estimated increase in pharmacy costs.
- Estimate the impact of insurer retention (administrative costs and profit) on premiums.
- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2017 to 2021).
- Multiply the PMPM costs by the corresponding membership to get annual incremental cost.

Section 4 describes these steps in more detail.

### 3.4. Limitations

While estimating costs using data in the APCD is relatively straightforward, this analysis also requires assumptions that hold more uncertainty. For example, the analysis relies on estimates of the prevalence of the relevant diagnoses from published studies and input from a clinical expert at Boston Children’s Hospital.<sup>6</sup> Similarly, an estimate of the portion of these diagnosed patients whose use of enteral formulas is medically necessary is also based on input from a clinical expert.

These uncertainties are addressed by modeling a range of assumptions within reasonable judgment-based limits, and producing a range of estimates of incremental cost by varying these parameters. The more detailed step-by-step description of the estimation process outlined in the next sections addresses these uncertainties further.

## 4. Analysis

This section describes the calculations outlined in the previous section in more detail. The analysis includes development of a best estimate “middle-cost” scenario, as well as a low-cost scenario using assumptions that produced a lower estimate, and a high-cost scenario using more conservative assumptions that produced a higher estimated impact.

Current Massachusetts law requires coverage of enteral formulas for certain diagnoses when medically necessary. H.B. 3488 expands this law to include new diagnoses, as well as others proven medically necessary, and explicitly covers both oral and tube-feeding methods of administration. The marginal cost of the new mandate is calculated by multiplying the number of newly-covered users of enteral formulas by the annual cost of the formulas for each user, and applying increases for inflation and for insurer retention.

### 4.1. Number of enteral formula users not currently covered

Current Massachusetts law mandates coverage for enteral formulas for several diagnoses, and H.B. 3488 adds coverage for eosinophilic gastrointestinal disorders (EoE) and multiple, severe food allergies. While the mandate also explicitly covers oral and tube feeding administration, carrier surveys indicate that both methods are already included for those diagnoses currently covered.

Therefore, prevalence rates for these two new diagnoses are multiplied by fully-insured membership to estimate the number of users of enteral formulas attributable to this mandate, using 2014 as a baseline. According to clinical input, the majority of patients who would be affected by the proposed mandate have been diagnosed with EoE, with a smaller number diagnosed with food allergies. Therefore, the prevalence rate used in this analysis is based on estimations of EoE patients in the population, with a small adjustment included to account for food allergy patients.<sup>7</sup> Table 1 displays this rate as the mid-level scenario, with adjustments for higher and lower prevalence. These estimates are multiplied by the 2014 fully-insured membership, from the APCD, to calculate the estimated number of patients in the population with these diagnoses.

**Table 1:  
Patients Diagnosed with EoE or Multiple, Severe Food Allergies**

	Prevalence rate	Patients
Low Scenario	0.040%	710
Mid Scenario	0.050%	888
High Scenario	0.067%	1,184

Not all diagnosed patients will need treatment with enteral formulas, and those who do generally fall into three treatment profiles: those in need of full nutritional replacement for the long-term, those in need of non-elective supplemental nutritional replacement for the long-term, and those in need of full nutritional replacement for the short-term. Estimates of the percent of diagnosed patients in each of these treatment profiles are displayed in Table 2.

**Table 2:  
Estimated Percent of Diagnosed Patients and Enteral Formula Treatment Needs**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term	Diagnosed Patients Who Do Not Need Enteral Formula
Low Scenario	0.25%	25%	25%	49.75%
Mid Scenario	0.50%	30%	30%	39.50%
High Scenario	0.75%	35%	35%	29.25%

To obtain the number of users of enteral formulas subject to the mandate, the overall number of diagnosed patients is multiplied by each of these percentages to estimate the number of diagnosed patients needing enteral formula treatment. Table 3 displays the results.

