Skills and Value of the Dialysis Facility Medical Director

Executive Summary

A nephrologist in the role of a medical director is critical to the successful provision of dialysis services to patients with End Stage Renal Disease (ESRD) (Maddux & Nissenson, 2014) and Acute Kidney Injury (AKI) (Renal Physicians Association, 2012). The medical director role is distinct from direct patient care, although the medical director brings this unique clinical knowledge base to the oversight of the facility, staff, physicians and processes through which care is delivered. Formal nephrology training is critical to effectively serving as a dialysis facility medical director. Conscientious and regular involvement of the medical director helps to ensure the quality and safety of care in dialysis facilities. The medical director’s duties are delineated in the Medicare Conditions for Coverage (CfC) which were published in the Federal Register on April 15, 2008 (Centers for Medicare & Medicaid Services (CMS), 2008). The core responsibilities as defined in the CfC expect the medical director to be accountable for clinical outcomes, for supervision and training of the interdisciplinary staff, for coordination of the medical staff, for compliance with federal and state requirements and Quality Assessment and Performance Improvement (QAPI). Nephrologists must acquire unique skills to be effective medical directors – skills that are quite different from those of attending nephrologists. An engaged and effective medical director provides significant value to the dialysis patient and provider.

Background

The full responsibilities of the medical director are outlined in the RPA Position Paper on Dialysis Facility Medical Director Responsibilities Under the Revised CMS Conditions for Coverage for End-Stage Renal Disease Facilities (Renal Physicians Association, 2009). At the core of the medical director’s duties is the task of leading a robust quality assessment and performance improvement program (QAPI). This requires the medical director to have a strong understanding of quality improvement principles (The National Forum of ESRD Networks, 2010). The scope of the QAPI program is defined in the CfC. A successful QAPI program is dependent on a strong facility culture of quality and safety, led by the medical director (The National Forum of ESRD Networks, 2012). But dialysis facilities are only one venue of care for patients with ESRD, as these patients receive costly and complex care at multiple sites under the supervision of many physicians. The medical director’s responsibility also involves coordinating care delivery among these multiple sites as they impact care provided at the dialysis facility. This responsibility for care coordination and effective communication is embedded in the National Quality Strategy ((AHRQ), 2011).
This position paper outlines the skills, expertise, and abilities that will enable a nephrologist to be a successful medical director. The document could provide the foundation for continuing education and professional development curricula. This paper also defines the value that the medical director brings to the care of ESRD patients. This value proposition needs to be communicated clearly so that patients who require dialysis always have the benefit of the oversight of a nephrologist medical director, and so that other stakeholders on the dialysis care delivery spectrum are cognizant of this value.

Discussion

Medical Director Skills

Success as a Medical Director requires harmonization of interpersonal skills, business and executive competence, and a specialized knowledge base (Appendix A). It is imperative that an individual serving in this role acquire the skills and devote the time necessary to be successful. Training in these skills is not usually fully developed in nephrology fellowship curricula.

Interpersonal Skills

Physicians are taught to recognize problems, formulate diagnoses and communicate orders to enable other individuals on the healthcare team to treat patients. Directing a dialysis facility requires teamwork, feedback, communication, negotiation, and consensus building. The medical director needs to function as the team leader and be aware of his/her leadership style and the impact it has on colleagues and other members of the team. Being cognizant of one’s unique leadership style and demonstrating emotional intelligence will enhance the medical director’s effectiveness.

The medical director must be instrumental in helping the facility team prioritize tasks. It is essential to commit to active listening, be attentive in meetings, be punctual, available and always follow up. In addition to leading the facility patients and staff, the medical director’s other responsibilities include communicating with the medical staff, various (often competing) practice groups, health systems, emergency rooms, and community hospitals each of which has a role in the quality of overall care delivered in the dialysis facility. It may be necessary to navigate conflicting priorities to align efforts toward the best care for the patients.

Business and Executive Competence

The medical director is contracted with a dialysis provider or hospital to provide a scope of services. Remuneration is based on time spent, skills needed and the fair market value of the position. It cannot be based upon referral of patients to the facility. The medical director should be very familiar with the contract that outlines these services for the dialysis facility (Trulove, 2014). The medical director should also be familiar with the unique liability risks associated with this role and ensure that they have adequate coverage for risk not included in general medical malpractice liability policies.
The medical director should be competent in setting agendas and managing and/or facilitating meetings. While the primary meeting responsibility will be the QAPI meeting, other gatherings of team members and physicians will require similar leadership.

