Medical Director Responsibilities for Inpatient Hemodialysis and Other Extracorporeal Services

Executive Summary

Although there is no regulatory requirement for a hospital inpatient Medical Director for extracorporeal services (unlike that required in the outpatient dialysis setting), physician leadership duties and responsibilities for these services bear striking similarities to those of their outpatient counterparts. Medical Director obligations in End-Stage Renal Disease facilities are formally described and mandated in the Conditions for Coverage released in 2008, as noted below. Moreover, the scope of extracorporeal services provided in hospitals has expanded beyond that of routine hemodialysis. RPA believes that the safe, effective, and quality provision of hospital extracorporeal services are best achieved under the guidance of a nephrologist with expertise and experience in these activities.

Background and Purpose

The End-Stage Renal Disease (ESRD) Facilities Conditions for Coverage (CFC), released by the Centers for Medicare & Medicaid Services (CMS) in April 2008, reshaped the roles of outpatient facility Medical Directors as part of a comprehensive update in standards with the goal of ensuring the provision of quality care to all dialysis patients. Subsequently, RPA developed the Position Paper on Dialysis Facility Medical Director Responsibilities under the Revised CMS Conditions for Coverage for End-Stage Renal Disease Facilities. In addition to outlining the general duties and responsibilities of medical directors and supporting the core principles underlying the revised regulations, RPA noted in this paper that Medical Directors of inpatient hospital dialysis facilities would likely bear duties and responsibilities parallel to their counterparts in outpatient facilities, despite the restriction of CFC to the outpatient arena.

Moreover, Medical Directors of dialysis in the inpatient hospital settings at times may oversee extracorporeal services beyond that of routine acute hemodialysis, as described below. The purpose of this document, therefore, is to comprehensively outline, whether applicable in part or in whole, the duties and responsibilities of a nephrologist in such a position. Other issues discussed are the scope of extracorporeal services typically falling under these positions, applicable regulations and standards, the appropriate expertise and characteristics a physician should possess to serve as a Medical Director, and issues related to Medical Director contractual agreements.
RPA intends for this document to be a resource for nephrologists not only for its content in the performance of these services but also to assist in the contracting process with hospitals or appropriate entities. This document may also be used to more fully inform hospital administrators of what is expected and required by The Joint Commission and other surveying agencies of hospitals providing extracorporeal services.

Discussion

Scope of Extracorporeal Services
As noted above, today’s inpatient dialysis medical director may have or be assigned supervisory responsibilities over a broad scope of services beyond hemodialysis. These services include but are not limited to:

- Hemodialysis
- Continuous Renal Replacement Therapies
- Peritoneal Dialysis
- Ultrafiltration (such as for CHF)
- Apheresis*

While each of these services may be distinct with regard to performance, they share in common the necessity of a similar scope of activities in oversight and quality improvement leadership that can best be delivered by a nephrologist serving as Medical Director.

*Apheresis is included herein only for those nephrologists who have education and/or experience in apheresis therapy which would qualify them as Medical Directors of these services where applicable (See www.apheresis.org; click ASFA Guidelines).

Applicability of Regulations and Standards
CMS and/or The Joint Commission (TJC) mandate that hospitals appoint Medical Directors for some but not all services provided in their facilities. For example, Medical Directors are required in Skilled Nursing Facilities, inpatient Psychiatry, Rehabilitation Units, and Laboratory Services, among others. A Medical Director for inpatient hemodialysis services is not a mandatory requirement of either CMS or TJC.

Nonetheless, the provision of all services in a hospital environment, whether delivered by the facility or contractually, is expected to conform to CMS’ and TJC’s regulations and standards. The intent of these expectations is to demonstrate basic principles in risk reduction, patient and staff safety, staff competence, and performance improvement. In addition to leadership oversight for overall quality care, a nephrologist Medical Director would be in the best position to positively impact these aspects of care delivery and management affecting the provision of extracorporeal therapies.

Throughout the remainder of this paper, references to CMS or TJC regulations and standards applicable to dialysis or other extracorporeal services provided in the hospital will be cited.
Choice of Medical Director
RPA believes that safe and effective performance of Medical Director responsibilities requires not only nephrology expertise with a solid grasp of data interpretation and performance improvement, but also an ability to address administrative and supervisory matters of staff and other physicians, often with some political and leadership skill. Therefore, at the basic level, a Medical Director must be a physician licensed in the state where the services are provided and in this role functions as a professional staff member of the hospital. He or she should meet the qualifications CMS mandates for End-Stage Renal Disease (ESRD) outpatient facilities, specifically in that he/she should have >12 months experience or training in the care of patients in the outpatient setting. Satisfactory completion of an accredited nephrology training program and current Nephrology Board Certification status are highly recommended. Moreover, the Medical Director must be willing and able to commit sufficient time to perform his/her duties and responsibilities above and beyond the activities of a practicing nephrologist.

