

Private Letter Ruling No. 09-019 Redacted Version Sales and Use Taxability of an Ingestible Medical Diagnostic Capsule September 14, 2009

This private letter ruling involves the sale and use of an ingestible medical diagnostic capsule. The Department's response is limited to the facts as presented.

Factual Scenario

As part of an endoscopy procedure a physician will furnish an ingestible medical diagnostic capsule (hereinafter referred to as "capsule") to patients for oral ingestion. Physically the capsule resembles a large vitamin capsule. The single-use capsule contains a micro camera, which when ingested travels through the body collecting images and data. The information is then transmitted via sensor arrays secured to the abdomen, to a data recorder affixed to a belt worn around the patient's waist. Once the exam is completed the data is transferred from the recorder belt to a workstation, which is used for reviewing, editing, archiving and e-mailing video images. The 8-hour examination can be conducted while the patient continues normal daily activities. When the exam period expires the patient returns the sensor arrays and the data recorded for processing. A physician then examines the video and data as part of the diagnostic process. The capsules are sold only to physicians, hospitals and other health care facilities. A separate charge is made for the sale of the sensor arrays and the data recorders which can be used multiple times.

Summary of Law

Louisiana Revised Statute 47:305(D)(1)(s) specifically exempts any and all medical devices used exclusively by the patient in the medical treatment of various diseases or administered exclusively to the patient by a physician, nurse, or other health care professional or health care facility in the medical treatment of various diseases under the supervision of and prescribed by a licensed physician from state sales and use tax for tangible personal property sold at retail, distributed, storage to be used or consumed in Louisiana.

Louisiana Revised Statute 47:305(D)(5)(b) provides a sales tax exemption for the administration of prescription drugs used exclusively by the patient in the medical treatment of various diseases or injuries when administered exclusively to the patient by a physician, nurse, or other health care professional in a physician's office where patients are not regularly kept as bed patients for twenty-four hours or more because it constitutes a professional service.

Requested Ruling

Is the sale of the capsule subject to Louisiana sales and use tax?

Analysis

Company A created capsule A and capsule B, which are the size of a vitamin and provide physicians with pictures of the esophagus and small intestine. The single use plastic capsule contains a tiny camera and a light source. The patient swallows the capsule with a glass of water. Capsule A is designed specifically to help physicians see inside the patient's small intestine to

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diagnose disorders such as Crohn's disease, Celiac disease, benign and cancerous tumors, ulcerative colitis as well as others disorders. Capsule A transmits images at a rate of two images per second for approximately eight hours, resulting in more than 50,000 images. Capsule B is designed specifically to help physicians see inside the patient's esophagus to diagnose diseases such as esophageal varices, which may result in fatal bleeding, gastrointestinal reflux disease (GERD) and Barrett's esophagus, which is an early indication for esophageal cancer. Capsule B provides a patient-friendly alternative to esophageal endoscopy and the associated sedation and discomfort. Capsule B contains an imaging device and light source at both ends of the capsule and takes up to 14 images per second or a total of 2,600 color images as it passes down the esophagus. As the capsule moves through the body, the camera takes pictures. The images from Capsule A or Capsule B are transmitted to a data recorder about the size of a Walkman attached to a padded waist belt that is worn by the patient. Several electronic leads are attached to the patient's torso and capture the images transmitted from the camera. The patient wears the belt for about eight hours. After the belt is removed, the physician downloads the images from the data recorder to the workstation for review and diagnosis. The software installed on the workstation contains an image atlas to help facilitate the analysis. Both capsules leave the body naturally.

To be exempt under La. R.S. 47:305(D)(1)(s) as a medical device, the following criteria must be met:

- 1. The capsules are prescribed by a physician;
- 2. The capsules are administered by a health care professional to a patient;
- 3. The capsules are for the exclusive use of one patient; and
- 4. The capsules are used to treat various diseases.

Based on the facts as presented, the capsules qualify for the medical device exemption and are not subject to sales and use tax. In addition, the capsules may also qualify as part of a professional service if the following criteria are met:

- 1. The capsules are prescribed by a physician;
- 2. The capsules are administered by a health care professional to a patient;
- 3. The capsules are for the exclusive use of one patient;
- 4. The capsules are used to treat various diseases; and
- 5. The capsules are sold to a physician's office where patients are not regularly kept as bed patients for twenty-four hours or more.

If the capsules are sold to a physician's office or health care facility where patients are not regularly kept as bed patients for twenty-four hours or more, the capsules are administered as part of a professional service, as set forth in La. R.S. 47:305(D)(5)(b), and not subject to sales and use tax. It is important to note that sales of the capsules to hospitals qualify as an exempt medical device under La. R.S. 47:305(D)(1)(s) while sales of the capsules to doctor's offices, outpatient clinics and other health care facilities where patients are not regularly kept as bed patients for twenty-four hours or more qualify as a medical device and as part of a professional service under La. R.S. 47:305(D)(5)(b).

Ruling

Assuming the facts as stated by Company A are accurate, based on La. R.S. 47:305(D)(1)(s) the nature and use of Capsule A and Capsule B qualify as exempt medical devices. In addition to the medical device exemption, Capsule A and Capsule B sales will qualify under La. R.S. 47:305(D)(5)(b), as part of a professional service, if the capsules are sold to facilities where patients are not regularly kept as bed patients for twenty-four hours or more. Therefore, no Louisiana sales and use tax is due when Capsule A and Capsule B are sold to physicians, hospitals and other health care facilities for the diagnosis of human beings.

If you have any questions or need additional information, please contact Michael Pearson, Director, or Raymond Tangney, Senior Policy Consultant, or Shanda J. McClain, Attorney, Policy Services Division, at (225) 219-2780.

Sincerely,

Cynthia Bridges Secretary

By: Shanda J. McClain Attorney Policy Services Division