

**TENNESSEE DEPARTMENT OF REVENUE
LETTER RULING # 01-10**

WARNING

Letter rulings are binding on the Department only with respect to the individual taxpayer being addressed in the ruling. This presentation of the ruling in a redacted form is informational only. Rulings are made in response to particular facts presented and are not intended necessarily as statements of Department policy.

SUBJECT

Application of Tennessee sales and use tax to the use of certain medical solutions by a healthcare service provider.

SCOPE

This letter ruling is an interpretation and application of the tax law as it relates to a specific set of existing facts furnished to the department by the taxpayer. The rulings herein are binding upon the Department and are applicable only to the individual taxpayer being addressed.

This letter ruling may be revoked or modified by the Commissioner at any time.

Such revocation or modification shall be effective retroactively unless the following conditions are met, in which case the revocation shall be prospective only:

- (A) The taxpayer must not have misstated or omitted material facts involved in the transaction;
- (B) Facts that develop later must not be materially different from the facts upon which the ruling was based;
- (C) The applicable law must not have been changed or amended;
- (D) The ruling must have been issued originally with respect to a prospective or proposed transaction; and
- (E) The taxpayer directly involved must have acted in good faith in relying upon the ruling; and a retroactive revocation of the ruling must inure to the taxpayer's detriment.

FACTS

[THE TAXPAYER] and its subsidiaries (all of whom are referred to hereinafter, in the singular, as "the Taxpayer") is a healthcare service provider owning and operating hospitals and related medical facilities [IN TENNESSEE AND ELSEWHERE]. The Taxpayer owns numerous facilities in Tennessee. The Taxpayer asks how the Tennessee sales and use tax laws apply to its use of irrigation solutions, IV solutions (i.e., solutions

administered to the patient by means of injection into the veins) and sterile water in the treatment of patients.

All the solutions used by the Taxpayer are administered to patients pursuant to an order or prescription of a Tennessee licensed physician. They are issued by a licensed pharmacist through Taxpayer's pharmacy or the pharmacy of a particular hospital or medical facility operated by the Taxpayer.

The prescribing physician may issue two types of prescription orders. One order is patient specific and states the detailed manner in which a procedure is to be completed.

The other order is also patient specific but is a written "standard of practice" order which is written by the departmental chief of staff (a licensed physician). These "standard of practice" orders are guidelines which must be followed by all medical staff. The "standard of practice" orders specify the type and amount of solution which should be utilized in each procedure. These standing orders eliminate the necessity for the attending physician to issue a detailed order each time a standard procedure is prescribed for a specific patient.

For example, a physician issuing a "standard of practice" order might prescribe sterile water in the cleaning of an open wound. Instead of the physician detailing every step of the procedure in a written order, the physician will merely list the procedure to be performed. The medical personnel would then turn to the "standard of practice" orders written by the departmental chief of staff for the detailed orders of the procedure.

All of the irrigation solutions and IV solutions and the majority of the sterile water administered by the Taxpayer are included in the National Drug Code (NDC) Directory and carry an NDC number. The NDC number is issued by the Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services.

The FDA is a public health agency charged with protecting American consumers by enforcing the Federal Food, Drug and Cosmetic Act. The FDA is the regulatory authority that determines the manner in which a drug can be sold without violating federal law.

Within the FDA is the Center for Drug Evaluation and Research (CDER). The CDER's function is to evaluate and regulate drugs and drug products before they can be sold. The CDER has oversight responsibility for all prescription, over-the-counter and generic drugs.

The CDER also issues an Electronic Orange Book that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug and Cosmetic Act. The Orange Book includes a list of prescription drugs with therapeutic equivalence evaluations and can be accessed electronically over the internet at <http://www.fda.gov/cder/ob/default.htm>.

All of the irrigation solutions and IV solutions and the majority of the sterile water administered by the Taxpayer carry a federal warning prohibiting the dispensing of the product without a prescription.

The Taxpayer's irrigation solutions are predominantly used for either urology procedures where they are instilled into the bladder as part of a surgical procedure or for the cleansing or debridement of a patient's wound. The pharmacist will add an antibiotic or other medication to the irrigation solution prior to delivering it to the medical professional administering the solution to the patient. The Taxpayer does not administer irrigation solutions to a patient unless it is medically necessary.

The Taxpayer's IV solutions are typically used to re-hydrate patients (i.e., replace missing body fluids) and are also used in combination with other drugs or combined with blood products. Taxpayer's IV solutions are not injected into a patient if it is not medically necessary.

The Taxpayer's sterile water solutions are predominantly used for the re-constituting of antibiotics and the treatment of urinary illness. Sterile water is combined with antibiotics in a powder state to produce a liquid form of the drug. It is also administered to the patient to flush out the urinary tract and for the treatment of wounds. Sterile water is differentiated from other types of water in that it must meet strict guidelines from the FDA. Not only is the water sterile but it is also de-ionized. The Taxpayer administers sterile water to a patient only when it is medically necessary.

QUESTIONS

1. Is the use of irrigation solutions, IV solutions and sterile water in Tennessee subject to the Tennessee Sales & Use Tax?
2. Does the Taxpayer's particular usage of irrigation solutions, IV solutions and sterile water qualify for tax exemption under Tennessee Code Annotated Section 67-6-320?