**Table 3:  
Estimated Number of Diagnosed Patients Needing Enteral Formula Treatment**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term
Low Scenario	2	178	178
Mid Scenario	4	266	266
High Scenario	9	414	414

A survey of 11 carriers in Massachusetts indicated that plans currently cover approximately 39.4 percent of fully-insured members for the newly mandated diagnoses. Therefore, the estimated number of patients needing enteral formula treatment is reduced to calculate the number of users not currently covered, who are therefore subject to the proposed mandate. Table 4 displays these estimates.

**Table 4:  
Estimated Number of Diagnosed Patients Needing Enteral Formula Treatment  
without Current Coverage**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term
Low Scenario	1	108	108
Mid Scenario	3	161	161
High Scenario	5	251	251

#### 4.2. Annual cost per user of enteral formula

Enteral formulas are generally purchased in powdered form by can when used to treat these diagnoses. Each treatment profile varies in the number of cans a patient uses each month and the number of months per year of treatment. Table 5 estimates the number of cans per month for each treatment profile, and Table 6 outlines the months per year of treatment for each user.

**Table 5:  
Estimated Number of Cans of Enteral Formula Per User Per Month**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term
Low Scenario	8	3	8
Mid Scenario	10	4	10
High Scenario	12	5	12

**Table 6:  
Estimated Months of Use Per Year Per User of Enteral Formula**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term
Low Scenario	12	12	1.0
Mid Scenario	12	12	1.5
High Scenario	12	12	2.0

Table 7 displays estimates of the cost of a can of enteral formula based on paid claims in the APCD.

**Table 7:  
Estimated Carrier Paid Amount per Can of Enteral Formula**

	Cost Per Can
Low Scenario	\$25
Mid Scenario	\$35
High Scenario	\$45

To calculate the annual cost per user for these formulas for each treatment profile, the number of cans a patient would use per month is multiplied by the number of months of use per year, and the cost per can. Table 8 displays cost per user for each treatment profile under three scenarios.

**Table 8:  
Estimated Annual Cost per User of Enteral Formula**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term
Low Scenario	\$2,400	\$900	\$200
Mid Scenario	\$4,200	\$1,680	\$525
High Scenario	\$6,480	\$2,700	\$1,080

### 4.3. Annual incremental cost of enteral formula by treatment profile

The cost per user is then multiplied by the number of users who are not currently covered to calculate the total annual marginal cost of enteral formulas, displayed in Table 9.

**Table 9:  
Estimated Annual Marginal Cost of Enteral Formula**

	Full replacement: Long-term	Supplemental replacement: Long-term	Full replacement: Short-term
Low Scenario	\$2,400	\$97,200	\$21,600
Mid Scenario	\$12,600	\$270,480	\$84,525
High Scenario	\$32,400	\$677,700	\$271,080

### 4.4. Annual and PMPM incremental cost of enteral formula

The costs of the three treatment profiles are then added to calculate the total annual incremental cost of enteral formula under each scenario. Each annual cost is then divided by the 2014 fully-insured membership, from the APCD, and by 12 months to calculate the estimated baseline PMPM incremental cost attributable to the mandate. These results are listed in Table 10.

**Table 10:  
Total and PMPM Marginal Cost of Enteral Formula**

	Total Annual Cost	Baseline PMPM cost
Low Scenario	\$121,200	\$0.01
Mid Scenario	\$367,605	\$0.02
High Scenario	\$981,180	\$0.05

#### 4.5. Projected PMPM cost of enteral formula

This baseline PMPM cost was then projected from 2014 through the end of the study period, increasing the cost per can by an average of 5.0 percent annually, based on estimates of inflation for health care services.<sup>8</sup> These results are shown in Table 11.

**Table 11:**  
**Estimated Marginal PMPM Cost of Enteral Formula Projected for Study Period**

	2014 Baseline	2017	2018	2019	2020	2021
Low Scenario	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
Mid Scenario	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02
High Scenario	\$0.05	\$0.05	\$0.06	\$0.06	\$0.06	\$0.06

#### 4.6. Carrier retention and increase in premium

Assuming an average annual retention rate of 11.0 percent based on CHIA's analysis of administrative costs and profit in Massachusetts,<sup>9</sup> the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 12 shows the result.

