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

Ref: QSO-25-17-ESRD

DATE: March 24, 2025

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: **REVISED**: Preconfigured Hemodialysis Systems

Memo Revision Information:
Revisions to: *S&C-16-32[ESRD]* ***Original release date:*** *July 29, 2016*

Memorandum Summary

- *Preconfigured dialysis systems are designed to deliver water and dialysate quality that meet safety standards, simplifying dialysis treatment for both in-center and home use.* Preconfigured hemodialysis systems differ from traditional hemodialysis water systems and therefore all the requirements of 42 CFR 494.40 Water and Dialysate Quality may 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 verifying that the *Food and Drug Administration (FDA)* and manufacturer's labeling for the machine are followed by the facility.

- *Facilities are expected to ensure dialysis machines and equipment are operated and maintained in accordance with the manufacturer's directions for use and applicable FDA labeling for machine use and monitoring of the water and dialysate quality.*

The initial guidance published in S&C-16-32 is being revised to expand its applicability to any pre-configured hemodialysis system that has received FDA clearance for home and in-center use.

Background:

Technological advancements have led to the availability of several preconfigured dialysis systems for use in the in-center and home dialysis settings. These systems are designed to be easy to use and require minimal user intervention during dialysate preparation. 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 *when using a preconfigured, FDA-approved hemodialysis system designed, tested, and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate,* the system's FDA-

approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality.

Discussion:

Preconfigured hemodialysis systems refer to a dialysis machine that comes ready to use with all necessary settings and components pre-set, often including a water purification system, to deliver the patient's dialysis treatment versus relying on a centralized water system as typically encountered in the in-center dialysis setting. Although primarily used for home therapies, a preconfigured hemodialysis system may be used in-center. Such use might be for training a home patient, for back-up treatment of home patients, or for routine in-center treatment. In all cases, the system's FDA-approved labeling must be followed for machine use and monitoring of the water and dialysate quality.

Because *preconfigured hemodialysis* systems do not share the same design or configuration *as* traditional in-center hemodialysis water systems, 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.

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.

The 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 pre-configured systems.

Facilities are expected to ensure dialysis machines and equipment are operated and maintained in accordance with the manufacturer's directions for use and any applicable FDA labeling for machine use and monitoring of the water and dialysate quality.

Contact:

For questions or concerns relating to this memorandum, please contact ESRDQuestions@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

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- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

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