

**M e m o r a n d u m****425.0310**

To: Oakland Auditing

Date: March 24, 1986

From: Headquarters - Legal  
Robert J. Stipe

Reg. 1591  
The "Dialyser Reprocessing System"  
and the "Data Management System" are  
considered to be peripheral to dialysis  
machines and do not qualify as exempt  
related supplies.

Subject: Regulation 1591 (Prescription Medicines)  
S---, Inc. SR -- XX-XXXXXX

Your letter of February 24, 1986 has been referred to me for a response. You request our opinion whether a "dialyzer reprocessing system" or a "data management system" qualify as exempt medicines. Both systems are used in conjunction with kidney dialysis machines.

The "dialyzer reprocessing system" cleans, tests and sterilizes the dialyzer (kidney machine filter) after each use. The dialyzer can then be reused. Normal procedure would be for the dialyzer to be used once and then disposed of.

The "data management system" is a mini-computer with software and is connected to the "dialyzer reprocessing system." It records dialyzer reuse history by patient and prints out dialyzer labels.

Tax does not apply to the sale of prescription "medicines" as that term is defined under section 6369 of the Revenue and Taxation Code and Sales and Use Tax Regulation 1591. Subsection (j) of Regulation 1591 provides that certain "appliances and related supplies necessary as the result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste, shall be deemed to be dispensed on prescription within the meaning of [Revenue and Taxation Code] section 6369." Included within the meaning of the term "appliances and related supplies" are kidney dialysis machines and certain related supplies.

In order to qualify as a "related supply," it is our position that an item must be a necessary and integral part of the machine or device itself, or a substance or preparation intended for external or internal application to the body of the patient undergoing dialysis. Accordingly, items which are used by a technician during the operation of the dialysis machine, or items which are peripheral to the dialysis process are not exempt from tax.

Using the above guidelines, we are of the opinion that the “data management system” and the “dialyzer reprocessing system” do not qualify under Regulation 1591(j) as “related supplies” since we consider the use of these systems to be peripheral to the dialysis process. The systems are not an integral part of the dialysis machine since, with the normal procedure of replacing the used filter, the dialysis machine can operate without either system. Additionally, the “systems” are not a “substance or preparation intended for external or internal application to the body of the patient undergoing dialysis”. Therefore, the “dialyzer reprocessing system” and the “data management system” do not qualify as exempt medicines.

RJS:sr