



## TEXAS DEPARTMENT OF STATE HEALTH SERVICES

**August 5, 2014**

Patient Quality Care Unit  
Health Facility Compliance  
Re: End Stage Renal Disease Facilities (ESRDs) in  
Texas and Dialysis Machines in New Facilities

Position statement regarding the number of dialysis stations and the presence of un-used dialysis machines for new dialysis facilities:

According to 25 TAC §117.2 (69) the definition of a station in an ESRD facility is “an area in the facility in which a patient receives in-center dialysis treatment, or dialysis instruction, (i.e. home hemodialysis training, or peritoneal dialysis training).” For initial and ongoing licensure, the facility should meet the space requirements, loop connections, and Life Safety Code requirements necessary to provide dialysis treatments for the number of stations specified on the facility’s license.

Chapter 117, §117.16 establishes the license fees for dialysis facilities, based the number of stations being licensed. If the number of patients being treated at the facility is less than the full capacity to occupy all of the stations for which the facility is licensed, such as when awaiting initial CMS Certification, then the unused stations may exist without the presence of non-structural equipment necessary for treatment (i.e. dialysis machines, chairs, etc.). If the facility intends to permanently cease use of the station, then the facility should contact this department’s licensing group and decrease the number of stations on their license.

Regarding initial licensure, facilities must continue to submit water chemical analysis, and bacteriological and endotoxin levels of product water in compliance with 25 TAC §117.32 (relating to Water Treatment, Dialysate Concentrates, and Reuse), as required in 25 TAC §117.12 (relating to Application and Issuance of Initial License). For dialysis machines at the facility (in-use and backup), and as new machines are added in new facilities, each dialysis machine should be tested for bacterial growth and the presence of endotoxins in dialysate, and a schedule should be developed to ensure each hemodialysis machine is tested quarterly (reference 25 TAC §117.32(c)(4)(A)). These dialysate cultures do not need to be submitted to this department for initial or continued licensure.

The intent of this rule clarification is to allow new dialysis facilities in Texas to begin operations without having to install every dialysis machine on every licensed station at the time of start-up. When a new dialysis facility receives an approval letter from CMS regarding an access to care request or an “aged 855,” so an initial Medicare survey can be scheduled according to the CMS tiered system, the dialysis facility can then order, install, and test the machines to be used for the remaining licensed stations and the machines should still be under warranty. Compliance should be maintained for the ratio of in-use machines to backup machines, as specified in 25 TAC 117.31(c) (relating to Equipment).

Please contact Mr. Patrick Waldron, Health Facility Compliance Branch Manager at [patrick.waldron@dshs.state.tx.us](mailto:patrick.waldron@dshs.state.tx.us) or call at (512) 834-6700 ext. 2625 if you have any questions.