

SC PRIVATE REVENUE OPINION #01-4

SUBJECT: Enteral Nutrition Formulas, Total Parenteral Nutritional Solutions, and Disposable Medical Supplies
(Sales and Use Tax)

EFFECTIVE DATE: Applies to all open periods under the statute, except that the sales of items exempt from the tax under Code Section 12-36-2120(28)(c) are exempt only with respect to sales made on or after August 17, 2000.

REFERENCES: S. C. Code Ann. Section 12-36-2120(28) (2000)
S. C. Regulation 117-174.257
S. C. Regulation 99-2

AUTHORITY: S. C. Code Ann. Section 12-4-320 (2000)
S. C. Code Ann. Section 1-23-10(4) (2000)
SC Revenue Procedure #99-4

SCOPE: A Private Revenue Opinion is a written statement issued to a specific taxpayer by the Department to apply principles of law to a specific set of facts or a particular tax situation. A Private Revenue Opinion does not have the force or effect of law, and is not binding on the person who requested it or the public. It is, however, the Department's opinion limited to the specific facts set forth, and is binding on agency personnel only with respect to the person to whom it was issued and only until superseded or modified by a change in statute, regulation, court decision, or advisory opinion, providing the representations made in the request reflect an accurate statement of the material facts and the transaction was carried out as proposed.

Questions:

1. Are sales of enteral nutrition formulas by XYZ to individuals exempt from the sales and use?
2. Are sales of total parenteral nutrition ("TPN") solutions by XYZ to individuals exempt from the sales and use?
3. Are sales of enteral supplies, such as bags, tubing, feeding tubes and syringes, by XYZ to individuals exempt from the sales and use?
4. Are sales of total parenteral nutrition supplies, such as bags, tubing, and syringes, by XYZ to individuals exempt from the sales and use?

Conclusions:

1. It is the opinion of the department that sales of enteral nutrition formulas by XYZ to individuals are exempt from the sales and use tax under Code Section 12-36-2120(28)(a) as medicines sold by prescription only if the enteral nutrition formula is of a type that, under the law, requires a prescription to be sold to the patient. Sales of enteral nutrition formulas that do not require a prescription to be sold to the patient are subject to the sales and use tax.
2. It is the opinion of the department that sales of total parenteral nutrition (“TPN”) solutions by XYZ to individuals are exempt from the sales and use tax under Code Section 12-36-2120(28)(a) as medicines sold by prescription since federal law requires that total parenteral nutrition (“TPN”) solutions be sold by prescription when sold to the patient.
3. It is the opinion of the department that sales of enteral nutrition supplies, such as bags, tubing, feeding tubes and syringes, by XYZ to individuals are not exempt from the sales and use tax under Code Section 12-36-2120(28)(c) since such supplies are not used for the intravenous administration of enteral nutritional formulas.
4. It is the opinion of the department that sales of total parenteral nutrition (TPN) supplies, such as bags, tubing, feeding tubes and syringes, by XYZ to individuals are exempt from the sales and use tax under Code Section 12-36-2120(28)(c) since such supplies (1) are dispensed by a licensed pharmacist in accordance with an individual prescription written for the use of a human being by a licensed health care provider; (2) are used for the intravenous administration of a prescription (required under federal law) drug or medicine; (3) come into direct contact with the prescription drug or medicine; and (4) are used in the treatment of a patient outside of a hospital, skilled nursing facility, or ambulatory surgical treatment center.

Note: The exemption for medical supplies under Code Section 12-36-2120(28)(c) only applies to “disposable” medical supplies sold on or after August 17, 2000 and does not apply to items that are reusable such as electronic pumps and other medical equipment. In addition, the exemption does not apply to supplies, such as gauze, that do not require a prescription to be sold to the patient.

Facts:

XYZ is a publicly traded company engaged in the home health care business from locations throughout the United States. XYZ has two primary lines of business: (1) sales of drug infusion therapies and (2) sales and rentals of medical devices, medical equipment and disposable medical supplies.

XYZ’s infusion drug therapies are provided to patients pursuant to a doctor’s prescription. All drugs and supplies related to the infusion therapies are dispensed by a registered pharmacist and typically delivered by XYZ to the patient’s home using company owned trucks. XYZ employs registered nurses that train the patient or caregiver and monitor the patient’s progress. Depending on the type of therapy prescribed (e.g., chemotherapy, antibiotic, enteral, and TPN) a registered nurse may visit the patient’s home to assist in actual administration of the therapy.

XYZ's medical device and equipment products as well as the disposable supply items are sold and rented to individuals pursuant to a doctor's prescription.

XYZ generally receives payment from Medicare, Medicaid and private insurance companies for sales and rentals made to patients. As a requirement of reimbursement, the drugs, medical equipment and devices, and supplies sold and rented by XYZ to its patients must be prescribed by a physician.

