STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

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| HEALTH OPTIONS, INC., | ) | |
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| Petitioner, | ) | |
| | ) | |
| vs. | ) | Case No. 06-1183 |
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| OFFICE OF INSURANCE REGULATION, | ) | |
| | ) | |
| Respondent. | ) | |
| | ) | |

## FINAL ORDER

This case is before Administrative Law Judge T. Kent Wetherell, II, on a stipulated record pursuant to the agreement of the parties. Closing arguments were heard by telephone on August 8, 2006.

## APPEARANCES

For Petitioner: Daniel Alter, Esquire
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For Respondent: Paul A. Norman, Esquire
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## STATEMENT OF THE ISSUE

The issue is whether Petitioner is required to provide coverage for the gastric electrical stimulation device requested by subscriber B.N.[1]

## PRELIMINARY STATEMENT

By letter dated January 27, 2006, the Office of Insurance Regulation (Office) approved the recommendation of the Subscriber Assistance Panel and directed Petitioner, Health Options, Inc. (HOI), to "authorize coverage for the Subscriber's Medtronic Enterra Therapy System." HOI timely filed a petition for hearing, and later an amended petition for hearing, contesting that directive.

On April 5, 2006, the Office referred this case to the Division of Administrative Hearings (DOAH) for the assignment of an Administrative Law Judge to conduct the hearing requested by HOI. The final hearing was scheduled for June 14, 2006.

On June 8, 2006, during the telephonic hearing on a Joint Motion to Continue Final Hearing, the parties agreed that an evidentiary hearing was not necessary and that this case could be decided based upon a stipulated record. See Order Canceling Hearing dated June 8, 2006. A Scheduling Order was issued on June 20, 2006, to establish deadlines for filing the agreed upon components of the stipulated record.

In accordance with the Scheduling Order, on July 10, 2006, the parties filed Joint Exhibits 1 through 27, and on July 28, 2006, the Office filed the deposition Dr. Thomas Abell and HOI filed the deposition of Dr. Paul Hyman. On August 24, 2006, the Office filed a typed errata sheet for Dr. Abell's deposition

because the handwritten errata sheet included in the deposition was illegible. On August 28, 2006, HOI filed two pages that had been inadvertently omitted from Joint Exhibit 1. The stipulated record comprises those materials and the stipulations of fact and law contained in the Amended/Supplemented Joint Pre-hearing Stipulation, filed June 27, 2006.

HOI's motion to exclude a document that the Office intended to offer into evidence was granted through a detailed Order dated July 7, 2006. That document -- a letter from HOI to another subscriber dated November 24, 2003 -- is not part of the stipulated record.

The parties were afforded an opportunity to present closing arguments by telephone on August 8, 2006. The original deadline for the parties' proposed final orders was August 18, 2006, but the deadline was extended to August 25, 2006, at the parties' request. Each party timely filed a "proposed recommended order" even though, as noted in the Order Granting Extension of Time dated August 16, 2006, and as discussed in the Conclusions of Law, DOAH has final order authority in this case. The parties' post-hearing filings and oral arguments have been given due consideration in preparing this Final Order.

All statutory references in this Final Order are to the 2005 version of the Florida Statutes.

## FINDINGS OF FACT

### A. HOI and the HMO Plan

1. HOI is a health maintenance organization (HMO) licensed to do business in Florida.

2. HOI issued a small group HMO contract to Austin Nunez Creative Solutions, Inc., for the benefit of the company's employees and their eligible beneficiaries (hereafter "the HMO Plan").

3. The effective date of the HMO Plan was April 15, 2003.

4. The operative provisions of the HMO Plan are contained in the Certificate of Coverage, which was received into evidence as Joint Exhibit 1.

5. The Certificate of Coverage provides that expenses for health care services will be covered if, among other things not implicated in this case, the services are "Medically Necessary" and "not specifically limited or excluded." One type of service specifically excluded from coverage under the HMO Plan is "Experimental or Investigational services."

6. With respect to medical necessity, the Certificate of Coverage states:

> HOI does not cover or provide benefits for any service which is otherwise covered if, in the opinion of HOI, such service is not Medically Necessary, as defined in the Glossary Section. . . . .

> HOI's Medical Necessity decisions under this Certificate of Coverage are solely for the purpose of coverage or payment. In this respect, HOI may review medical facts in making a coverage or payment decision, however, any and all decisions that require or pertain to independent professional medical judgment or training, or the need for medical services, must be made solely by the Covered Person and the Covered Person's treating Physicians. It is possible that a Covered Person or the Covered Person's treating Physician may conclude that a particular service is beneficial, appropriate, or desirable even though expenses for such services may be denied as not being Medically Necessary.

(Emphasis in original).

7. "Medically Necessary" is defined in the Certificate of Coverage to mean that:

> a medical service or supply is required for the identification, treatment or management of a Condition, and is, in the opinion of HOI:
>
> A. consistent with the symptom, diagnosis, and treatment of the Covered Person's Condition;
>
> B. widely accepted by the practitioners' peer group as efficacious and reasonably safe based upon scientific evidence;
>
> C. universally accepted in clinical use such that omission of the service or supply in these circumstances raises questions regarding the accuracy of diagnosis or the appropriateness of the treatment;
>
> D. not Experimental or Investigational;
>
> E. not for cosmetic purposes;

> F. not primarily for the convenience of the Covered Person, the Covered Person's family, the Physician or other provider; and
>
> G. the most appropriate level of service, care or supply which can be safely provided to the Covered Person. . . . .