Duties and Responsibilities

Matters of Quality and Patient Safety

- Oversee the inpatient extracorporeal services, assuring the proper coordination and functioning of all activities within each program consistent with the written contract and objectives and goals, policies, bylaws and rules and regulations of the hospital and/or other involved entity.
- Be accountable to the hospital leadership for the overall quality of medical care provided to patients receiving extracorporeal services. (CMS 482.22; TJC LD.01.05.01)
- Address any conflict of interest that affects or could affect the safety or quality of care, treatment or services provided. (TJC LD.02.02.01)
- Identify and resolve any disruptive physician activities, including but not limited to inappropriate prescription, scheduling, interpersonal behavior, or nonconformance to applicable policies, rules, or regulations.
- Lead and participate in regularly scheduled data-driven quality assessment and performance improvement activities (CMS 482.21; TJC MS.05.01.01) to include but not be limited to:
  - Measurable improvement in program quality indicators
  - Performance improvement projects
  - Identification and reduction in medical errors
  - Reporting of these activities within hospital medical staff leadership hierarchy.
- Ensure that extracorporeal services are accounted for in the hospital’s program for prevention, control and investigation of infections and communicable diseases (CMS 482.42) that may involve as necessary vascular accesses, dialysis water quality, equipment cleaning, gowning and gloving, and hand hygiene.
- Review reports of federal, state, or local hospital surveys related to provision of services and participate in development and implementation of plans of correction as necessary.
- Ensure that there is a sufficient number of competent staff who receive initial and ongoing training necessary to support the care, treatment, and services to meet the needs of the applicable population. (TJC HR.01.01.01)
- Ensure participation in the hospital’s Patient Safety Program (TJC LD.04.04.05) to include compliance as applicable with National Patient Safety Goals:
• Utilization of two patient identifiers when administering medications, blood or blood components, collecting blood samples, or performing treatments
• Timely reporting of critical tests and critical results
• Medication safety
• Activities to reduce risk of health-care associated infections
• Ensure creation and implementation of processes utilizing ongoing collaboration/communication between hospitals and providers of outpatient services where applicable in order to provide safe and quality transitioning of patient care in and out of the hospital.

Matters of Administration within Hospital

➢ Review, approve, and implement policies that guide and support patient care, treatment, and involved services (TJC LD.04.01.11) in collaboration with hospital leadership or other involved entity as applicable.
➢ Ensure that adequate physician coverage exists for all inpatient services to be provided.
➢ Collaborate with hospital’s or other involved entity’s personnel who have operational responsibility for these services to oversee adequate nursing services and backup support.
➢ Assist in developing policies and procedures for care of patients requiring extracorporeal services in disaster scenarios.
➢ Ensure that documentation related to quality assessment and performance improvement activities, whether technical or professional, is forwarded to hospital medical staff committee with oversight over extracorporeal services.
➢ As requested by hospital, participate in hospital committees related to provision of inpatient services and assist in preparations for regulatory surveys.
➢ If inpatient extracorporeal services are provided on a contractual basis, address improvement efforts if services do not meet expectations described in contract. (TJC LD.04.03.09)

Considerations in Medical Director Contracts
A specifically detailed written contract is expected to secure the commitment of the Medical Director in fulfillment of duties and responsibilities and the time involved. The parties to the contract may vary depending on the circumstances of the provision of the services. In one situation, a hospital that directly provides personnel and equipment for the provision of extracorporeal services may simply enlist a qualified nephrologist as Medical Director. In another circumstance, a dialysis organization may contractually provide the services for the hospital, in which case the nephrologist might contract with the organization.

RPA urges nephrologists to contemplate the following considerations when entering into contractual discussions for Medical Director arrangements with hospitals, health systems, or other entities:

➢ Hospital leadership/administration and/or other involved entity have obligations to assist medical director as necessary to effectively carry out duties and responsibilities.
➢ The hospital or other involved entity should bear responsibility for legal support for activities involved, as duties and responsibilities described herein remain separate from those of an attending nephrologist.
The necessity and benefits of establishing a process for succession of leaders.

While hospitals may not likely request a non-competition covenant, Medical Director contracts with dialysis organizations often will include one.

Monetary compensation should be at fair market value taking into consideration the scope of the services outlined, the expertise of the nephrologist, and the time involved in order to fulfill obligations described in contract.

Summary

Given that physician roles tend to evolve with the development of newer technologies and services provided as well as with changes in regulations, it should be recognized that the duties, responsibilities and considerations listed herein in time will likely change.

Nonetheless, RPA believes that this document serves to comprehensively and accurately reflect the scope of those activities occurring at the time this paper was approved by the RPA Board of Directors.