

Approved by RPA Board 3/20/2009

RPA Position Paper on Dialysis Facility Medical Director Responsibilities Under the Revised CMS Conditions for Coverage for End-Stage Renal Disease Facilities

Executive Summary

RPA endorses the core principles that form the basis for the CMS Conditions for Coverage (CFC) for ESRD facilities, and supports the key roles established for the dialysis facility Medical Director set forth in the CFC. RPA believes that the specialized cognitive and technical skills of nephrologists make them the most qualified individuals to serve as facility Medical Directors, and that Medical Directors must possess and employ good leadership skills in order to maintain a high performing and safe dialysis facility. RPA supports the use of the Quality Assessment and Performance Improvement (QAPI) process, under the leadership of the facility Medical Director, as an integral component of the delivery of high quality care in the dialysis facility, and recognizes the importance of documentation of the patient's clinical indicators in that process.

Background

In 1972, legislation enabling patients with End-Stage Renal Disease (ESRD) to be eligible for Medicare benefits (as the only disease-specific Medicare entitlement) was first enacted. Subsequently, the Federal Government developed regulations establishing the criteria that dialysis facilities were required to fulfill in order to be eligible to provide care to Medicare beneficiaries. These regulations, called the Conditions for Coverage (CFCs) for ESRD Facilities, determined that Medical Directors were a necessary part of the dialysis facility team, and specified a central role for the Medical Director in the clinical oversight of the dialysis facility. Therefore, the role of the dialysis facility Medical Director has been defined since the advent of regulation overseeing the Medicare ESRD program.

In April 2008, after years of issuing drafts and soliciting comments from the renal community, a final rule implementing the first revisions since 1976 to the regulations governing the operation of dialysis facilities in general, and the expectations for Medical Directors specifically, was released by the Centers for Medicare and Medicaid Services (CMS). These revised CFCs were effective in October 2008. In addition to the final rule, CMS also issued Interpretive Guidelines for the CFCs, which provide guidance to state surveyors on how to implement the CFCs on a point of contact basis, offering direction on how to review the activities and processes in dialysis facilities, and which include a "Measures Assessment Tool", which is discussed in detail later in this paper. The complete Conditions for Coverage final rule can be found at: www.cms.hhs.gov/CFCSSsAndCoPs/downloads/ESRDfinalrule0415.pdf, and the Interpretive Guidelines with the Measures Assessment Tool can be found at: www.nraa.org/Documents/SC-09-01_ESRDIGs1%201_memo.pdf.

Nephrologists and other physicians who have contracted with the facilities to serve as Medical Directors will be expected to know the content and the processes thoroughly in order to comply with the terms of their contracts. For the facility to retain its right to treat Medicare and Medicaid beneficiaries, substantial compliance with the CFCs is necessary.

Broadly, the oversight function of the Medical Director includes responsibility for processes of care and outcomes, staff education, dialysis technology, water quality and reuse, and infection control. The Medical Director is also responsible for developing and implementing the Quality Assessment and Performance Improvement (QAPI) program related to patient care described in the CFCs, in conjunction with the facility's interdisciplinary care team. Additionally, the Medical Director is expected to be knowledgeable about all the aspects of facility operation for which he/she is responsible, and should be prepared to demonstrate this knowledge if requested by state surveyors. Further, the Medical Director is accountable for the patient care processes and outcomes achieved by members of the medical staff of the facility, and is responsible for facilitating the quality improvement of underperforming physicians.

While RPA recognizes the challenges presented to dialysis facility Medical Directors by the revised CFCs, it nonetheless strongly endorses the core principles which form the basis for these rules. During the formative writing processes for these rules and guidelines, the RPA provided recommendations and other critical information to CMS and had substantial influence on the development of important modifications. Accordingly, the RPA endorses the vast majority of the CFCs provisions as they foster the improvement of patient outcomes and the effective use of resources at the provider level. RPA recognizes that high quality medical direction of dialysis facilities is a critically important component in the provision of high quality medical care to ESRD patients.

