DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-32-ESRD

DATE: **July 29, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Preconfigured Hemodialysis Systems- NxStage System One with Pureflow SL

Memorandum Summary

- The NxStage System One with PureFlow SL is a preconfigured hemodialysis system that is Food and Drug Administration (FDA) approved to meet the Association for the Advancement of Medical Instrumentation (AAMI) standards for water quality and dialysate.
- Preconfigured hemodialysis systems differ from traditional hemodialysis water systems and therefore all the requirements of 42 CFR 494.40 *Water and Dialysate Quality* will not be applicable to the function of a preconfigured hemodialysis system.
- Consistent with 42 CFR 494.40 (e) surveyors must evaluate water and dialysate quality for preconfigured hemodialysis machines by ensuring that the FDA and manufacturer's labeling for the machine are followed by the facility.

Background

NxStage is a manufacturer of dialysis products for use in homes, hospitals, and dialysis centers. The NxStage System One with PureFlow SL is a preconfigured hemodialysis system approved by the FDA for in-center and home hemodialysis. The NxStage System One with PureFlow SL has been tested and validated by the FDA to deliver water quality and dialysate that meets AAMI standards.

The End Stage Renal Disease (ESRD) regulation applicable to preconfigured hemodialysis systems is located at 42 CFR 494.40 (e) "*Standard: In-center use of preconfigured hemodialysis system*. **Follow FDA labeling.**" The referenced regulation states that the system's FDA approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. Because this system does not share the same design or configuration of a traditional in-center hemodialysis water system, all the requirements of §494.40 *Water and Dialysate Quality* will not be applicable. Accordingly, for purposes of surveying water and dialysate quality with preconfigured hemodialysis machines, the surveyor determines whether the facility follows the

FDA and manufacturer's labeling for the machine. If that is confirmed, the surveyor may conclude that the preconfigured machine meets the requirements of 42 CFR 494.40 (e) and the AAMI requirements at RD52.

For your information we have listed below the applicable FDA website links for FDA labeling of preconfigured hemodialysis machines.

https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140571.pdf - NxStage Pureflow SL (water purification system)

https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140526.pdf - NxStage System One (machine)

This policy memorandum addresses water and dialysate quality only. All other portions of the ESRD regulations continue to apply as written regardless of the type of hemodialysis machine in use.

Maximum levels for contaminants including chlorine, bacteria and endotoxins in water and dialysate recommended by AAMI apply to both traditional in-center hemodialysis water systems and preconfigured systems.

Contact: For questions please contact Jennifer Milby at Jennifer.Milby@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management

The contents of this letter support actions to improve patient safety and increase quality and reliability of care and promote better outcomes.