RULINGS

1. Yes, unless the particular solution used qualifies for exemption as otherwise provided by law.
2. Provided that a particular solution used by the Taxpayer is listed in the Electronic Orange Book, its use should qualify for the tax exemption afforded by T.C.A. Section 67-6-320(b).

ANALYSIS

1. Under the Retailers' Sales Tax Act, T.C.A. Section 67-6-101 et. seq., the legislature has declared it a taxable privilege for a person to use or consume in this state any item or article of tangible personal property as defined in Chapter 6 of Title 67 of the

Tennessee Code. T.C.A. Section 67-6-201(b). A tax is levied on the cost price of each item or article of tangible personal property when the same is not sold but is used, consumed, distributed, or stored for use or consumption in this state. T.C.A Section 67-6-203(a).

"Tangible personal property" means and includes personal property, which may be seen, weighed, measure, felt or touched, or is any manner perceptible to the senses . . ." T.C.A Section 67-6-203(a). Since the irrigation solutions, IV solutions and sterile water used by the Taxpayer in its provision of healthcare services can each be seen, weighed, measured, felt and touched, and are fully perceptible to the senses, they each constitute tangible personal property subject to tax to the extent they are used or consumed by the Taxpayer in Tennessee.

2. However, T.C.A. Section 67-6-320 provides a tax exemption in the case of certain drugs or medicines. The statute provides, in part, as follows:

(a) There is exempt from the tax imposed by this chapter any prescription drug or medicine issued by a licensed pharmacist in accordance with an individual prescription written for the use of a human being by a practitioner of the healing arts licensed by the state of Tennessee.

(b) There is also exempt from the tax imposed by this chapter any prescribed drug or medicine sold to a practitioner of the healing arts licensed by the state of Tennessee or issued by a licensed pharmacist for use in the treatment of a human being.

While irrigation solutions, IV solutions and sterile water each generally seem to be products conducive to the healing process and medical treatment and procedures, they would not commonly be considered drugs or medicines in their own right, even if prescribed by a physician.

Therefore, in determining the applicability of exemption to these medical solutions under T.C.A. Section 67-6-320, the first line of inquiry is to establish whether they are drugs or medicines under applicable Tennessee law.

T.C.A. Section 67-6-320 does not specifically define "drug" or "medicine". Neither are these terms defined anywhere in the sales & use tax laws compiled in Chapter 6 of Title 67 of the Tennessee Code.

However, Tennessee Code Annotated Section 63-10-404(14) defines "drug" to mean "(A) Articles recognized as drugs or drug products in any official compendium or supplement thereto . . ."

Both the NDC Directory and the Electronic Orange Book may be considered official compendiums under this definition. However, only the Electronic Orange Book actually identifies items listed as drugs or drug products.¹

Therefore, if a particular irrigation solution, IV solution or sterile water product of the Taxpayer is listed in the Electronic Orange Book, it may be considered a drug for purposes of the prescription drug tax exemption statute, T.C.A. Section 67-6-320.

Subsection (b) of the statute provides that the tax exemption applies to ". . . any **prescribed** drug or medicine . . ." (Emphasis added.) In the facts presented, since the solutions at issue are each administered pursuant to an order or prescription of a Tennessee licensed physician, the solutions are obviously "prescribed" by a physician and, thus, fulfill that requirement of the exemption.

Subsection (b) also provides that a prescribed drug, in order to be exempt under the law, must be ". . . **issued by a licensed pharmacist for use in the treatment of a human being.**" (Emphasis added.) The facts are that a licensed pharmacist issues each medical solution subsequently administered by the Taxpayer to its patients. Additionally, since in each case, the use of the solution in question is administered only when determined to be medically necessary by a Tennessee licensed physician, it can readily be concluded that the solutions are used in the treatment of human beings.

Therefore, provided that a particular irrigation solution, IV solution or sterile water product of the Taxpayer is listed in the Electronic Orange Book, it would qualify for the sales & use tax exemption under T.C.A. Section 67-6-320(b).²

Thomas R. Bain
Tax Counsel

APPROVED: Ruth E. Johnson
Commissioner

DATE: 5-2-01

¹The NDC Directory listing, and the award of an NDC number, does not constitute recognition of the products listed and numbered as drugs or drug products.

The NDC Number on a product identifies the labeler/vendor, the product and the trade package size. The NDC System was originally established as an essential part of an out-of-hospital drug reimbursement program under Medicare. Currently, all drug establishments, foreign and domestic, must list all their drug products in commercial distribution in the United States. However, registration of a drug establishment, or assignment of an NDC Number, does not in any way denote approval of the firm or its product.

Therefore, even though the presence of an NDC Number on a particular product, such as one of the solutions in question, indicates some FDA recognition of the product, it does not indicate the FDA has recognized the product as a "drug or drug product" in its compendium (or directory).

² The general facts the Taxpayer has already presented (and additional fact the Taxpayer might be capable of presenting regarding a particular solution) may well support a finding of exemption based on subsection (a) of T.C.A. Section 67-6-320 (applicable to any "prescription drug or medicine").

However, the Department reserves judgment on those matters since the ruling above is in favor of the exemption.