Discussion

General Duties and Responsibilities of the Dialysis Facility Medical Director

As noted above, the federal government has recently instituted unfamiliar rigor to the processes for which the Medical Director is responsible. In reviewing the revised regulations, the RPA leadership has concluded that, despite the challenges of compliance with the requirements, they are in principle a correct approach. Further, it is RPA's opinion that once the Medical Director decides to deploy strong leadership, concern for the operations of the facility, and care of the patients under his/her administrative supervision, he/she will find that the dialysis facility owners and managers will likely reciprocate by providing the necessary tools to support these objectives.

Safe and effective performance of the Medical Director duties requires not only medical expertise, but sophisticated knowledge of group data, control charts and their interpretation, methods of performance improvement, and an instinct to understand the values of leadership, problem solving, delegation and good record keeping. In addition,

knowledge of many specific operational details such as the methods of dialysate water preparation, of bacteriological safety, and of dialysis technology is needed.

The recent rules and guidelines are more explicit regarding the interaction of the Medical Directors' role and that of the governing body of the facility, as well as the responsibilities of medical direction. The government requires an annual estimate of the time devoted by the Medical Director to carry out these roles. This estimate is transmitted in a cost report document by the facility owner based on information provided by the Medical Director or the practice acting on his behalf.

Specific Responsibilities of the Dialysis Facility Medical Director Set Forth in the CFCs

To elucidate the roles of the Medical Director, this document will review them in an outline of the government's expectations of the operation of the dialysis facility. The general approach of the CFCs is to assert what must be done within each area of activity and to accompany that with reference to accountability of the Medical Director. Most of these activities are the direct responsibility of the facility staff and its senior experts in water preparation, log maintenance, organization of meeting responsibilities and so forth. RPA believes that in all cases, while the Medical Director is not expected to carry out these individual tasks, he/she is ultimately responsible for the oversight of their conduct and completion. Further, he must be recognized by the staff of the facility as a person who cares about the activities, who queries the responsible staff, and who takes the documentation seriously. Most important is the leadership expected in initiation and support of Quality Assessment and Performance Improvement (QAPI) activities.

Specific areas under his purview (with comments about minimal required activity and knowledge base) include:

1. Operate the unit according to the regulations in order to be paid for services by CMS.
2. Understand that state surveyors are acting on behalf of the federal government and should be treated respectfully while they fulfill their responsibilities.
3. Implement QAPI procedures. These processes presume a staff and Medical Director culture which embraces and uses QAPI to continue the efforts build better practices in the facility. The Medical Director must have a thorough knowledge of QAPI processes (examples of managing QAPI process are given in appendix A) and is responsible for seeking opportunities to deploy this method and to guide the process. Surveyors will in most situations be reviewing clinical outcomes data and the records of the QAPI activities of the facility, and will interview responsible staff, including the Medical Director. Failure to produce evidence of compliance with this process may threaten the facility's certification.
4. Maintain a focused and continuous surveillance process for infection control data. Evidence for this will be sought by the surveyors, including observations of care delivery, interviews with staff and patients, review of medical records, facility logs, and policies and records of QAPI procedures. The Medical Director must

therefore be aware of trends, and promptly lead processes to review and act on trends which are unfavorable.