Each dialysis provider has unique characteristics, medical staff bylaws, and policies/procedures that guide operations and patient care. The medical director should understand each of these and have access to all necessary documents. The medical director must review and, when needed, modify these documents through participation in the facility Governing Body. The CfC vest the facility Governing Body with overall responsibility for the policies and procedures affecting clinical operations. From a practical standpoint, the medical director’s role is usually one of approving policies and procedures authored by someone else and/or revising current policies and procedures. Authorship, revision, and approval are only the first steps in an effective policy and procedure process. It is necessary to get feedback from staff impacted, design an implementation plan (including competencies if training is required), and follow up for adherence. The medical director should understand and guide all phases of development, implementation and revision of clinical policies and procedures.

The medical director should also understand the specific requirements of protocols related to medications. Medication policy and procedures in dialysis units often include initiation and dose changing protocols. The medical director must assure that the medical staff approves and understands the limitations of the protocol, and that there is a signed copy of the protocol in each patient’s record. Where the protocol gives the RN the authority to initiate therapy or adjust doses, the medical director must assure that these actions are consistent within the scope of practice of the RN and the rules and regulations of the state board of pharmacy.

The medical director should have a general understanding of facility operations such as staff and patient ratios, schedules, and human resources. While not directly responsible for human resource functions, the medical director should understand these well enough (performance evaluation, discipline, etc.) to be helpful to the facility manager and ensure quality service and care.

Finally, the medical director must be able to make the business case for quality. In the budgeting process, the medical director needs to justify new, often expensive technology, as well as additional lines of service such as home and in-center nocturnal dialysis modalities. The medical director must be able to read a balance sheet, cash flow report, and profit and loss statement.

Specialized Knowledge

The medical director must have specialized knowledge of the care of patients with kidney disease and the dialysis treatment modalities. Nephrology fellowship training prepares the physician with this fundamental knowledge base. Areas of expertise needed to be effective as a dialysis facility medical director include, though are not limited to, kidney diseases, fluid and electrolyte interactions, acid-base physiology, hypertension, volume regulation, vascular access, anemia, bone-mineral metabolism and transplantation. Additionally, the medical director must be knowledgeable about all aspects of all dialysis modalities – technology, treatment, and complications.
The regulatory guidelines covering the care provided in ESRD facilities are complex and compelling. The core regulatory document is the Medicare CfC. The CMS survey and certification group writes rules for the conduct of the program consistent with legislation passed by Congress. Within the CfC, CMS “incorporates by reference” regulations for other federal agencies and guidelines of industry or professional bodies. When a “guideline” is incorporated into the CfC, it has the force of a regulation, even if the authoring body of the document did not intend it to be prescriptive. Medical directors, while not likely to be experts in rules and regulations, will understand the domains of authority of these rules and practical implications. The “interpretive guidance” is a companion document to the CfC (Centers for Medicare & Medicaid Services, 2008). It explains the intent, practical application of the CfC, and the criteria needed to document compliance. The document is intended for the state surveyors to assist their facility survey and certification activities. The survey process itself is defined in public documents (Centers for Medicare & Medicaid Services (CMS), 2014). The current practice is called the “core survey.” The medical director should be knowledgeable about the CfC, interpretive guidance and core survey process. The current core survey process requires the surveyor to interview the medical director. In this interview, the medical director should be able to demonstrate his or her leadership of facility quality and safety processes.

Involuntary discharge or transfer (IVD/IVT) is a topic worthy of specific mention. The medical director should be familiar with all rules and regulations related to IVD/IVT. These rules are established to protect patients and ensure that every effort is made in the QAPI process to address patient grievances, avoid escalation and minimize risk of IVD/IVT. The ready availability of the medical director helps diffuse conflict and address grievances before they escalate (Jones & Goldman, Managing disruptive behavior by patients and physicians: a responsibility of the dialysis facility medical director, 2014). The state departments of health and the ESRD networks (DeOreo & Wish, 2014) are involved in the IVD/IVT process, and other federal agencies can be brought into the conflict. The medical director must assure compliance with the process as outlined in the CfC. Failure to comply with conditions or standards outlined in the CfC may lead to sanctions, need for corrective action, and possible revoking of the facility’s Medicare provider number.

