DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality

Ref: QSO-24-16-ESRD

DATE: July 10, 2024

TO: State Survey Agency Directors

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

SUBJECT: Clarification of Medical Director Board Certification Requirements

Memorandum Summary

- Professional board certification is a voluntary process by which a physician (or other professional) demonstrates advanced knowledge and skills beyond minimal standards. The Medicare Conditions for Coverage (CfCs) for End-Stage Renal Disease facilities at 42 CFR §494.140(a)(1) require dialysis facility medical directors to be a physician who is "board-certified" in internal medicine or pediatrics, has completed a board-approved training program in nephrology, and has at least 12 months of experience providing care to patient receiving dialysis.
- This memo is clarifies that the Centers for Medicare & Medicaid Services (CMS) expects the board certifying the physician to be a nationally recognized professional board, while not explicit on the particular Board from which certification must be obtained.
- CMS is clarifying in this guidance the expectations for determining compliance with the requirements at 42 CFR §494.140(a)(1).

Background:

CMS establishes minimum health and safety standards for ESRD facilities to ensure patient care is provided by medical professionals who are qualified and demonstrate the competencies necessary to serve the comprehensive needs of dialysis patients. The CfCs for outpatient dialysis facilities require that all medical directors be "board-certified" in internal medicine or pediatrics by a nationally recognized professional board or have a CMS-approved waiver (described below).

Through the survey and oversight procedures, CMS, State Survey Agencies (SA), or CMSapproved Accrediting Organizations (AO) review the dialysis facility's medical director qualifications to ensure compliance with the requirements at <u>42 CFR 494.140(a)</u>, e.g. confirm active licensure to practice medicine and active board certification status. This memo aims to clarify CMS' expectations for determining compliance with the Federal requirements at $\frac{42 \text{ CFR}}{494.140(a)(1)}$.

Discussion:

"Board-certification" is a voluntary process by which a physician (or other professional) demonstrates advanced knowledge and skills that go beyond mandatory state licensing requirements. The process for initial and continuing board certification is specified by the individual board. Board certification is recognized as an accepted industry standard for evidence of proficiency in a specialty. Nephrology is a specialty that requires specialized knowledge and training. Health and safety standards for outpatient dialysis facilities require that each dialysis facility have a medical director who is, among other things, board-certified in internal medicine or pediatrics by a nationally recognized professional board.

The CfC requirements specify that the professional board must be nationally recognized in internal medicine or pediatrics. Currently, there are several recognized professional boards that certify physicians. Medical boards are independent organizations that establish common standards for physicians to achieve and maintain the board's certification. To be considered "board-certified," a physician successfully achieves initial board certification, which is most commonly obtained through a board certification examination. Once an individual is board-certified, they maintain their certification by demonstrating compliance through a Maintenance of Certification (MoC) program, or a comparable pathway for continuous certification. This board overseeing the MoC may or may not be the same as the board that issued the initial certification.

In the <u>2008 ESRD CfC Final Rule</u>, CMS received several comments about the medical director board certification requirement to which CMS replied that "the medical director must be "board-certified" in internal medicine or pediatrics by a nationally recognized professional board". The regulatory requirement is not explicit on the particular board from which the certification must be obtained, however, the "board" that is certifying the physician must be a nationally recognized professional board:

- **Nationally Recognized:** The professional board by which the medical director is certified is well-known, prominent, and widely recognized by entities across the United States that serve the dialysis population, e.g. The American Board of Pediatrics (ABP).
- **Board-certified:** The medical director's board certification status must be current and active.
- **Professional**: The composition and governance of the individuals who are appointed to serve on the board represent a broad range of experience in patient care, quality improvement, health policy, and education.
- Verification: The physician must have a valid, unrestricted license to practice medicine in the state where they are employed. Additionally, health surveyors must verify that the information received for credentialing is accurate. Verification can be performed by interviewing the individual(s) who oversee the facility's credentialing process.

Like all dialysis facility staff, medical directors must also meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.

CMS Waiver to the Medical Director Qualification Requirement

CMS is aware of instances when a physician meeting the medical director qualification is not available to direct a certified dialysis facility. If a dialysis facility cannot secure a medical director that meets the requirements at 42 CFR 494.140(a)(1), it can employ a physician to serve in that capacity under a waiver (42 CFR 494.140(a)(2)) submitted by the dialysis facility and approved by CMS. CMS will verify that good-faith efforts have been made to secure a qualified medical director before making any determination for approval or denial of the waiver. A dialysis facility seeking to place an alternate physician in the role of the medical director must contact their CMS Location to request a waiver. Medical director waivers are not indefinite and are reviewed by the CMS Location at least annually to determine whether approval criteria for the waiver are still applicable. Refer to the State Operations Manual, Chapter 2, Section 2281B for additional guidance on Medical Director waivers.

Contact:

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

Effective Date:

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

Karen L. Tritz Director, Survey & Operations Group David R. Wright Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

/s/

- Understand surveyor evaluation criteria
- *Recognize deficiencies*
- Incorporate solutions into your facility's standards of care

See the <u>Quality</u>, <u>Safety</u>, <u>& Education Portal Training Catalog</u>, and select Quality in Focus

Get guidance memos issued by the Quality, Safety and Oversight Group by going to <u>CMS.gov</u> page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.