425.0011.100

Memorandum

To: Mr. Brian Manuel Date: October 28, 2003

Supervising Tax Auditor Refund Section (MIC:39)

From: John L. Waid Telephone: (916) 324-3828

Senior Tax Counsel (MIC:82)

Subject: [No Permit Number]

Multi-Use Central Line Catheters

I am responding to Program Planning Manager Charlotte Paliani's memorandum to Assistant Chief Counsel Janice L. Thurston dated June 13, 2003. I apologize for the delay. Ms. Paliani asked the Legal Department to respond directly to your memorandum to her dated June 9, 2003. You asked for advice regarding the applicability of tax to sales of central line catheters use for many purposes, including TPN.

You attached a memo to Refund Section Supervisor Robert Buntjer, dated May 20, 2003, from Santa Ana District Supervising Tax Auditor II Paul G. Junkeit. Mr. Junkeit poses several different questions:

- "Are single-lumen central line catheters used by hospitals for TPN subject to tax?
- "Are multiple lumen central line catheters used by hospitals for many purposes including TPN subject to tax?
- "Are multiple-lumen central line catheters used by hospital for many purposes, Not including TPN subject to tax?
- "Are multiple-lumen central line catheters used by hospital for many purposes, Not including TPN, then at a later date the line is used for TPN subject to tax?"

Mr. Junkeit attached to his memorandum a narrative discussing the issues involved.

"A central line is a special intravenous (IV) line that, generally, is surgically inserted through the chest and threaded into one of the large veins that lie close to the heart. ... Central lines, including tunneled catheters and PICC lines, can consist of one or more noncommunicating vascular access lumens with a singular catheter body. The lumen(s) remain outside of the body and the end of the lumens' access ports are

color-coded. Each lumen is used for a separate purpose such as blood sampling, drug infusion, pain management infusion, monitoring of central venous pressure, chemotherapy, TPN infusion, etc. A lumen that is assigned a specific use is, generally, never used for another purpose due to the possibility of infection or drug incompatibility....

$[\P\P]$

"The motive for central line insertion varies by patient. Central lines are often placed in patients who never receive TPN. Conversely, central lines are often placed specifically because the patient needs TPN. In these cases, it is normal for the hospital staff to insert a multiple-lumen catheter for convenient access for numerous purposes. Further, a central line is often inserted for other purposes and at a later date TPN is prescribed for the patient....

"The auditor has concluded that single lumen central line catheters used for TPN are exempt from tax, since they are used "primarily to dispense the TPN", as required per ... Regulation 1591(b)(5). ... A single-lumen catheter used for another purpose, such as pain management, chemotherapy, or drug infusion, would remain subject to tax."

"Multiple-lumen central line catheters are used for many purposes, such as infusion of drugs, pain management therapies, blood draws, infusion of drugs via needle injection, and TPN. Multiple-lumen catheters are not used *primarily to dispense nutrition*...." (Italics in original.)

OPINION

Under Regulation 1591(c)(2), instruments and other appliances are generally not included in the term "medicines," with the result that their sales are subject to tax. Regulation 1591(b)(5), in part, discusses the application of tax to sales of devices used to deliver TPN to patients as follows:

"For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are

integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN." (Emphasis added.)

Mr. Jungkeit reports that the auditor has concluded that multiple-lumen central line catheters do not qualify as medicines under the regulation, because they are not used primarily for the delivery of TPN, as the regulation requires.

There has always been a primary-purpose test in evaluating whether or not certain medical devices that are capable of multiple uses qualify as medicines. The retailer has to know the status of the item at the time of sale in order to accomplish his tax return. The status of the item cannot be made to turn on events that may happen some time after the sale. (See, e.g., Annot. 425.0399 (11/22/94).)

We concur with the auditor that single-lumen catheters used to deliver TPN are included as medicines under Regulation 1591(b)(5). The sole purpose of the catheter in that case is to deliver TPN. As a result, sales of single-lumen catheters used to delivery TPN are not subject to tax.

We also concur with the auditor that sales of multiple-lumen catheters are subject to tax under the regulation. Such catheters are not used primarily for the delivery of TPN. Indeed, they may never be used to deliver TPN at all, or, if they are, such use may not occur until a long time after the catheter is sold. The retailer's reporting cannot be made dependent on the business choice of the purchaser, especially when that choice may not come until well after the sale. Clearly, if the catheter is never used for delivering TPN, no issue as to exemption could arise. Its sales are subject to tax.

Since, as Mr. Jungkeit relates, multiple-lumen central line catheters have no primary use, it appears that they would be classified as appliances and devices for all purposes. We do not, however, give an opinion herein on whether or not there is any other possible use to which such catheters may be put that might give rise to an exemption.

JLW/ef

cc: Ms. Jeanine Candelaria - District Auditing (EH)

Ms. Charlotte Paliani (MIC:92)

Ms. Laura Jonoubei (MIC:50)

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