The medical director’s responsibility for administering QAPI enables him or her to apply clinical expertise in the care of patients to advance the care of a population (census of the facility). The medical director should have reasonable understanding of quality improvement principles (DeOreo, Wilson, & Wish, 2012), and the QAPI process in dialysis facilities is to be data driven and based on the best clinical evidence. The medical director can work with the medical staff to develop up to date protocols, and with the facility staff to implement and monitor those protocols. The QAPI program should employ standardized data such as internal corporate reports, reports from the Dialysis Facility Report, the measures assessment tool (MAT) incorporated in the interpretive guidance, and other benchmarking data. QAPI and the interdisciplinary care planning process complement each other. The QAPI process must monitor, recognize and address variations and gaps in patient care, adverse outcomes, and outliers. Patient issues identified in the care planning process (e.g. compliance, education, modality choice, etc.) may be productively addressed in system of care changes managed by the QAPI team.
An effective QAPI program creates a culture in the facility that supports both quality and safety. Medical director leadership in this regard sets the example (Gutman, 2007). Since quality and safety both are evidence based, there needs to be data to drive the processes. Barriers to good data collection include daily time pressures, inadequate technology support, fear of self-incrimination, culture of blame, and sense of futility if the effort is seen as a formality to satisfy a monthly meeting requirement. Staff needs to believe that the effort will result in improved, safer care. The medical director must lead the QAPI team in such a way that the team learns from their experience.

The medical director will need knowledge of QAPI tools to define and analyze problems identified by following leading indicators. The medical director will recruit members of the medical staff to participate in structured problem solving. The team takes actions based on the perceived causes, monitors the effect of the intervention, refines and then ultimately implements changes to address the problem.

The medical director must ensure that systems of care are designed to reduce error and risk. Drills and simulations for fire, evacuation, quick disconnection, cardiac arrest, air embolus and others can be conducted to prepare staff for low frequency high risk events. The safety program should account for the anticipation of likely errors and mitigate their risk and impact. An effective safety program encourages “near-miss reporting” which fosters the studying of near misses and underlying latent errors in the process of care that can align to cause serious harm. The safety team searches for system errors to remediate, not a human agent to blame. The medical director and facility leadership can make safety rounds to listen to staff about their concerns about safety and work processes. The safety program should be credible to staff and patients when it addresses issues identified by the staff and patients as important and it should also increase staff and patient engagement.

While not specifically required under the CfC, ensuring coordination of care outside of the dialysis facility is increasingly becoming part of the medical director’s responsibility (Jones & Hostetter, 2014). Better communication among and between care givers about patients in different venues of care is necessary to reduce the risk of acting (or not) on incomplete information. Transitions between states of health (e.g. CKD to ESRD, failed transplant to dialysis) or venues of care (e.g. dialysis facility, hospital, emergency room, outpatient surgery, physicians’ office, nursing home) are opportunities for errors in commission or omission. The medical director is uniquely positioned to improve transitions of care (Hakim & Collins, 2014) through involvement in the medical staff of these various venues. Reducing admissions and readmissions will reduce morbidity and the cost of care. Working to spare veins, avoiding peripherally inserted central catheter (PICC) lines, arranging for arterio-venous fistula (AVF) placement during CKD hospitalizations, and communicating medication changes among other activities will likely reduce morbidity, prevent hospitalization and lower readmission rates. These cost savings measures will become increasingly important as more global payment systems such as countable care organizations—ACOs and, specific to kidney disease, ESRD Seamless Care Organizations—ESCOs—develop.

Effective and safe dialysis requires well maintained dialysis machines, water and dialysate (acid and bicarbonate) production and distribution systems. Each should be used maintained according to manufacturer’s directions for use. The systems need to meet or exceed the pyrogen and bacteriology standards incorporated in the CfC. The medical
director should be familiar with the applicable standards and oversee all aspects of the biomedical department – dialysis machine and water treatment. The medical director should assure that records documenting this compliance are up to date and complete, and should also know the function of each component, its limitations, and risk to patients if it fails. The QAPI team, guided by the medical director, should have contingency plans when the water system fails. The medical director should understand the dialysis machines, including how the machine operates, what the alarm states mean and how to use the accessories such as on line clearance, access flow monitoring, and various profiles controlling temperature, ultrafiltration and dialysate sodium. Where practiced, reprocessing of hemodialysis filters poses unique risks to the patient. Various automated methods exist. The medical director should understand the risks of each step in the process of dialyzer reprocessing if his or her facility employs re-use.

