The Evolving Role of the Medical Director of a Dialysis Facility

Franklin W. Maddux* and Allen R. Nissenson†

Abstract
The medical director has been a part of the fabric of Medicare’s ESRD program since entitlement was extended under Section 2991 of Public Law 92-603, passed on October 30, 1972, and implemented with the Conditions for Coverage that set out rules for administration and oversight of the care provided in the dialysis facility. The role of the medical director has progressively increased over time to effectively extend to the physicians serving in this role both the responsibility and accountability for the performance and reliability related to the care provided in the dialysis facility. This commentary provides context to the nature and expected competencies and behaviors of these medical director roles that remain central to the delivery of high-quality, safe, and efficient delivery of RRT, which has become much more intensive as the dialysis industry has matured.


History of the Role of the Medical Director in ESRD Care
The Medicare program was 7 years old when entitlement was extended in 1972 to those with disabilities independent of age. The definition of “disabled” included those with CKD who required dialysis or a kidney transplant for survival—they “shall be deemed disabled” for purposes of Medicare parts A and B (1). What was thought to be a small, socially redeeming program, has grown to >600,000 patients with increasingly complex chronic comorbid conditions, and a total cost of >$40 billion. Currently, 1.3% of all Medicare beneficiaries are covered under the ESRD Program and consume nearly 8% of all Medicare dollars.

With the implementation of the entitlement in 1973, there was gentle growth in outpatient dialysis facilities. These were part of academic institutions or in the community, and had clinical oversight provided by nephrologists, who participated in administration of the facility (“medical director”) as well as provided individual patient care (“attending nephrologist”). As the program began to grow, it became clear that regulatory oversight by the US Centers for Medicare and Medicaid Services (CMS), then the Health Care Financing Administration (HCFA), needed to be codified. Thus, the initial Conditions for Coverage (CfC) were issued to govern the operation of dialysis facilities.

The initial CfC mandated that every facility have a physician as medical director whose responsibilities included creating, reviewing, and updating facility policies and procedures; ensuring appropriate modality education and selection for all patients; overseeing training of staff; and ensuring safe and effective dialysis treatments. The physician director was to be board eligible or certified in internal medicine or pediatrics and had to have at least 12 months of experience caring for patients on dialysis. The same nephrologists were delivering direct patient care and participating on the governing body to ensure that the facility was running properly. This proved confusing for some nephrologists who could not separate the patient care role from the administrative role as medical director. Some physicians seemed to treat the medical directorship as an “honorary” position without setting aside specific administrative time to accomplish the job. Of note, even the HCFA had a lack of clarity about the medical director role. When facilities were found deficient during routine surveys, the facility (not the medical director) was cited even if the area of deficiency was a direct medical director responsibility.

As the dialysis industry consolidated during the 1990s, nephrologists were contracting with dialysis companies to provide medical director services. This contractual relationship came with more explicit expectations of the duties of the medical director and rudimentary systems of accountability to monitor delivery of these duties. In 2002, the US Department of Health and Human Services Office of Inspector General (OIG) issued a report titled “Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare” (2). Among a number of recommendations to the CMS in that report to help improve the healthcare outcomes for dialysis patients was that the CIC be revised so that they “require facility medical directors to exert leadership in quality improvement” (2). In 2008, a revised CIC was published that spelled out the responsibilities of the medical director more clearly and completely, as recommended by the OIG report in concert with CIC Interpretive Guidelines to foster correct interpretation of the CIC (3). The medical director is not solely held responsible for every aspect of care provided in the dialysis facility, but is recognized in 53 V-Tag segments of the interpretive...
guidelines to the CIC (4) (Supplemental Table 1). The facility is still the entity sanctioned by the CMS if a medical director does not carry out his or her responsibilities, although dialysis organizations are developing increasingly specific contracts that delineate medical director expectations and consequences for underperformance. Being a medical director is not an entitlement; rather, it is an essential role to ensure high performance and high reliability in providing care within the dialysis facility.

**Evolution of the Delivery System for ESRD Care**

Dialysis facilities were initially developed with a governing body including the facility administrator or chief/head nurse, a medical director, and an interdisciplinary team. The latter consisted of registered nurses, machine technicians, dietitians, and social workers. Before 1990, dialyzers were commonly reprocessed and few injectable medications were administered during dialysis beyond intravenous antibiotics. By 1990, as the patient population expanded and technical and medication advances were adopted, the system for delivering care changed when many more patients began dialyzing with reprocessed dialyzers, dialysis equipment became more sophisticated with enhanced safety features, and dialyzers and concentrate solutions obviated the severe hypotension seen with earlier-generation therapies. In addition, the widespread availability of intravenous erythropoietin, iron, and vitamin D improved anemia and metabolic bone disease management. With the introduction of erythropoietin and intravenous vitamin D, registered nurses were needed to spend more time administering medications than caring directly for patients, whereas increasing responsibility for placing dialysis needles and setting up and tearing down machines was part of the job of the technician. During this time, the dialysis facility administrators were often not nurses, but business administrators. These changes in the interdisciplinary team along with an increasing acuity of patients have made the role of the medical director increasingly one of senior leadership, coach, and head of the care team and facility medical staff. The medical director role emphasizes enhanced accountability for oversight of a more complex technical and regulatory environment of the modern dialysis facility.