**Table 12:**  
**Estimated Total PMPM Cost of Enteral Formula Projected for Study Period**

	2017	2018	2019	2020	2021
Low Scenario	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
Mid Scenario	\$0.02	\$0.02	\$0.02	\$0.03	\$0.03
High Scenario	\$0.06	\$0.06	\$0.07	\$0.07	\$0.07

#### 4.7. Projected fully-insured population in Massachusetts

Table 13 shows the fully-insured population in Massachusetts age 0 to 64 projected for the next five years. The attached appendix describes the sources of these values.

**Table 13:**  
**Projected Fully-Insured Population in Massachusetts, Ages 0-64**

<u>Year</u>	<u>Total (0-64)</u>
2017	2,432,626
2018	2,407,114
2019	2,380,914
2020	2,353,701
2021	2,326,576

## 4.8. Total marginal medical expense

Multiplying the total estimated PMPM cost by the projected fully-insured membership over the analysis period results in the total cost (medical expense) associated with the mandate, shown in Table 14. This analysis assumes the bill, if enacted, would be effective January 1, 2017.<sup>i</sup>

**Table 14:**  
**Estimated Marginal Cost of Enteral Formula Mandate**

	2017	2018	2019	2020	2021
Low Scenario	\$135,581	\$197,757	\$205,581	\$213,799	\$222,747
Mid Scenario	\$411,222	\$599,807	\$623,535	\$648,462	\$675,602
High Scenario	\$1,097,600	\$1,600,953	\$1,664,288	\$1,730,819	\$1,803,260

## 4.9. Carrier retention and increase in premium

Multiplying the total estimated PMPM cost by the projected fully-insured membership over the analysis period yields the total cost, including carrier retention, associated with the mandate, shown in Table 15. This analysis assumes the bill, if enacted, would be effective January 1, 2017.

**Table 15:**  
**Estimate of Increase in Carrier Premium Expense**

	2017	2018	2019	2020	2021
Low Scenario	\$152,306	\$222,152	\$230,941	\$240,173	\$250,225
Mid Scenario	\$461,950	\$673,798	\$700,454	\$728,455	\$758,943
High Scenario	\$1,232,998	\$1,798,444	\$1,869,591	\$1,944,330	\$2,025,707

## 5. Results

The estimated impact of the proposed mandate on medical expense and premiums appears below. The analysis includes development of a best estimate “mid-level” scenario, as well as a low-level scenario using assumptions that produced a lower estimate, and a high-level scenario using more conservative assumptions that produced a higher estimated impact.

The impact on premiums is based primarily on estimates of the number of patients diagnosed with the new diagnoses included in the mandate for whom the use of enteral formulas is medically necessary under three treatment profiles, and whose insurance does not currently cover these diagnoses for enteral nutrition. The three treatment profiles include full nutritional replacement in

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<sup>i</sup> The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2017. The impact of the mandate on cost in 2017 was estimated at 71.3 percent of the annual cost, using an assumed renewal distribution by month, by market segment, and by the Massachusetts market segment composition.

the long-term, non-elective supplemental nutrition in the long term, and full nutritional replacement in the short term.

Starting in 2020, the federal Affordable Care Act will impose an excise tax, commonly known as the “Cadillac Tax”, on expenditures on health insurance premiums and other relevant items (health savings account contributions, etc.) that exceed specified thresholds. To the extent relevant expenditures exceed those thresholds (in 2020), H.B. 3488, by increasing premiums, has the potential of creating liability for additional amounts under the tax. Estimating the amount of potential tax liability requires information on the extent to which premiums, notwithstanding the effect of H.B. 3488, will exceed or approach the thresholds and is beyond the scope of this analysis.