Contrasts between Responsibilities of Attending Nephrologists and Medical Directors

The skills required to be an effective medical director are quite different than those required to provide nephrology care to individual patients in the dialysis facility. While the medical director needs to have the same fundamental nephrology knowledge base as the attending nephrologist, he or she is focused on the quality, processes and outcomes of the facility patients as a group (population management). This contrasts sharply with the attending nephrologist who evaluates and manages individual patients to obtain the best outcome for their unique situation. The attending nephrologist is a diagnostician and clinician, evaluating the individual patient’s health and response to treatment, and writing orders directing individual patient care. An effective medical director involves the attending nephrologist in the development and implementation of facility wide protocols that ensure treatment is evidence based and consistent within the facility. As the attending nephrologist regularly evaluates patients to recognize who is doing well with the protocol treatment and who requires individualized adjustments because of unique circumstances, the opportunity to enhance patient care is optimized. Medical directors typically serve within the facility as both directors (responsible for QAPI, etc.) and attending nephrologists. The effective medical director is able to transition from treatment of an individual patient to a population outcome focus depending on the role at the time.

The attending physician has responsibilities mandated by the CfC. He or she is expected to participate in the interdisciplinary team (IDT) and formulate the care plan for the patient. The attending physician can participate in person or telephonically, and is expected to provide the complete assessment and the point of care note. (The patient is to be offered the opportunity to attend the point of care meeting.) The responsibilities of the attending physician are to abide by the regulations of the CfC, state regulations, and facility roles and responsibilities. Attending physicians should be cognizant of how the medical director responsibilities set forth in the medical director agreement impact the attending physician’s responsibilities within the facility. The minimum requirements include a monthly visit with appropriate documentation by either the nephrologist or his or her advanced practitioner. In addition, quarterly visits by the nephrologists while the patient is on dialysis should occur. It should be pointed out that CMS regulations establish a floor for outcomes and processes. One should review the facility bylaws for direction but most require attending medical staff meetings and participating in the QAPI process.
As an essential member of the patient care team, the attending physician needs to participate in appropriate activities to optimize the achievement of quality outcomes. The medical director oversees the development of protocols and processes which could result in quality outcomes congruent with the goals of the dialysis company, as well the objectives of other programs (e.g., Quality Incentive Program, Five Star program, etc.) and entities (e.g., ESRD Networks). The attending physician should not be a spectator in the quality improvement process, but rather an active participant working with the medical director to accomplish established protocols and outcomes. Lastly, despite the number of patients they may be rounding on for that month, the attending physicians should participate in the facility’s quality improvement programs.

**Medical Director Value**

The effective medical director has clinical, business and leadership acumen, and is therefore critically important to patients, dialysis facilities, and agencies charged with oversight of dialysis care delivery (State Health Departments, Renal Networks, etc.). A highly functioning medical director brings great value to a dialysis facility’s patients, staff, attending physicians, and owners. In this unique role, medical directors function as scientists, teachers, coaches, peer mentors, mediators and negotiators – serving the patient’s interests.

**Value as a Nephrology Clinician**

Nephrology training is fundamental to being an effective medical director. The nephrologist has specialized knowledge of kidney diseases, fluid and electrolytes, volume regulation, hypertension, anemia, bone-mineral metabolism, vascular access, pharmacology, and other comorbid conditions that impact on patient care and outcomes. Additionally, the nephrologist has detailed knowledge of dialysis modalities and their application to patient care, and also has an understanding of the diagnosis and management of complications that can arise during the dialysis treatment. The nephrologist medical director should be able to assess the scientific validity of protocols guiding dialysis patient care. Except in very unusual circumstances, the dialysis medical director should have the fundamental knowledge base of completing nephrology fellowship training.

**Value as Quality and Safety Officer**

The Medical Director leads the physician staff of a dialysis clinic. In this pivotal role, the goal is to establish uniform high quality care, delivered by all practicing physicians (Van Wyck, Robertson, Nissenson, Provenzano, & Kogod, 2010). This includes physicians adopting facility policies, corporate initiatives, or regulatory mandates. The medical director has quality assessment and performance improvement expertise which allows him or her to guide continuous improvement efforts.