(Emphasis supplied).

8. The use of the word "and" to connect the paragraphs in this definition means that a service or supply is medically necessary only if it meets each paragraph. Thus, a service or supply is not medically necessary if any of the paragraphs in the definition are not met.

9. "Experimental or Investigational" is defined in the Certificate of Coverage to mean:

> any evaluation, treatment, therapy, or device . . . if, as determined solely by HOI:
>
> A. such evaluation, treatment, therapy, or device cannot be lawfully marketed without approval of the United States Food and Drug Administration or the Florida Department of Health and approval for marketing has not, in fact, been given at the time such is furnished to the Covered Person;
>
> B. such evaluation, treatment, therapy, or device is provided pursuant to a written protocol which describes as among its objectives the following: determination of safety, efficacy, or efficacy in comparison to the standard evaluation, treatment, therapy, or device;
>
> C. such evaluation, treatment, therapy, or device is delivered or should be

delivered subject to the approval and supervision of an institutional review board or other entity as required and defined by federal regulations;

D. reliable evidence shows that such evaluation, treatment, therapy, or device is the subject of an ongoing Phase I or II clinical investigation, or the experimental or research arm of a Phase III clinical investigation, or under study to determine: maximum tolerated dosage(s), toxicity, safety, efficacy, or efficacy as compared with the standard means for treatment or diagnosis of the Condition in question;

E. reliable evidence shows that the consensus of opinion among experts is that further studies, research, or clinical investigations are necessary to determine: maximum tolerated dosage(s), toxicity, safety, efficacy, or efficacy as compared with the standard means for treatment or diagnosis of the Condition in question;

F. reliable evidence shows that such evaluation, treatment, therapy, or device has not been proven safe and effective for treatment of the Condition in question, as evidenced in the most recently published medical literature in the Untied States, Canada, or Great Britain, using generally accepted scientific, medical, or public health methodologies or statistical practices;

G. there is no consensus among practicing Physicians that the treatment, therapy, or device is safe and effective for the Condition in question; or

H. such evaluation, treatment, therapy, or device is not the standard treatment, therapy, or device utilized by practicing

> Physicians in treating other patients with the same or similar Condition.

(Emphasis supplied).

10. The use of the word “or” to connect the paragraphs in this definition means that a service or supply is considered to be experimental or investigational if any of the paragraphs are met. Thus, the fact that one paragraph is not met does not mean that a service or supply is not considered to be experimental or investigational, if one of the other paragraphs is met.

11. “Reliable evidence,” as used in the definition of “Experimental or Investigational,” is defined in the Certificate of Coverage to mean:

> A. records maintained by physicians or hospitals rendering care or treatment to Covered Person or other patients with the same or similar Condition;
>
> B. reports, articles, or written assessments in authoritative medical and scientific literature published in the United States, Canada, or Great Britain;
>
> C. published reports, articles, or other literature of the United States Department of Health and Human Services or the United States Public Health Service, including any of the National Institutes of Health, or the United States Office of Technology Assessment;
>
> D. the written protocol or protocols relied upon by the treating physician or institution or the protocols of another physician or institution studying substantially the same evaluation, treatment, therapy, or device;

> E. the written informed consent used by the treating physician or institution or by another physician or institution studying the substantially the same evaluation, treatment, therapy, or device; or
>
> F. the records (including any reports) of any institutional review board of any institution which has reviewed the evaluation, treatment therapy, or device for the Condition in question.

12. The Certificate of Coverage also includes this notation following the definitions of "experimental or investigational" and "reliable evidence":

> Services or supplies which are determined by HOI to be Experimental or Investigational are excluded . . . . In making benefit determinations, HOI may also rely on predominant opinion among experts, as expressed in the published authoritative literature, that usage of a particular evaluation, treatment, therapy, or device should be substantially confined to research settings or that further studies are necessary in order to define safety, toxicity, effectiveness, or effectiveness compared with standard alternatives.[2]

## B. The Subscriber

### (1) Generally

13. The subscriber whose treatment is at issue in this case is a 45-year old female who, at all material times, was insured under the HMO Plan.

14. The subscriber is not diabetic.

15. The subscriber has been diagnosed with intestinal dysmotility with gastroparesis, resulting in secondary symptoms of recurrent nausea and vomiting.

16. The subscriber has a history of depression.

17. The subscriber has a history of bulimia, which is an eating disorder. Her medical records include a handwritten notation that the bulimia was present at the time of her divorce and that the condition has been "resolved."[3]

18. The subscriber is obese. She is five feet, two inches tall and, as of March 2006, she weighed 192 pounds.

(2) Pertinent Medical History

19. In January 2005, the subscriber saw her primary care physician, Dr. Christine Norton, complaining of stomach pain, nausea, and vomiting.

20. Dr. Norton referred the subscriber for radiological evaluations of her liver and gallbladder. The results of the evaluations were normal.

21. Dr. Norton also referred the subscriber for an esophagogastroduodenoscopy. The procedure was performed by Dr. Iswari Prasad on February 18, 2005.