**Perspectives on the Medical Director Role**

The medical director of a dialysis facility incorporates both clinical knowledge and administrative capabilities in helping to guide the facility toward high performance and high reliability. There are three primary focus areas with regard to this administrative role, including regulatory requirements, medical practice standards, and operational oversight with the dialysis provider business leadership (5–11). The medical director is not asked to care directly for any given patient; rather, the medical director provides population management and implement processes, methods, and tools for delivering care of the highest quality in a safe and efficient manner.

The CIC and associated interpretive guidelines define areas in which the medical director has distinct responsibility and accountability for overseeing and leading facility performance independent of the ownership or organizational characteristics of the dialysis facility. These areas of influence include infection control, water and dialysate quality, reuse of dialyzers, physical environment, patient assessment standards, patient plan of care processes, quality assessment and performance improvement, personnel qualifications, and governance of the facility.

Each of the CIC regulated areas is noted in a distinct nomenclature known as the V-Tag (a computer-identified tag in interpretive guidelines to the CIC). For example, infection control references the medical director in two V-Tags, in which the medical director participates in defining the infection control culture and policies and is expected to be responsive to a surveyor when asked about the infection control program and reporting mechanisms. Furthermore, there are 16 V-Tags related to water quality. Each of these recognizes the expectation that the medical director is knowledgeable of the water treatment system installed in order to be sure that the water quality meets the Association for the Advancement of Medical Instrumentation water quality standards for dialysis.

The physical environment, patient assessment, and plan of care areas have three to four V-Tags, each of which relate to the medical director’s role in ensuring that emergency equipment and drugs are available and that staff are properly trained. Patient assessment frequencies and content are regulated by the CIC, including ensuring that each patient has a valid dialysis prescription delivered in a safe physical environment. The quality assessment and performance improvement V-Tag recognizes the medical director’s role in leading the interdisciplinary team in the measurement, observation, interpretation, and planning for quality care process improvement within the dialysis facility.

There are four V-Tags in which the medical director must provide assessment of clinical and medical staff capability within the dialysis facility, as well as the disciplines surrounding patient care technician (PCT) training. Furthermore, support of governing body rules for staffing and employing technical, PCT, and nursing positions are part of the medical director role. This includes staff education, training and competency assessment of staff, and logistics of admitting patients to facilities.

Finally, the medical director is recognized no less than seven times in V-Tags related to the governance of dialysis facilities, having close communication with the governing body regarding quality assessment and performance improvement, orientation and communication with the medical staff, assurance of compliance to governing body decisions, clear plans for dealing with patient grievances, and decision making on whether any condition with the facility would prohibit the ability to deliver safe treatments (12).

**A Clearer Role**

Originally, the medical director role was narrow and focused singularly on the clinical policies and procedures in the dialysis facility. In the early years after the Medicare entitlement, the dialysis facility medical directorship was prestigious and an honor. The revision to the CIC in 2008 became explicit about the expectations of the work involved gauged to accommodate 25% of the medical directors’ total work time. This move toward active and engaged executive
leadership was a tremendous change in the responsibility and accountability for medical directors. As the dialysis providers began to consolidate, the medical director became the central authority for observing and molding practice patterns by the full medical staff in their facility, guided by the medical leadership of the dialysis provider organization. Such facility practice patterns are dictated by the clinical and medical needs of the patients, the safe environment of the facility, and a highly integrated reporting and analysis process. The role of the medical director has evolved into a key decision-making component on both the delivery of clinical services and operations at the dialysis facility.

Skill Sets

Distinctive Roles for Patient Care and Administration
Most medical directors are also attending physicians with some number of patients being treated at the dialysis facility. One of the great distinctions of the medical director role is that the primary purpose is not the care of any individual patient or clinical circumstance; rather, the medical director manages both the administrative and population management needs of the facility as a whole. The development of a strong clinical staff and the ability to distinguish individual patient care decisions as an attending nephrologist and the administrative role as a medical director in the dialysis facility are challenges that each medical director must master.

A Need for Facility Population Management Skills
Although not explicitly stated in the CfC, to fulfill the contemporary responsibilities as medical director, the nephrologist is accountable for the health outcomes of a discrete population of patients, those who are receiving care within their dialysis facility (13). If this is done well, the need for emergency department visits, hospitalizations, and costly procedures will be minimized. This concept is not one that nephrologists fully understand or have been exposed to in training. Overall facility measurement of outcomes, generally driven by protocols and algorithms, are key to successful population management, and robust data and analytics are necessary to provide the medical director with the information needed to manage the population. This is one of the most challenging parts of a medical director role because it means working with other physicians in the facility to ensure adoption of standardized care protocols and organized systems of care, always recognizing that the art of medicine is deciding when a protocol should not be followed. Finally, true population management requires the medical director to work with the interdisciplinary team, attending nephrologists, and patients to engage patients in their own care, which is essential for driving the best outcomes. The need for discreet population management skills is consistent with the requirement for medical directors to provide a patient-centered safe environment of quality care as articulated by Medicare in its Quality Strategy Document 2014 (14).