### 5.1. Five-year estimated impact

For each year in the five-year analysis period, Table 16 displays the projected net impact of the mandate on medical expense and premiums using a projection of Massachusetts fully-insured membership. Note that the relevant provisions of H.B. 3488 are assumed effective January 1, 2017.<sup>10</sup>

The low scenario impact is \$233 thousand per year on average, and is due to the lower estimates of the number of patients diagnosed with the newly-included conditions, the number of these who will need enteral formula treatment, the number of cans each will require in a month, a lower cost per can of enteral formula, and a lower number of months of required use in one treatment profile. The high scenario has an average cost of \$1.89 million per year, and reflects higher assumptions for each of these variables. The middle scenario has average annual costs of \$706 thousand, or an average of 0.005 percent of premium.

Finally, the impact of the proposed law on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides, and on how the benefits will change under the mandate.

**Table 16: Summary Results**

	2017	2018	2019	2020	2021	Weighted Average	5 Yr Total
Members (000s)	2,433	2,407	2,381	2,354	2,327		
Medical Expense Low (\$000s)	\$136	\$198	\$206	\$214	\$223	\$207	\$975
Medical Expense Mid (\$000s)	\$411	\$600	\$624	\$648	\$676	\$629	\$2,959
Medical Expense High (\$000s)	\$1,098	\$1,601	\$1,664	\$1,731	\$1,803	\$1,678	\$7,897
Premium Low (\$000s)	\$152	\$222	\$231	\$240	\$250	\$233	\$1,096
Premium Mid (\$000s)	\$462	\$674	\$700	\$728	\$759	\$706	\$3,324
Premium High (\$000s)	\$1,233	\$1,798	\$1,870	\$1,944	\$2,026	\$1,885	\$8,871
PMPM Low	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
PMPM Mid	\$0.02	\$0.02	\$0.02	\$0.03	\$0.03	\$0.02	\$0.02
PMPM High	\$0.06	\$0.06	\$0.07	\$0.07	\$0.07	\$0.07	\$0.07
Estimated Monthly Premium	\$463	\$473	\$483	\$493	\$503	\$483	\$483
Premium % Rise Low	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%
Premium % Rise Mid	0.005%	0.005%	0.005%	0.005%	0.005%	0.005%	0.005%
Premium % Rise High	0.013%	0.013%	0.014%	0.014%	0.014%	0.014%	0.014%

## 5.2. Impact on the GIC

The proposed mandate is assumed to apply to both fully-insured and self-insured plans operated for state and local employees by the GIC, with an effective date for all GIC policies on July 1, 2017.

Because the benefit offerings of GIC plans are similar to those of most other commercial plans in Massachusetts, the estimated PMPM effect of the proposed mandate on GIC medical expense is not expected to differ from that calculated for the other fully-insured plans in Massachusetts. This is consistent with carrier survey responses which, in general, did not indicate differences in coverage for the GIC.

To estimate the medical expense separately for the GIC, the PMPM medical expense for the general fully-insured population was applied to the GIC membership starting in July of 2017.

Table 17 breaks out the GIC-only fully-insured membership and the GIC self-insured membership, and the corresponding incremental medical expense and premium. Note that the total medical expense and premium values for the general fully-insured membership displayed in Table 16 also include the GIC fully-insured membership. Finally, the proposed mandate is assumed to require the GIC to implement the provisions on July 1, 2017; therefore, the results in 2017 are approximately one-half of an annual value.