22. Dr. Prasad observed a small hiatal hernia in the subscriber's esophagus, and reported an impression of "erosive

antral gastritis." He prescribed Nexium, Zelnorm, Reglan, and herbal preparations.

23. Dr. Prasad referred the subscriber for a gastric emptying study to determine whether she had gastroparesis. A gastric emptying study is the "gold standard" for diagnosing and evaluating that condition.

24. Gastroparesis is a chronic medical condition characterized by a delay in stomach emptying in the absence of a mechanical obstruction. The symptoms of gastroparesis include nausea, vomiting, bloating, and upper abdominal discomfort after eating.

25. Gastroparesis differs from the related condition of dyspepsia in that patients with dyspepsia have bloating or discomfort after eating, but they typically do not have the nausea and vomiting associated with gastroparesis.

26. A gastric emptying study is performed by a nuclear medicine physician using radioactivity to measure how food is emptying from the stomach. The patient eats a meal containing radioactive material, and images are taken as the food passes through the stomach into the digestive system. If more than 10 percent of the material remains in the stomach after a period of four hours, the patient has gastroparesis.

27. The medical literature reflects that a gastric emptying study should be performed over a two to four hour

period. It is possible to make a diagnosis of gastroparesis based upon a study lasting less than two hours, but the shorter the study, the less reliable its results are because of normal variations in gastric emptying.

28. The subscriber's gastric emptying study was performed on March 3, 2005. The study was only 90 minutes in length.

29. The study showed that the subscriber had "74% gastric retention at 90 minutes" and a "calculated T one half of 207 minutes," which resulted in an impression of "delayed gastric emptying."

30. The subscriber next saw Dr. Hasan Hashmi, a board certified colon and rectal surgeon. The subscriber's medical records reflect that Dr. Hashmi surgically removed all or part of the subscriber's colon in 2003 in an effort to address her colonic dysmotility or hypomotility.

31. Dr. Hashmi reviewed the results of the gastric emptying study and referred the subscriber to Dr. Juan Cendan, a surgeon with the Shands Clinic at the University of Florida (Shands).

32. The subscriber met with Dr. Cendan for an initial evaluation on April 27, 2005. Dr. Cenden reviewed the subscriber's medical history and physically examined her at that visit. He prescribed a six-week trial of erythromycin, which is a prokinetic drug intended to promote gastric motility.

33. The subscriber agreed to proceed with the trial of erythromycin, but according to Dr. Cendan's notes, she was "disheartened" by that recommended course of treatment because "she was hoping [Dr. Cendan] could simply put in a gastric pacemaker and fix the problem." Dr. Cendan's notes reflect that he explained to the subscriber that a "gastric pacemaker" was not a "fix for [her] problem" because even though it "allows a significant improvement in gastroparesis symptoms," it "does not cause her stomach to empty any faster."

34. The subscriber returned for a follow-up visit with Dr. Cendan on June 8, 2005. Dr. Cendan's notes from that visit state that the subscriber "has had some improvement in her colonic function with the erythromycin, but continues to have nausea and vomiting, and notes not much change with that since her last visit." Dr. Cendan's notes also state that the subscriber "has had some difficulty with erythromycin from a rash standpoint," but that she was taking another medication to counteract the rash and "that she is doing better with it."

35. Dr. Cendan's notes from the June 8, 2005, visit state that the subscriber was referred to Shands' internal gastroenterology group "for any further recommendations in an effort to avoid surgical intervention." The record does not reflect whether the subscriber ever saw anyone in that group.

36. At the June 8, 2005, visit, the subscriber completed a screening form for “consideration towards a gastric pacemaker placement.” On the screening form, the subscriber indicated a frequency of nausea of seven days per week and a frequency of vomiting of three to four times per week, with no hospitalizations due to her illness in the preceding year.

37. In a letter to HOI dated July 5, 2005, Dr. Cendan requested a predetermination of coverage/prior authorization “for the use of Medtronic Enterra Therapy for Gastroparesis,” and in that letter, he referred to the subscriber as “an excellent candidate for this therapy.” HOI denied coverage, as described below.

38. The subscriber saw Dr. Norton again in April 2006, complaining that her nausea and vomiting were worsening, and that she was suffering from dizziness. Dr. Norton diagnosed these symptoms as side effects of the subscriber’s recurrent nausea and vomiting secondary to gastroparesis.

39. In a letter dated April 17, 2006, Dr. Norton described the subscriber’s symptoms to include “nausea and vomiting daily” and she characterized the Enterra Therapy System recommended by Dr. Cendan as the subscriber’s “last and only option to regain her health."

(3) Denial of Coverage and Internal Review by HOI

40. In a letter to Dr. Cendan dated August 2, 2005, HOI denied coverage of the Medtronic Enterra Therapy System (METS) recommended for the subscriber (hereafter "original denial letter"). The letter explained the basis of the denial as follows:

> The medtronic enterra therapy for gastroparesis meets the definition of Experimental/Investigational as defined in the Member Handbook. Specifically, it meets this definition because the consensus of opinion among experts is that further studies, research, or clinical investigations are necessary to determine its safety, efficacy, or efficacy as compared to standard means for the treatment of the Condition in question.