Patient safety is perhaps the area where the value of an effective Medical Director is most apparent. By creating an atmosphere of open, active communication between patients, staff and administrators, an effective medical director encourages the reporting, evaluation and correction of safety issues. Through his or her attentiveness to detail, integrity, and accountability, the medical director serves as a role model for facility staff.
Value as Facility Leader

As the key leader in the dialysis facility, the medical director sets the example of compassion and professionalism within the facility. He or she should be regularly present in the facility – interacting with staff and patients to observe firsthand the operations and issues. The medical director is a resource for the clinic manager, and the two work closely together to address all aspects of facility operations, and should also be a resource for patients who may have concerns related to facility staff, operations or their own clinical care. The medical director communicates with other attending physicians to obtain their input and keep them informed.

Value as Business Partner

The medical director may not be the owner of the dialysis facility, but a competent medical director will positively impact the facility’s business operations, as the dialysis facility’s financial performance is increasingly tied to the individual physician’s performance in patient care. This includes documentation of care, management or coordination of patients' comorbidities, coordination with hospitals, and documentation requirements for complex bonus payments. Through the medical director’s leadership, performance of attending physicians can lead either to payment reduction or enhancement.

The medical director is instrumental in the provision of cost effective care for the facility in a number of ways. An effective QAPI process reduces hospitalizations, missed treatments, and enhances patient satisfaction and compliance. Currently, up to a 2% penalty in annual Medicare payments can be withheld if the facility fails to meet CMS Quality Incentive Program (QIP) goals. The medical director can help to ensure these quality goals are met. By reducing the risk of adverse events, the medical director reduces liability for the dialysis provider. Finally, the medical director can identify and remediate wasteful practices within the clinic, and provide advice on capital expenditures. An effective medical director can positively impact staff turnover by improving job satisfaction and morale.

Value as Regulatory Liaison

The medical director should have a working knowledge of the role of various agencies and regulatory bodies that interact with the dialysis facility (Appendix B). The medical director, with the facility manager, interacts with the ESRD Network, State Health Department, CMS or other bodies charged with oversight of the facility. Through personal involvement in any issue of patient or staff conflict or grievance, the medical director ensures the facility complies with regulations related to discrimination, IVD/IVT, admission, or other adverse action. During state and federal certification surveys, the active participation of the medical director can greatly improve the probability of a positive outcome. Surveyors often look to the medical director for cooperation and willingness to constructively consider ideas for improvement.

Conclusion

The dialysis facility medical director plays a pivotal role in ensuring high quality, patient-centered dialysis care. The responsibilities of the medical director as outlined in the CfC are extensive and expect the medical director to commit ample time to this endeavor. An
engaged and effective medical director is critical to ensuring high quality dialysis patient outcomes. Nephrologists work hard to fulfill this role but at times struggle with two significant barriers: training and time.

Nephrology training is fundamental – but insufficient by itself. The skills required of effective medical directors involve many activities that are not inherent to current nephrology fellowship training. Nephrologists who aspire to be medical directors must seek out and obtain training to develop additional leadership, business and quality improvement skills. Dialysis providers should require this additional training for both new and established medical directors, and medical directors should avail themselves of continuing education related to the medical director role.

Nephrology practice does not automatically allow adequate time to be an effective medical director. The medical director must be regularly present in the dialysis facility so that he or she can directly observe operations, staff and patient interactions and other care delivery issues. He or she must be able to interact personally with the clinic manager and other facility staff – as well as with patients from all days and shifts. Additionally, the medical director must be available by phone at all times that the facility is open so that if urgent issues arise he or she can assist with decision making. Nephrology practices and medical directors are obligated to dedicate the time required to effectively serve the facility and patients in this role.

The educated and engaged medical director is key to a successful dialysis facility, one that delivers high quality, cost efficient care with satisfied patients, staff and physicians.

**Recommendations**

1. A medical director with nephrology training and expertise is critical to the quality and safety of dialysis patient care.
2. The nephrologist who serves as medical director should have specific training to ensure that they are equipped with the skills required.
3. The medical director must dedicate significant time and attention to fulfilling this role.
4. Medical directors should engage in the management of their facility’s ESRD patient population beyond the walls of the facility.
References


Appendix A: Skills Inventory

**Interpersonal Skills**
- Team skills
- Communication
- Negotiation
- Consensus building
- Awareness and mastery of personal impact and style
- Active listening
- Attention in meetings
- Punctuality
- Availability
- Follow through
- Align conflicting priorities to work towards best care for patients