Beyond this, the medical director retains a responsibility for the clinical strength of the interdisciplinary team members including clinical nursing staff, PCTs, dieticians, social workers, and any other ancillary staff that interact with the patient population. The medical director should include in his or her purview the operational leadership that has great effect on the patients’ experience of care and ultimately quality of life. The close working relationship of this team is frequently the critical factor in developing a high-performing and highly reliable dialysis facility. The medical director must present clear leadership that distinctly sets the tone and culture for all staff that work with patients in the facility and exemplifies the primary goal of delivering high-quality, safe, and effective RRT.

Business Acumen
An effective medical director is asked to be more capable of influencing effective operations, culture, staff development, education, and sustainability of the facility. Medical directors should seek and obtain background in basic business principles so that they can understand how to influence good decisions about equipment, standardized processes, and hiring. This knowledge supports the need for developing a sustainable, healthy dialysis facility. Although specifics regarding business competency are not a regulatory requirement of the CfC, such expertise enhances the effectiveness of the medical director. When a medical director does not participate in the business and operational decisions regarding the promotion of safe, effective, and efficient care, the facility will suffer sustainability risk. Therefore, as the senior clinical leader within an individual dialysis facility, the medical director should take an active and engaged role in fostering strategies to improve the facility performance regarding clinical quality, operational excellence, and financial viability.

Technical Skills and Background
The medical director should have completed a full, comprehensive fellowship in nephrology that includes hands-on care of hemodialysis and peritoneal dialysis patients. It is highly desirable for training to include technical aspects of dialysis in addition to the medical care of dialysis patients. Experience such as setting up dialysis equipment, inserting dialysis needles, monitoring treatments, and shadowing biomedical personnel are invaluable to a prospective medical director. Finally, an understanding of the regulatory environment in which dialysis facilities operate is essential for a medical director because he or she is responsible for ensuring that all regulatory requirements are met so that high-quality, safe, and efficient dialysis is delivered to all patients at all times (15,16).

Managing a Medical Staff
One of the most challenging responsibilities of a medical director is overseeing the activities of the medical staff, some members of whom may be part of the medical director’s nephrology group and others may be part of competing groups. All consider themselves equals with the medical director, which can create points of conflict. This part of a medical director’s role is one of the most challenging, but really involves developing, fostering, and reinforcing a true team mentality among the medical staff.
members independent of the practice relationships represented within an individual facility medical staff (17,18). This effort is most effective when the medical director can get the medical staff to have a shared vision and goal for the facility, as well as clarity about the distinctive roles of the medical director and attending nephrologist. This includes robust, frequent, clear communication, and creation of a culture of mutual trust, respect, and adoption of evidenced-based care pathways or protocols.

**Governing Body Leadership**

The medical director plays an active role in helping to guide and influence the governing body toward rational choices and correct decisions in the development of a high-performing and highly reliable dialysis facility. The medical director may be the chief executive officer of the facility in some cases, whereas the medical director may simply be a member of the governing body in others. This governing body’s role is to recognize both the direct business interests, as well as relationships between the dialysis provider and the clinical care paradigm supported at the facility. The medical director’s role includes ensuring that the governing body is aware and effectively addresses ongoing quality improvement processes that lead to effective evidence-based quality improvements in care at the facility. The governing body meetings should be regular and should have both regular routine and topical components to the agenda that include assessment of performance of the facility from financial, operational, and clinical quality standpoints. The governing body must set the tone for development of a strong, highly educated, proficient, and professional staff. The governing body must also adjudicate any conflicts and create a rational observation of the clinical staff ability to deliver safe and effective therapy. In many cases, the medical director is the most senior person at the governing body meeting within the organization and should thus take on a substantial role in providing leadership, direction, and active participation in governing body decisions.

As the Medicare ESRD Program enters its 40th year, now is a good time to reflect on the role of the medical director as well as the value that an effective medical director can bring to patients, medical staff members, the interdisciplinary team, and the organization of which he or she is a part. In the early years of the ESRD entitlement, the medical director worked with the chief nurse to develop and oversee policies and procedures within the facility. This limited role was seen by many nephrologists as largely an entitlement to their companies, but getting significant participation is a challenge. It is time to come together with industry, academic institutions, and renal organizations to recommend the best methods to train future medical directors.

**Acknowledgments**

We thank John Larkin and Jackie Wenzler for assisting in the preparation of this article.

**Disclosures**

F.W.M. is employed by Fresenius Medical Care and holds stock in the company. A.R.N. is employed by DaVita Health Care Partners and holds stock in the company.

**References**


Published online ahead of print. Publication date available at www.cjasn.org.

This article contains supplemental material online at http://cjasn.asnjournals.org/lookup/suppl/doi:10.2215/CJN.04920514/-/DCSupplemental.