41. The subscriber "appealed" the denial of coverage to HOI's Internal Review Panel (IRP).

42. The IRP affirmed the denial of coverage in a letter to the subscriber dated September 1, 2005. The basis of the IRP's decision was the same as that set forth in the original denial letter, i.e., the METS is experimental or investigational as defined in the HMO Plan.

43. In making its decision, the IRP received the input of an external medical consultant who was board certified in internal medicine and gastroenterology and who reviewed the subscriber's medical records. The consultant's report noted the limited published studies on the efficacy of the METS,

particularly with respect to idiopathic, non-diabetic patients such as the subscriber.

44. The subscriber requested review of the IRP's decision by HOI's Board of Directors Grievance Committee.

45. In a letter to the subscriber dated September 19, 2005, the Grievance Committee affirmed the denial of coverage for the same reason as set forth in the original denial letter, i.e., the METS is experimental or investigational as defined in the HMO Plan.

46. The Grievance Committee's letter advised the subscriber of her right under Section 408.7056, Florida Statutes, to seek review of the denial of coverage through the Subscriber Assistance Panel (Panel).

(4) Review of the Denial by the Panel and the Office

47. The subscriber timely requested that the Panel review HOI's denial of coverage for the METS recommended by Dr. Cendan.

48. The Panel obtained a medical consultation from Dr. Eugene Trowers at the Florida State University College of Medicine.

49. Dr. Trowers is board certified in internal medicine with a subspecialty in gastroenterology.

50. Dr. Trowers was of the opinion that the METS is not experimental because it has received approval from the U.S. Food and Drug Administration (FDA) under the humanitarian device

exemption. Dr. Trowers did not refer to the definition of "experimental or investigational" in the HMO Plan.

51. The Panel held a hearing on December 19, 2005. The subscriber made a presentation at the hearing, as did a representative of HOI.

52. The Panel issued its proposed recommended order on December 27, 2005, finding in favor of the subscriber and recommending that HOI be ordered to provide coverage for the subscriber's METS.

53. The Office approved the Panel's decision in a letter dated January 27, 2006. The letter stated that "[t]he Office concurs with the Panel's Proposed Recommended Order that the Enterra Therapy system is not 'experimental' and hereby orders [HOI] to authorize coverage for the Subscriber's Medtronic Enterra Therapy System."

54. The letter advised HOI of its right to request a summary hearing to contest the Office's decision pursuant to Sections 120.574 and 408.7056(13), Florida Statutes.

55. HOI timely requested a hearing, which gave rise to this DOAH proceeding.

56. HOI argues that it is not required to provide coverage for the METS requested by the subscriber for two reasons: (1) the device meets the definition of "Experimental or Investigational" in the HMO Plan and, therefore, is specifically

excluded from coverage; and (2) the subscriber is not an appropriate candidate for gastric electrical stimulation based upon her medical history and, therefore, the device is not "Medically Necessary" for the subscriber as that term is defined in the HMO Plan.

57. The first point is the basis upon which coverage was denied in the original denial letter and throughout the review process that culminated in the Panel's recommendation, which was accepted by the Office. The second point was not raised during the review process, but rather was raised for the first time in this DOAH proceeding.

C. Medtronic Enterra Therapy System

(1) Generally

58. The METS is a gastric electrical stimulation device (GESD), and has been described in layman's terms as a "stomach pacemaker."

59. The METS is for use in patients with "chronic intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology."

60. The METS is surgically implanted in the patient and delivers an electrical pulse that stimulates the stomach muscle and/or the enteric nervous system. The surgical procedure was described by Dr. Cendan as follows in his letter requesting pre-authorization coverage for the subscriber's device:

> The [subscriber] will be admitted to the hospital as an inpatient. Hospitalization for the procedure is overnight. The implant procedure takes approximately 1-3 hours and is performed while the [subscriber] is under general anesthesia. Two unipolar intramuscular leads are implanted in the muscle wall of the stomach, about 1.0 cm apart, either via laparotomy or laparoscopic technique. (To reduce the possibility of stomach wall perforation, endoscopy is used interoperatively.) The leads are connected to the neurostimulator, which is placed in a surgically created subcutaneous pocket in the abdomin.

61. Gastric electric stimulation is an emerging therapy for gastroparesis, but as discussed below, its efficacy for treating and managing gastroparesis has not yet been proven.

62. Gastroparesis is typically treated/managed with dietary restrictions, drug therapies, and/or supplemental nutrition through enteral or parenteral feeding. The drug therapies include combinations of prokinetic drugs (such as erthomycin) to promote gastric motility, and antiemetic drugs to alleviate symptoms of nausea and vomiting. The use of a GESD is appropriate only where the patient does not respond to the other treatments.

(2) FDA Approval

63. The METS was approved for use by the FDA in March 2000 as a Humanitarian Use Device (HUD) pursuant to the humanitarian device exemption (HDE) in federal law.

64. A HUD is a device that is intended to benefit patients by treating or diagnosing a condition that affects fewer than 4,000 individuals per year in the United States.

65. The METS may be lawfully marketed in the United States by virtue of its status as an HUD.

66. The METS is the only GESD that has received approval under the HDE and, as a result, it is the only GESD available for use in the United States.

67. FDA approval of a device under the HDE does not require a showing that the device is effective. It only requires a showing that the device is probably effective.