**Table 17:  
GIC Summary Results**

	2017	2018	2019	2020	2021	Weighted Average	5 Yr Total
<b>GIC Fully-Insured</b>							
Members (000s)	54	54	54	54	54		
Medical Expense Low (\$000s)	\$2	\$4	\$5	\$5	\$5	\$5	\$21
Medical Expense Mid (\$000s)	\$6	\$13	\$14	\$15	\$16	\$14	\$64
Medical Expense High (\$000s)	\$17	\$36	\$38	\$39	\$42	\$38	\$172
Premium Low (\$000s)	\$2	\$5	\$5	\$5	\$6	\$5	\$24
Premium Mid (\$000s)	\$7	\$15	\$16	\$17	\$17	\$16	\$72
Premium High (\$000s)	\$19	\$40	\$42	\$44	\$47	\$43	\$193
<b>GIC Self-Insured</b>							
Members (000s)	270	270	269	268	268		
Medical Expense Low (\$000s)	\$11	\$22	\$23	\$24	\$26	\$24	\$106
Medical Expense Mid (\$000s)	\$32	\$67	\$70	\$74	\$78	\$71	\$321
Medical Expense High (\$000s)	\$85	\$179	\$188	\$197	\$208	\$191	\$858

## Appendix: Membership Affected by the Proposed Mandate

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance issued by a Massachusetts-licensed company (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and, in some cases, lives covered by GIC self-insured coverage. Membership projections for 2017 to 2021 are derived from the following sources.

Total Massachusetts population estimates for 2013, 2014, and 2015 from U. S. Census Bureau data<sup>11</sup> form the base for the projections. Distributions by gender and age, also from the Census Bureau,<sup>12</sup> were applied to these totals. Projected growth rates for each gender/age category were estimated from Census Bureau population projections to 2030.<sup>13</sup> The resulting growth rates were then applied to the base amounts to project the total Massachusetts population for 2017 to 2021.

The number of Massachusetts residents with employer-sponsored or individual (direct) health insurance coverage was estimated using Census Bureau data on health insurance coverage status and type of coverage<sup>14</sup> applied to the population projections.

To estimate the number of Massachusetts residents with fully-insured employer-sponsored coverage, projected estimates of the percentage of employer-based coverage that is fully-insured were developed using historical data from the Medical Expenditure Panel Survey Insurance Component Tables.<sup>15</sup>

To estimate the number of non-residents covered by a Massachusetts policy – typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage – the number of lives with fully-insured employer-sponsored coverage was increased by the ratio of the total number of individual tax returns filed in Massachusetts by residents<sup>16</sup> and non-residents<sup>17</sup> to the total number of individual tax returns filed in Massachusetts by residents.

Projections for the GIC self-insured lives were developed using GIC base data for 2013,<sup>18</sup> 2014,<sup>19</sup> and 2015,<sup>20</sup> and the same projected growth rates from the Census Bureau that were used for the Massachusetts population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