The following is a brief description of the items in question:

Enteral Nutrition Formulas:

Enteral therapy is prescribed for patients who due to illness or disease are unable to consume food products orally. The formula prescribed is selected by the physician based on the caloric and metabolic needs of the individual patient. The formula may include specific nutrients to treat specific metabolic disorders such as sodium imbalances and protein needs. Most enteral formulas do not require a prescription to be sold to a patient. However, some, by law, do require a doctor's prescription to be sold to a patient.

Enteral Supplies Including Bags, Tubing, Feeding Tubes and Syringes:

Enteral therapy provided by XYZ is typically administered by one of two methods: (1) a gravity fed bag and tubing connected to a feeding tube inserted in the patient or (2) an electronic pump which also requires bags and tubing and connects to a feeding tube or catheter inserted in the patient.

The enteral supplies all come in direct contact with the enteral formula. Pursuant to requirements established by the Food and Drug Administration, these bags, tubes, feeding tubes, and syringes may only be sold by prescription.

Total Parenteral Nutrition (TPN) Solutions:

TPN Therapy is prescribed for patients who due to illness or disease have non-functioning gastrointestinal tracts. TPN is an intravenous solution which includes glucose, amino acids, vitamins, minerals and lipids. TPN is administered intravenously to patients. During the compounding process (preparation of the prescribed solution by a pharmacist), additional legend drugs (i.e., antibiotics) may be incorporated into the solution for intravenous administration.

TPN may be dispensed only pursuant to a doctor's prescription and each dose is specifically compounded for the individual patient based on the patient's nutritional and medical needs.

TPN Supplies Including Bags, Tubes and Syringes:

TPN Therapies are all administered intravenously and generally require the use of an infusion pump. In addition, TPN patients require the use of disposable supplies such as

tubes, needles, drug cartridges and syringes. All of the TPN supplies come in direct contact with the prescribed TPN solution. Pursuant to requirements established by the Food and Drug Administration, these bags, tubes, and syringes may only be sold by prescription.

Discussion:

Medicines:

Code Section 12-36-2120(28)(a) exempts from the sales and use tax the gross proceeds of sales, or sales price, of:

(28)(a) medicine and prosthetic devices sold by prescription,

SC Regulation 117-174.257 defines “medicine” as a “substance or preparation used in treating disease.”

The State Board of Pharmacy Regulation 99-2, Subsection C, defines the terms "drug" and "medicine" to mean:

- (1) Articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, the official National Formulary, or any supplement to any of them; and
- (2) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; and
- (3) Articles (other than food) intended to affect the structure of any function of the body of man or other animal; and
- (4) Articles intended for use as a component of any article specified in C(1), C(2), or C(3) of this Regulation; but does not include devices or their components, parts, or accessories.

Subsection E of that same regulation defines the term "prescription" as:

- (1) Prescription means a lawful order of a practitioner permitted to prescribe, for a drug or device for a specific patient, issued for a legitimate medical purpose within the prescriber's course of legitimate professional practice and issued in the following manner:
 - (a) An oral order given individually for the person for whom prescribed, directly from the prescriber or the prescriber's authorized agent to the pharmacist or the pharmacist's authorized agent, which shall bear the name of the patient; name, strength, and quantity of the drug or device prescribed; directions for use; date of issue; name of the prescriber; and, if a controlled substance is prescribed, the prescriber's Federal registration number; or

(b) A written order signed by the prescriber, which shall bear the name of the patient; name, strength, and quantity of the drug or device prescribed; directions for use; date of issue; and, either rubber stamped, typed, printed by hand, or typeset, the name, address, telephone number and degree classification of the prescriber, and, if a controlled substance is prescribed, the prescriber's Federal registration number.

(c) A written order for noncontrolled substances only may be transmitted by facsimile machine directly from the prescriber or the prescriber's authorized agent to a facsimile machine physically located within the prescription department of a pharmacy. The original prescription and the facsimile must contain the name of the pharmacy to which the facsimile is being transmitted, the name or initials of the person who is actually transmitting the prescription, and the date of transmission. Prescriptions transmitted via facsimile machine must be executed and maintained in a manner which ensures that the prescription will remain nonfading and readable for the minimum amount of time required by statute and regulation. The transmission of a prescription by facsimile machine shall occur only at the option of the patient, or the patient's agent, to a pharmacy of the patient's choice. No pharmacy or individual related to such pharmacy, may provide facsimile equipment or supplies to a prescriber nor may a prescriber provide facsimile equipment or supplies to a pharmacy or individual related to such pharmacy.

(2) Every oral or written drug prescription shall provide an authorization from the practitioner as to whether or not a therapeutically equivalent generic drug may be substituted. A written prescription shall have two signature lines at opposite ends on the bottom of the form. Under the line at the left side shall be clearly printed the words "Dispense as Written." Under the line at the right side shall be clearly printed the words "Substitution Permitted." The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. No written prescription shall be valid without the signature of the practitioner on one of these lines. An oral prescription from the practitioner shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law.