68. A manufacturer that seeks approval of a device under the HDE is not required to present results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. However, the applicant must present sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from use. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that the applicant could not otherwise bring the device to market.

69. The data presented to the FDA to demonstrate the probable effectiveness of the METS was primarily from a 33-patient clinical study referred as the WAVESS Study. The study showed reductions in vomiting episodes for patients using the METS, but the reductions were more significant for diabetic patients than for idiopathic patients.

70. The FDA imposes restrictions on manufacturers whose medical devices are approved under the HDE. For example, the manufacturer must include a label on the device stating that even though the sale/use of the device is authorized by federal law, its effectiveness for a specific indication has not been proven.

71. The label for the METS complies with this requirement, and specifically states that "[t]he effectiveness of this device has not been demonstrated."

72. The use of a HUD is subject to the review and approval of a health care facility's institutional review board (IRB). The IRB is responsible for initial and continuing review of the HUD, and it may approve the use of the device under a protocol or on a case-by-case basis.

73. The FDA does not require informed consent from the patient prior to using a HUD, but each of the university health centers where the parties' testifying experts are affiliated require patients to sign special consent forms. The forms

advise patients that the safety and efficacy of the METS has not been proven, but that it is probably effective and that it has received approval from the FDA under the HDE.

74. The consent form used by the Office's testifying expert witness at the University of Mississippi Medical Center also advises patients that their data will be collected and analyzed "to determine the safety and effectiveness of the device over time." The record does not reflect whether or not Shands, the facility where the subscriber's device will be implanted, uses a consent form with similar language.

(3) Medical Literature

75. The stipulated record includes a number of articles discussing gastric electrical stimulation and the treatment of gastroparesis.[4]

76. The articles are peer-reviewed articles published in authoritative medical journals and meet the definition of "reliable evidence" in the HMO Plan, even though some of the studies discussed in the articles have been criticized for their limitations.[5]

77. Several of the articles conclude that gastric electrical stimulation benefits patients with severe gastroparesis by decreasing vomiting frequency and improving quality of life. However, as discussed below, the articles do not reflect a consensus of opinion that gastric electric

stimulation is a safe and efficacious treatment for gastroparesis, particularly with respect to idiopathic patients such as the subscriber.

78. Many of the articles, including several of those that have favorable conclusions about gastric electrical stimulation, were "sponsored in part" or "supported in part" by Medtronic, Inc., which manufactures the METS. Medtronic has an obvious financial interest in the METS gaining as much legitimacy as possible in the scientific community, and favorable articles in the medical literature is one way for it to do so.

79. The most current article received into evidence is an April 2006 article published in the Journal of Neurogastroenterology and Motility titled "Treatment of Gastroparesis: A Multidisciplinary Clinical Review" (hereafter "the April 2006 article").[6]

80. The April 2006 article is a comprehensive "consensus document" developed by the American Motility Society Task Force on Gastroparesis[7] to "review[] the current treatment options for management of gastroparesis." The article summarizes the research studies on gastroparesis that have been published in the medical literature from 1966 to 2005 in an effort to provide "practical therapeutic guidelines" for treating and managing patients with gastroparesis.

81. The April 2006 article reports that only two multi-center trials have been conducted to evaluate the efficacy of gastric electrical stimulation. Only one of those studies -- the WAVESS Study -- was a "sham-simulation controlled study."

82. The WAVESS Study showed a statistically significant reduction in vomiting when the GESD was on, but it found that "the benefits of treatment were predominately, if not exclusively, experienced by the diabetic group." On this point, the August 2003 article that presented the results of the WAVESS Study stated:

> The symptom improvement observed in this study was more consistent in the diabetic (vs. idiopathic) subgroup. This may be because the idiopathic patients reflect a relatively heterogeneous population when compared with the diabetic patients. More specifically, idiopathic gastroparesis may be related to any of a number of factors, including viral illness, gastroespohageal reflux, nonnuclear dyspepsia, abdominal pain, and depression. Idiopathic patients tend to have a longer symptom duration and poorer quality of life than that seen in other subgroups with gastroparesis, perhaps explaining the more limited improvement we observed with that etiology.[8]

83. After discussing the limited clinical studies that have been performed to date, the April 2006 article concludes that "[w]hile the results of these investigations are encouraging, the clinical benefits of gastric electrical stimulation have not been unequivocally demonstrated . . . ."

84. The April 2006 article also notes that "[t]he mechanism(s) underlying the clinical benefits of the [GESD] are not fully understood." In layman's terms, this means that the researchers do not know why gastric electrical stimulation appears to provide symptom reductions for some patients in the studies.

85. The medical literature suggests that gastric electrical stimulation may provide a "placebo effect" for the patient, which means that the patient feels better simply because he or she has the device and is being closely monitored by physicians. In this regard, one of the articles noted that the placebo effect of the device "could not be ruled out."[9]

86. The April 2006 article states that "[c]andidates for implantation of the [GESD] include patients with chronic diabetic or idiopathic gastroparesis with relentless nausea or vomiting who are not responding to appropriate diet and medication thereapy." The article does not explain what is meant by "relentless" nausea or vomiting.