**Business and executive competence**
- Understand the medical director contract
- Competent at setting agendas and managing meetings
- Able to make business case for quality
- Able to read balance sheet, cash flow report, and profit and loss statement
- General understanding of facility operations
- Understand and guide all phases of development, implementation and revision of clinical policies and procedures
- Understand the specific requirements of protocols related to medications

**Specialized knowledge**
- Knowledge of clinical patient care
  - Kidney diseases
  - Dialysis – principles and practice of all modalities including complications
  - Kidney transplantation, basic understanding
  - Volume status and regulation
  - Vascular access
  - Anemia
  - Bone mineral metabolism
- Knowledge of regulatory issues
  - Understand the CfC, interpretive guidance and core survey process
  - Familiar with all rules and regulations related to IVD/IVT
  - Understand the role of regulatory agencies including: CMS, Renal Networks, State Departments of Health, AAAMI, NFPA, OSHA, EEOC, FDA, OCR, and CDC
  - Understand CDC recommendations for infection control and ensure facility policies and procedures are compliant with all infection control guidelines
- Knowledge of quality assessment and performance improvement
  - Understand quality improvement principles
  - Ability to lead QAPI including rapid cycle PDSA, root cause analyses, data display and analysis, etc
  - Understand how to lead a culture of safety
  - Understand the publicly reported data for the facility
• Knowledge of integrated care
  o Understand importance of care transitions to patient outcomes
  o Understand how to coordinate care among multiple sites and providers
  o Understand population health

• Knowledge of technology
  o Understand facility biomedical department issues including water system, dialysis machine, etc
  o Understand the areas of increased risk for patient safety within the dialysis facility
  o Understand the facility electronic medical record and quality data reporting capabilities
Appendix B: Regulatory Agencies

- **End Stage Renal Disease Networks (the “Network”)**
  - Under contract with CMS to advance the national ESRD quality and safety agenda, to assist providers in improving their performance and to receive, investigate, and resolve patient complaints and grievances. As part of their contracted statement of work (SOW), the networks have specific aims and tasks. These often require the cooperation and participation of facilities in the network. Facilities participate either by random selection, volunteering, or having an outlier status in one more quality indicators (e.g., mortality, catheter rate, etc.). While the networks are not able to force facilities to participate, facilities that consistently fail to cooperate with the networks can be referred to CMS for alternative sanctions by which Medicare funding is withheld until compliance is assured. The networks cooperate with the survey agencies in resolving quality of care issues, situations of immediate jeopardy and the process of involuntary discharge. It is more useful to see the Network as a resource and collaborator. They are a clearing house for tools, information and expertise in all aspects of safety and quality. They can and should be asked for their help with facility specific quality improvement projects. They are also able assist the staff in resolving conflicts with patients that reduce the chance of an IVD/IVT.

- **The Association for the Advancement of Medical Instrumentation (AAMI)**
  - Standards are incorporated by reference in the CfC. They define dialysis technology standards, water standards, and dialyzer reuse.

- **National Fire Protection Association (NFPA)’s Life Safety Code (LSC)**
  - Governs egress, emergency lighting, fire suppression equipment, evacuation, etc. There is a separate survey aimed at assessing compliance with the LSC.

- **Disaster planning and Emergency Preparedness**
  - Governed by specific CMS rules and regulation. The rules and regulations are currently under review. The proposed rules impose significant additional requirements specific to ESRD facilities.

- **Occupational Safety and Health Administration (OSHA)**
  - Standards define the obligation of the dialysis facility to the safety and health of employees.

- **The Equal Employment Opportunity Commission (EEOC)**
  - Protects employees from work place discrimination in hiring, promotion, discipline, and discharge.

- **Food and Drug Administration (FDA)**
  - Controls the use of medications, medical devices, and adverse (medication and device) event reporting. The major duty is to prescribe according to the directions for use (package insert) and to report possible adverse drug and device events.
• **Office of Civil Rights (OCR)**
  o Has enforcement authority over the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health act (HITECH). The state also has some standing and authority under HITECH. Both rules govern patient privacy and the safe transfer for protected health information (PHI). HITECH rules require risk assessment and mitigation practices. There are serious financial penalties for failure to comply or breaches.

• **Centers for Disease Control and Prevention’s (CDC)**
  o Rules for infection control are incorporated in the CfC. Beyond the rules, the CDC hosts a dialysis safety website that provides multiple tools and resources for infection control and intravascular catheter management. Participation in the National Health Safety Network is now mandated as part of the CMS Quality Incentive Payment program (QIP).