## Hall of the House of Representatives

88th General Assembly - Regular Session, 2011

Amendment Form

## Amendment No. 1 to House Bill No. 1915

Amend House Bill No. 1915 as originally introduced:

Delete everything after the enacting clause and substitute the following: "SECTION 1. Arkansas Code Title 23, Chapter 99, Subchapter 4 is amended to add an additional section to read as follows:

23-99-418. Gastric pacemakers.

- (a) As used in this section:
  - (1) "Gastric pacemaker" means a medical device that:
- (B) Transmits low-frequency, high-energy electrical stimulation to the stomach to entrain and pace the gastric slow waves to treat gastroparesis; AND
- (2)(A) "Gastroparesis" means a neuromuscular stomach disorder in which food empties from the stomach more slowly than normal.
- (B) In most people, undigested food moves from the stomach into the duodenum and small intestine within two (2) to four (4) hours after eating.
- (C) In contrast, a patients who has gastroparesis will retain a significant amount of food in his or her stomach hours after eating.
- (D) A Patient with gastroparesis experiences a variety of upper gastrointestinal symptoms that prevents him or her from eating normally and that may lead to dehydration, weight loss, and eventually life threatening electrolyte imbalances and malnutrition.
- (E) Moreover, delayed stomach emptying interferes with oral drug absorption and, in patients with diabetes mellitus, prevents effective control of blood glucose levels.
- (F) The Enterra Therapy for gastroparesis received Humanitarian Device Exemption approval from the Food and Drug Administration in March 2000.
- (G) The Humanitarian Device Exemption authorizes Medtronic to market Enterra Therapy for the treatment of chronic intractable, drug-refractory, nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.



- (H) The effectiveness of Enterra Therapy for this use has not been demonstrated.
- (I) Enterra Therapy may be used only in medical centers in which an institutional review board has approved use of the device.
- (J)(i) When the battery in a neurostimulator runs down, the physician will obtain prior authorization from the health insurance company and approval for a replacement surgery and then schedule a procedure.
- (ii) During the surgery, the physician will remove the neurostimulator and implant a new one.
- <u>(iii) The implanted leads will also be checked to make sure they are working properly.</u>
- (iv) If the leads are working properly, the new neurostimulator will be connected to the leads that are already in place.
- (v) If the leads are not working as they should be, they will also be replaced.
- (b) Except as provided under subsection (c) or subsection (d) of this section, a health benefit plan that is issued for delivery, delivered, renewed, or otherwise contracted for in this state shall provide coverage for gastric pacemakers.
- (c) Eligible charges and limits of or exclusions from coverage under subsection (b) of this section shall be based on medical necessity or the health benefit plan's coverage criteria for other medical services.
  - (d) A health benefit plan may:
- (1) Require prior authorization for a gastric pacemaker in the same manner that prior authorization is required for any other covered benefit; and
- (2) Impose copayments, deductibles, or coinsurance amounts for a gastric pacemaker if the amounts are no greater than the copayments, deductibles, or coinsurance amounts that apply to other benefits under the health benefit plan."

The Amendment was read	
By: Representative Tyler	
MGF/CDS - 03/14/11 08:45	
MGF407	Chief Clerk