87. The April 2006 article includes a table listing the "consensus opinions of the authors . . . regarding the organized approach to treating [gastroparesis]." The table includes gastric electrical stimulation as a treatment option, but it is the last option listed in the antiemetic therapy category after various types of drugs.

88. Thus, it appears from the April 2006 article that there is now a consensus of opinion that gastric electric stimulation may be appropriate for certain patients with gastroparesis, but only in the most severe cases. This is a change from November 2004, when it was noted that "[t]here is no consensus regarding management of patients with gastroparesis who do not respond to simple antiemetic or prokinetic therapy or who develop severe medication-induced side effects."[10]

89. There are additional ongoing studies designed to, among other things, confirm the safety and efficacy of the GESD and to help determine which patients are the most appropriate candidates for gastric electrical stimulation.

90. On this point, the American Gastroenterology Association noted in a comprehensive November 2004 technical review article that "[f]urther investigation is needed to confirm the effectiveness of gastric stimulation in long-term blinded fashion, which patients are likely to respond, the optimal electrode position, and the optimal stimulation parameters, none of which have been rigorously evaluated to date."[11] Other articles also recommended further studies and evaluation of the safety, efficacy, and optimal use of gastric electrical stimulation.

(4) Expert Opinions

91. HOI's testifying expert witness, Dr. Paul Hyman, is employed by the University of Kansas Medical Center. He is a professor of pediatrics and the head of pediatric gastroenterology at the university.

92. Dr. Hyman is board certified in pediatrics and pediatric gastroenterology. He is not board certified in gastroenterology or internal medicine.

93. Dr. Hyman has not authored any peer-reviewed articles regarding gastric electrical stimulation; he has not conducted any published clinical trials involving the use of the METS; and he has never performed a gastric emptying study on an adult.

94. Almost all of Dr. Hyman's gastroenterological experience is in the context of pediatric patients, but he testified that he collaborates with Dr. Richard McCallum on a daily basis about difficult adult gastroenterological patients that Dr. McCallum is seeing, including patients for whom "electrical pacing may be the answer to help them." Dr. Hyman described the nature of the collaboration as "very informal, everyday, kind of, back and forth" discussions, and the evidence was not persuasive that Dr. Hyman is responsible for or directly involved in the treatment of such patients.

95. Dr. McCallum is a recognized leader in the field of gastric electrical stimulation. He has implanted 200 to 300

METS, and he has published a number of articles detailing the reductions in nausea and vomiting episodes observed in patients who have received a METS. Dr. Thomas Abell, the Office's testifying expert witness, was a coauthor with Dr. McCallum on several of the articles.

96. Dr. Hyman opined that the subscriber is not an appropriate candidate for a GESD because she had not been properly diagnosed with gastroparesis because her 90-minute gastric emptying study was not long enough to fully assess the extent that her stomach emptied; because an antroduodenal manometry has not been performed to determine whether the subscriber has central nervous system issues rather than digestive system issues; because she has not pursued all possible drug therapies, such as doperidone and metoclopramide (which are prokenetic agents) and a trycyclic antidepressant such as Neurontin (which is an antiemetic agent); and because her history of bulimia excludes her from being a candidate for the METS since an eating disorder is "highly suggestive that there's central nervous system abnormalities" rather than digestive abnormalities.

97. Dr. Hyman also opined that there is not consensus in the medical literature that the METS is an efficacious treatment for idiopathic gastroparesis. In his opinion, the only scientifically valid study was the WAVESS Study and, as noted

above, that study showed no significant reduction in the number of vomiting episodes for idiopathic patients.

98. Dr. Hyman recognized Dr. Abell, the Office's testifying expert witness, as a leader in the field of gastric electrical stimulation who he respects and admires for his intelligence and compassion. He testified that Dr. Abell is the "best person to ask" about certain characteristics of idiopathic patients with gastroparesis.

99. Dr. Abell is employed by the University of Mississippi Medical Center in the internal medicine/digestive disease department.

100. Dr. Abell is board certified in family medicine, internal medicine, and gastroenterology.

101. Dr. Abell is recognized as leader in the field of gastric electrical stimulation. He has authored or coauthored numerous peer-reviewed articles regarding gastroparesis and gastric electrical stimulation, and he has been involved in several clinical trials involving the use of the METS.

102. Dr. Abell and the University of Mississippi Medical Center implant more METS than any other physician/center in the country.

103. Dr. Abell described himself as "a Medtronic guy." He does not own stock in the company, but he does have a contract with the company that has paid him an average of $2,000 per year

for the past 10 years. Medtronic also provided funds to the University of Mississippi Medical Center to sponsor Dr. Abell's work, although he testified that the support provided by the company "doesn't come anywhere close to covering our expenses."

104. Dr. Abell opined that the subscriber is "a good candidate" for the METS. In support of his opinion, Dr. Abell testified that the 74 percent retention reflected in the subscriber's 90-minute gastric emptying study was adequate for him to diagnose the patient with gastroparesis even though he acknowledged that a four-hour test is "helpful and better"; that an antroduodenal manometry would not add anything in the subscriber's case because that test is used when the patient's gastric emptying is close to normal or the patient had nausea but no vomiting, or pain and no nausea or vomiting; and that the subscriber's past history of bulimia and depression does not necessarily exclude her as a candidate for the METS even though those conditions were used as a basis to exclude patients from some of the studies that Dr. Abell conducted.