The pharmacist shall note the brand name or the manufacturer of the generic drug dispensed on the file copy of a written or oral prescription. The prescription label shall contain the brand name of the drug product dispensed, or the generic name of the drug product dispensed and its manufacturer, either written in full or appropriately abbreviated, unless the prescribing practitioner indicates that the name of the drug shall not appear upon the prescription label.

(3) Every prescription shall specify the number of times or the period of time for which the prescription may be refilled. A prescription marked "Refill P.R.N." or some similar, nonspecific designation is not considered a valid refill authorization

(4) Nothing in this definition shall be construed as altering or affecting in any way existing or future laws or regulations of the State or any Federal Act requiring a written and signed prescription for narcotic, barbiturate or other dangerous and restricted drugs.

Finally, in Commission Decision #90-39, the commission held:

Enteral formulas are formulas fed to individuals as their sole source of nutrition. In addition, they are specifically blended based on calories to treat certain metabolic disorders, i.e., protein or sodium imbalances. Due to differing needs, enterals cannot be bought over the counter but rather can only be purchased on a doctor's order. The question is whether these formulas can be considered prescription medicine for purposes of Section [12-36-2120(28)].

It would appear enterals meet Section [12-36-2120(28)'s] requirements. They are sold by prescription and aside from their nutritional aspect, have a medicinal application. In this latter respect, they are different from commercial dieting formulas marketed through physicians. Such commercial formulas are not generally used to treat diseases caused by metabolic disorders.

Finally, SC Technical Advice Memorandum #88-23 states "it is unreasonable to interpret the intent of the legislature so as to exempt...medicines and drugs merely because such items are sold pursuant to a prescription...Therefore...medicines [to be exempt] must *require* a prescription."

Based on the above, it is the opinion of the department that sales of enteral nutrition formulas and total parenteral nutrition ("TPN") solutions by XYZ to individuals are exempt from the sales and use tax under Code Section 12-36-2120(28)(a) as a "medicine ... sold by prescription" if the enteral nutrition formulas and total parenteral nutrition ("TPN") solutions may only be sold by prescription when sold to the patient.

Note: Private Revenue Opinions only apply to the specific set of facts submitted by the taxpayer and are only applicable to the person to whom it is issued. This Private Revenue Opinion is based on the specific facts provided by XYZ, the sales and use tax law, and the department's longstanding administrative policy concerning the application of the exemption found in Code Section 12-36-2120(28)(a) to enteral nutritional formulas that can only be purchased pursuant to a doctor's prescription. The issue as to whether a substance constitutes a medicine that can only be sold by prescription must be considered on a case-by-case basis.

Disposable Medical Supplies:

For sales made on or after August 17, 2000, Code Section 12-36-2120(28)(c) exempts from the sales and use tax the gross proceeds of sales, or sales price, of:

disposable medical supplies such as bags, tubing, needles, and syringes, which are dispensed by a licensed pharmacist in accordance with an individual prescription written for the use of a human being by a licensed health care provider, which are used for the intravenous administration of a prescription drug or medicine, and which come into direct contact with the prescription drug or medicine. This exemption applies only to supplies used in the treatment of a patient outside of a hospital, skilled nursing facility, or ambulatory surgical treatment center;

Based on the above, it is the opinion of the department that sales of enteral nutrition supplies, such as bags, tubing, feeding tubes and syringes, by XYZ to individuals are not exempt from the sales and use tax under Code Section 12-36-2120(28)(c) since such supplies are not used for the intravenous administration of enteral nutritional formulas.

However, it is the opinion of the department that sales of total parenteral nutrition (TPN) supplies, such as bags, tubing, feeding tubes and syringes, by XYZ to individuals are exempt from the sales and use tax under Code Section 12-36-2120(28)(c) since such supplies are (1) dispensed by a licensed pharmacist in accordance with an individual prescription written for the use of a human being by a licensed health care provider, (2) are used for the intravenous administration of a prescription drug or medicine, (3) come into direct contact with the prescription drug or medicine, and (4) are used in the treatment of a patient outside of a hospital, skilled nursing facility, or ambulatory surgical treatment center.

SOUTH CAROLINA DEPARTMENT OF REVENUE

s/Elizabeth Carpentier

Elizabeth Carpentier, Director

September 7 _____, 2001
Columbia, South Carolina

CAVEAT: This advisory opinion is issued to the taxpayer requesting it on the assumption that the taxpayer's facts and circumstances, as stated, are correct. If the facts and circumstances given are not correct, or if they change, then the taxpayer requesting the advisory opinion may not rely on it. If the taxpayer relies on this advisory opinion, and the Department discovers, upon examination, that the facts and circumstances are different in any material respect from the facts and circumstances given in this advisory opinion, then the advisory opinion will not afford the taxpayer any protection. It should be noted that subsequent to the publication of this advisory opinion, changes in a statute, a regulation, or case law could void the advisory opinion.