



# TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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## **Updated Position Statement for NxStage PureFlow and NxStage System One Home Dialysis Products**

The Texas Department of State Health Services (DSHS) has recently completed an extensive review of the NxStage home dialysis products, manufacturing manuals and supporting documentation, and met with the manufacturer's representative to determine whether said products can be safely used in Texas and be in compliance with the Texas licensing rules, 25 Texas Administrative Code Chapter 117. Also, neither the AAMI Standards nor the current licensing rules specifically address the delivery of dialysis treatment using these products.

Until the current licensing rules are amended, this document will provide guidance to DSHS survey staff and licensed ESRD facilities in Texas regarding the use of these products and is consistent with the recent CMS Conditions for Coverage. ESRD facilities that follow these guidelines when using the NxStage PureFlow product will be considered to be in compliance with the current licensing rules:

- **Chemical Quality of the Source and Treated Water:**

The facility shall perform an analysis of the source water used for dialysate to ensure the water quality meets the manufacturer's guidelines for source water purity every six months or if there is a change in the source water.

The chemical quality of the product water used for dialysis should be analyzed initially and at least every six months at the end of the Pack life or when any modifications are made to the Pack to ensure that the product water meets the primary standards of AAMI RD 52 2004.

- **Microbiological Quality of the Dialysate and Product Water:**

The microbiological quality of the dialysate should be analyzed monthly at the end of a prepared dialysate bag using cultures and endotoxin measurements.

- **Chlorine and Chloramines Testing:**

An appropriate volume of product water should be checked for the presence of chlorine / chloramines levels immediately prior to using each dialysate bag. Chloramines levels shall be <0.1mg/L. Results of testing shall be documented.

- **Verification of Dialysate:**

The user will no longer be required to verify the conductivity and pH of the dialysate batch with an independent device prior to the use of each dialysate batch.

The NxStage System One, in its existing form, meets the current licensing rule requirements. All other Texas ESRD licensing rules remain in effect and facilities must continue to be in compliance with those rules. Please contact your DSHS zone office should you have any questions.