105. Dr. Abell considers the METS to be "a proven device" and not experimental or investigational. In his opinion, the efficacy of the device has been accepted by the medical community as reflected in the April 2006 article discussed above. Another reason that Dr. Abell does not consider the METS

to be experimental or investigational is that it has been approved by the FDA under the HDE.[12]

D. Ultimate Findings

106. The preponderance of the evidence establishes that the subscriber is an appropriate candidate for the METS. She has been diagnosed with gastroparesis, and efforts to treat/manage her condition with drugs and other therapies have proven to be unsuccessful.

107. Dr. Abell's testimony that the subscriber is "a good candidate" for the device -- and not excluded because of the eating disorder in her past and/or the fact that she had only a 90-minute gastric emptying test -- was consistent with the assessments of the subscriber's treating physicians and is found more persuasive that Dr. Hyman's contrary testimony.

108. In making the foregoing finding, the undersigned took into account the reasons given by Dr. Hyman for his opinion that the subscriber is not an appropriate candidate for the METS as well as Dr. Abell's relationship with Medtronic and its interest in legitimizing the device. The weight given to Dr. Hyman's opinion is tempered significantly by his limited direct personal experience in diagnosing and treating adult patients with gastroparesis. Dr. Abell's relationship with Medtronic affected the weight given to his opinion, but it did not, in the

undersigned's view, undermine his ultimate opinion that the subscriber is "a good candidate" for the device.

109. Thus, contrary to HOI's argument, coverage for the METS recommended for the subscriber may not be denied on the basis that the device does not meet paragraphs A and G of the HMO Plan's definition of "Medically Necessary."[13]

110. However, the preponderance of the evidence establishes that the METS is "experimental or investigational" as that phrase is defined in the HMO Plan.

111. The evidence establishes that, at a minimum, the device falls within paragraphs C, E, and F of the definition of "experimental or investigational" in the HMO Plan because the use of the device is subject to the review and supervision of an IRB; the medical literature reflects a consensus of opinion that further studies are necessary to determine the device's efficacy (as compared to its probable efficacy that was shown to obtain FDA approval under the HDE); and the medical literature does not reflect a consensus of opinion that the device has been proven effective (as compared to probably effective), particularly in idiopathic patients such as the subscriber.

112. Because the METS is "experimental or investigational" as that phrase is defined in the HMO Plan, HOI is not required to provide coverage for the subscriber's device.

## CONCLUSIONS OF LAW

113. DOAH has jurisdiction over the parties to and subject matter of this proceeding pursuant to Section 408.7056, Florida Statutes.

114. This de novo proceeding is subject to the summary hearing procedures in Section 120.574, Florida Statues. See § 408.7056(13), Fla. Stat.

115. The Administrative Law Judge's decision in a proceeding under Section 120.574, Florida Statutes, is final agency action subject to judicial review and, therefore, is in the form of a Final Order rather than a Recommended Order. See § 120.574(2)(f), Fla. Stat.; Health Options, Inc. v. Agency for Health Care Admin., Case No. 02-3762, 2003 Fla. Div. Adm. Hear. LEXIS 299 (DOAH Mar. 3, 2003) (final order issued by Administrative Law Judge in a case arising under Section 408.7056, Florida Statutes); Foundation Health v. Dept. of Insurance, Case No. 00-5007, 2001 Fla. Div. Adm. Hear. LEXIS 2479 (DOAH Feb. 28, 2001) (same).

116. The HMO Plan is an "employee welfare benefit plan" under the Employee Retirement Income Security Act (ERISA), 29 U.S.C. Section 1001, et seq.

117. The rights and obligations of Petitioner and the subscriber under the HMO Plan are governed by the terms of the

plan, as well as all applicable state and federal laws and regulations.

118. When construing an insurance policy such as the HMO Plan, the policy must be read as a whole and each provision must be given its full meaning and operative effect. See Excelsior Ins. Co. v. Pomona Park Bar & Package Store, 369 So. 2d 938, 941 (Fla. 1979).

119. When the language of an insurance policy is clear and unambiguous, it must be interpreted according to its plain meaning, giving effect to the policy as it was written. See Swire Pacific Holdings, Inc. v. Zurich Ins. Co., 845 So. 2d 161, 165 (Fla. 2003). The court may not rewrite the policy, add meaning that is not present, or otherwise reach a result that is contrary to the intention of the parties. Id. (quoting Excelsior, supra).

120. However, if the language of the policy is susceptible to more than one reasonable interpretation, it is ambiguous, and the court will resolve the ambiguity in favor of the insured and against the insurer who drafted the policy. Id.; Auto-Owners Ins. Co. v. Anderson, 756 So. 2d 29, 34 (Fla. 2000).

121. An insurance policy is not automatically rendered ambiguous simply because a provision in the policy is complex and requires analysis for application. See Swire Pacific Holdings, 845 So. 2d at 165.

122. If the insurer fails to define a term in a policy, the insurer cannot take the position that the term should be given a narrow, restrictive interpretation. See State Farm Fire & Casualty Co. v. CTC Development Corp., 720 So. 2d 1072, 1076 (Fla. 1998). However, where, as here, the policy defines an operative term, the term should be construed in accordance with the definition in the policy even if that definition is more narrow than the ordinary understanding or usage of the term.

