



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

To: All End-Stage Renal Disease (ESRD) Centers

From: Oksana Likhova, Program Manager, Federal Unit, Office of Health Care Quality
Oksana Likhova

Date: June 21, 2024

Re: Equipment Quality Control and Physical Environment Requirements

The Office of Health Care Quality (OHCQ) is the agency within the Maryland Department of Health that licenses and conducts surveys in dialysis centers to determine compliance with State and federal regulations. This transmittal is to remind all centers of the equipment quality control and physical environment requirements. The State licensure requirements establish the minimum health and safety requirements to obtain and maintain a license to operate in Maryland. The federal certification requirements establish the minimum health and safety standards that are required for participation in the Medicare and Medicaid programs.

Certified dialysis centers are required to maintain and operate dialysis equipment in accordance with the manufacturer's recommendations. This includes following the manufacturer's instructions during set-up of the equipment, performance of safety testing prior to initiation of dialysis treatment, troubleshooting of the equipment alarms, completing preventative maintenance, repairing any malfunctioning equipment, and removing any equipment that is malfunctioning from service. All malfunctioning equipment must be removed from service until the repairs are completed.

The following requirements address equipment maintenance for dialysis centers.

Code of Maryland Regulations (COMAR) 10.05.01.08E, Equipment Quality Control for Free-Standing Ambulatory Care Facilities, states the administrator shall ensure that the facility develops a quality control procedure to monitor the safety and performance of all biomedical equipment.

Additionally, the Centers for Medicare & Medicaid Services (CMS) requirement at 42 CFR § 494.60(b) states: "The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations."

If you have any questions regarding this transmittal, please contact Oksana Likhova, Program Manager, Federal Programs, 410-402-8041, oksana.likhova@maryland.gov.