## Endnotes

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- <sup>1</sup> The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill 3488, “An Act providing for certain health insurance coverage.” Accessed 26 April 2016: <https://malegislature.gov/Bills/189/House/H3488>.
- <sup>2</sup> M.G.L. c.32A §17A, c.175 §47I, c.176A §8L, c.176B §4K, c.176G §4D.
- <sup>3</sup> M.G.L. c.32A §17A, c.175 §47I, c.176A §8L, c.176B §4K, c.176G §4D.
- <sup>4</sup> M.G.L. c.32A §17A, c.175 §47I, c.176A §8L, c.176B §4K, c.176G §4D.
- <sup>5</sup> M.G.L. c.175 §47C, c.176A §8B, c.176B §4C, c.176G §4.
- <sup>6</sup> Elizabeth Hait, MD, MPH. Attending physician; Co-Medical Director, Eosinophilic Gastrointestinal Disease (EGID) Program, Boston Children’s Hospital. Assistant Professor of Pediatrics, Harvard Medical School.
- <sup>7</sup> Hruz P. Epidemiology of eosinophilic esophagitis. *Dig Dis.* 2014;32(1-2):40-7. Accessed 27 April 2016: <http://www.ncbi.nlm.nih.gov/pubmed/24603379>.
- <sup>8</sup> Centers for Medicare and Medicaid Services (CMS), Office of the Actuary. National Health Expenditure Data, NHE Projections 2014-2024 - Forecast Summary. Accessed 27 April 2016: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>.
- <sup>9</sup> Massachusetts Center for Health Information and Analysis. Annual Report on the Massachusetts Health Care System, September 2015. Accessed 19 January 2016: <http://www.chiamass.gov/annual-report>.
- <sup>10</sup> *Ibid.*
- <sup>11</sup> U.S. Census Bureau. Annual Estimates of the Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2015. Accessed 28 April 2016: <http://www.census.gov/popest/data/state/totals/2015/index.html>.
- <sup>12</sup> U.S. Census Bureau. PEPYASEX-Geography-Massachusetts: Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States, States, and Puerto Rico Commonwealth: April 1, 2010 to July 1, 2014 Accessed 28 April 2016: <http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>.
- <sup>13</sup> U.S. Census Bureau. File 4. Interim State Projections of Population by Single Year of Age by Sex: July 1, 2004 to 2030, U.S. Census Bureau, Population Division, Interim State Population Projections, 2005. Accessed 28 April 2016: <http://www.census.gov/population/projections/data/state/projectionsagesex.html>.
- <sup>14</sup> U.S. Census Bureau. Table HIB-4. Health Insurance Coverage Status and Type of Coverage by State All Persons: 1999 to 2014. Accessed 28 April 2016: <http://www.census.gov/hhes/www/hlthins/data/incpovhlth/2014/acs-tables.html>. Where source i and iv are slightly different projections, we use iv because the sampling is more current. Sampling methods and margin for error described at the link: [http://www2.census.gov/programs-surveys/acs/tech\\_docs/accuracy/ACS\\_Accuracy\\_of\\_Data\\_2014.pdf](http://www2.census.gov/programs-surveys/acs/tech_docs/accuracy/ACS_Accuracy_of_Data_2014.pdf).
- <sup>15</sup> Agency for Healthcare Research and Quality. Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and State (Table II.B.2.b.1), years 1996-2012: 1996 (Revised March 2000), 1997 (March 2000), 1998 (August 2000), 1999 (August 2001), 2000 (August 2002), 2001 (August 2003), 2002 (July 2004), 2003 (July 2005), 2004 (July 2006), 2005 (July 2007), 2006 (July 2008), 2008 (July 2009), 2009 (July 2010), 2010 (July 2011), 2011 (July 2012), 2012 (July 2013), 2013(July 2014), 2014(July 2015). Medical Expenditure Panel Survey Insurance Component Tables. Generated using MEPSnet/IC. Accessed 25 January 2016: [http://meps.ahrq.gov/mepsweb/data\\_stats/state\\_tables.jsp?regionid=18&year=2014](http://meps.ahrq.gov/mepsweb/data_stats/state_tables.jsp?regionid=18&year=2014).
- <sup>16</sup> IRS. Table 2. Individual Income and Tax Data, by State and Size of Adjusted Gross Income, Tax Year 2010. Accessed 6 March 2014: <https://www.irs.gov/uac/SOI-Tax-Stats-Historic-Table-2>.
- <sup>17</sup> Massachusetts Department of Revenue. Massachusetts Nonresident Personal Income Tax after Credit by State for Tax Year 2010. Accessed 23 January 2014: <http://www.mass.gov/dor/tax-professionals/news-and-reports/statistical-reports/>.

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<sup>18</sup> Group Insurance Commission. GIC Health Plan Membership by Insured Status FY2013. Accessed 28 March 2016: <http://www.mass.gov/anf/docs/gic/annual-report/annualreportfy2013.pdf>.

<sup>19</sup> Group Insurance Commission. GIC Health Plan Membership by Insured Status FY2014. Accessed 28 March 2016: <http://www.mass.gov/anf/docs/gic/annual-report/fy2014annual-report.pdf>.

<sup>20</sup> Group Insurance Commission, Group Insurance Commission Fiscal Year 2015 Annual Report. Accessed 25 January 2016: <http://www.mass.gov/anf/docs/gic/annual-report/gic-annual-reportfy15.pdf>.