123. The HMO Plan is not ambiguous with respect to the scope of coverage for medically necessary services or the scope of the exclusion of experimental or investigational services. The HMO Plan defines the operative terms "medically necessary" and "experimental or investigational" with great specificity and even defines some of the terms -- e.g., "reliable evidence" -- used in those definitions.

124. Under ERISA, insured has the burden to prove that she is entitled to the benefits being sought. See Horton v. Reliance Standard Life Ins. Co., 141 F.3d 1038, 1040 (11th Cir. 1998).

125. Similarly, Florida law governing the interpretation of insurance contracts provides that the insured has the initial burden to establish coverage under the policy. See, e.g., East Florida Hauling, Inc. v. Lexington Ins. Co., 913 So. 2d 673, 678 (Fla. 3d DCA 2005).

126. Thus, the Office (on behalf of the subscriber) has the burden to prove by a preponderance of the evidence that the subscriber is an appropriate candidate for the METS based upon her medical history and presentation.

127. The Office met its burden of proof on this issue. See Findings of Fact 106-109.

128. Once the insured establishes that a claim falls within the scope of coverage provided by the policy, the insurer has the burden to prove that the loss arose from a cause that is excepted under the policy. State Farm Mutual Automobile Ins. Co. v. Pridgen, 498 So. 2d 1245, 1248 (Fla. 1986). See also East Florida Hauling, 913 So. 2d at 678 ("Once the insured shows coverage, the burden shifts to the insurer to prove an exclusion applies to the coverage.")

129. Thus, HOI has the burden to prove by a preponderance of the evidence that the METS is excluded from coverage under the terms of the HMO Plan and, specifically, the definition of "experimental or investigational."

130. The definition of "experimental or investigational" in the HMO Plan must be given effect as written even though, as suggested in Dr. Abell's testimony and Dr. Trowers report, the definition in the plan differs from the FDA's usage of the terms experimental and investigational.

131. HOI met its burden of proof on this issue. See Findings of Fact 110-112.

132. Section 408.7056(13), Florida Statutes, provides that "[i]f the managed care entity does not prevail at the hearing, the managed care entity must pay reasonable costs and attorney's fees of the . . . office incurred in that proceeding."

133. There is no corresponding provision requiring the Office to pay the managed care entity's costs and attorney's fees where, as here, the managed care entity prevails at the hearing.

134. Therefore, no costs or attorney's fees are awarded to either party.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that HOI is not required to provide coverage for the gastric electrical stimulation device requested by the subscriber.

DONE AND ORDERED this 11th day of September, 2006, in Tallahassee, Leon County, Florida.

T. KENT WETHERELL, II
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Filed with the Clerk of the
Division of Administrative Hearings
this 11th day of September, 2006.

## ENDNOTES

[1]/ Identifying information about the subscriber was redacted from the medical records and other documents included in the joint exhibits, and she will be referred to only as "the subscriber" in this Final Order. See § 408.7056(14)(a), Fla. Stat.

[2]/ Certificate of Coverage, page 1-7 (supplement to Joint Exhibit 1 filed by HOI on August 28, 2006).

[3]/ Joint Exhibit 2 (second page of Enterra Therapy Screening Form). See also Joint Exhibit 26, at 12 (subscriber's presentation to the Subscriber Assistance Panel that her divorce was "15 years ago," that she went through counseling for her eating disorder, and that it "has been resolved and was resolved many years ago").

[4]/ See Joint Exhibits 3, 19(1)-(5), 25(1)-(9). Each article was reviewed, but particular focus was given to the articles referred to by the parties at oral argument -- e.g., Joint Exhibits 19(3), 19(5), 25(1)-(4), 25(6) and 25(9).

[5]/ See, e.g., Joint Exhibit 19(4), at 13 (raising a number of questions about the "validity and generalizability" of the existing studies, including the WAVESS Study).

[6]/ The article is Exhibit 2 to Dr. Thomas Abell's deposition.

[7]/ The Office's testifying expert, Dr. Thomas Abell was a member of the task force and a coauthor of the article, as was Dr. Richard McCallum, who works with HOI's testifying expert witness at the University of Kansas Medical Center.

[8]/ Joint Exhibit 25(1), at 427.

[9]/ See Joint Exhibit 25(9), at 25. That article, published in January 2006, also stated that "[f]uture well-controlled studies to investigate the efficacy of GES therapy and to clarify the major contributing mechanisms will be important and are currently being conducted." Id.

[10]/ Joint Exhibit 19(3), at 1610.

[11]/ Joint Exhibit 19(3), at 1612.

[12]/ See Dr. Abell's deposition, at 17-18 (explaining his opinion that the METS is not experimental or investigational in relation to the FDA standards related to those terms) and 127 (explaining that "experimental [is] strictly for experiment like one patient which is the FDA definition of the word" and that "[i]nvestigation is something that has an IDE, Investigational Device Exemption").

[13]/ Those paragraphs were the focus of HOI's argument that the subscriber is not an appropriate candidate for the METS. See HOI's Proposed Recommended Order, at ¶ 59.

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## NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original Notice of Appeal with the agency clerk of the Division of Administrative Hearings and a copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.