5. Follow the recommendations governing water and dialysate preparation (as promulgated by of the Association for the Advancement of Medical Instrumentation's—AAMI's—"American National Standard for Dialysate for Hemodialysis"). The Medical Director is ultimately responsible for the safety and quality of the water used for patient treatments. Additionally, the Medical Director will be expected to sign logs and forms demonstrating knowledge that the process is operating safely. Medical Director must understand the principles of water preparation, including the various steps taken to achieve efficient and safe water, as well as the key monitoring steps.
 - Oversee programs and policies to ensure safe mixing of water and dialysate. The regulations focus on the risk that there might be a mismatch of machines and the concentrate designed to be used at a different ratio. The Medical Director should thus understand these processes and lead programs which ensure correct mixing.
 - Ensure the installation and operation of safe water and dialysate distribution systems. The Medical Director will have to be aware of the possibility that certain disinfectants can alter the integrity of the piping.
 - Oversee monitoring and analysis of safe central bicarbonate mixing procedures. The Medical Director must have a basic understanding of the principles of mixing bicarbonate, and the special hazards of contamination of this fluid.
 - Ensure that personnel carrying out reuse processes are properly trained and certified. The guidelines specify that the Medical Director must sign off on any reuse training completed. Any training programs must be approved by the Medical Director.
 - Oversee monitoring of safe water regulations and specifications. The language in the regulations make clear the necessity for the Medical Director to understand the inherent risks in clearing incoming water of chloramines, chlorine, copper, aluminum and other potential hazardous materials.
 - Ensure that the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting applicable requirements at the time of installation.
6. Implement patient assessment requirements. The regulations surrounding this issue are quite detailed. The surveyor has been instructed to look for evidence that the nurse, physician, dietitian and social worker act together as an "interdisciplinary care team" (ICT) to perform an extensive list of activities. This list includes documentation of all co-morbidities, evaluation of the entire dialysis prescription, review of immunization, laboratory value surveillance, regulation of anemia control and nutrition, and evaluation of the hemodialysis access. The Medical Director is expected to manage and resolve differences of opinion within the ICT. These requirements are quite detailed and will, in most cases, be guided by the Dialysis Organization operating the facility. Documentation requirements to demonstrate adherence are difficult and require evidence of an attempt to

involve the patient and/or the family. The Medical Director also has the responsibility for maintaining an ongoing, improvement-oriented culture of compliance. These requirements include, but are not limited to, initial assessments by the staff and attending physicians, and establishing corrective action plans (which can state that no further remedies are available) when individual patient goals are not met (Appendix B has additional information about the “Measurement Assessment Tool”).

- All of the documentation guidelines noted in the CFCs have specific time line requirements. These include: an annual complete assessment as the minimal expectation applicable to “stable patients” (mostly defined by the ICT); monthly evaluations for unstable patients, and patients with unexpected deterioration of medical, social, nutritional or psychological status, until “stability” is declared. There has been acknowledgement by the government that very sick patients whose conditions are unchanged may be characterized as “stable” as long as documentation of their status is complete. (Appendix C provides the definition of “unstable patient” as indicated in the CFCs.)
 - The documentation should include evidence that the ICT supervised by the Medical Director has recorded evidence of proper consideration and referral for transplantation, home dialysis modalities, and vocational rehabilitation.
 - The documentation should address plan development for so-called “unstable patients” and, again, the Medical Director shares responsibilities for maintaining the culture of the facility that creates habitual practices of this sort.
7. Develop or oversee all policies and procedures.
 8. Take a leadership role in developing requirements of education and performance by the medical staff including hiring of medical staff and, where necessary, counseling of members of the medical staff.
 9. Develop and monitor implementation of a policy to address concerns emanating from disruptive patients. The Medical Director will often be called upon to play a role in problem solving for such issues. The specific language from the Interpretative Guidelines is: *“The medical director must monitor and review each involuntary patient discharge to ensure that the facility interdisciplinary team follows the discharge and transfer policies and completes the steps required under the Condition for Governance.”*

Qualifications and Time Expectations of the Medical Director:

The specific personnel requirement for a Medical Director in the final rule for the CFCs was that he be board-certified in internal medicine or pediatrics. However, based on recommendations made by RPA and other renal organizations, the Interpretive Guidelines were revised to include the following language:

According to the websites of the American Board of Internal Medicine (ABIM) and the American Board of Pediatrics (ABP), a physician does not need to maintain certification in internal medicine or general pediatrics to recertify in nephrology or pediatric nephrology. Therefore, a medical director may maintain

current certification in nephrology or pediatric nephrology or current certification in internal medicine or general pediatrics. CMS accepts the position of the ABIM and ABP and accepts current board certification in internal medicine, pediatrics, nephrology, or pediatric nephrology as meeting this requirement

Exceptions are allowed in special circumstances; a model letter for seeking a waiver of the Medical Director personnel requirements and a table outlining the procedures for seeking the waiver are included in Appendix D.

The RPA also believes that the qualified Medical Director is a person who is committed to the processes of leadership, motivation, and quality improvement. There can be only one Medical Director for the facility, and co-medical direction is forbidden. However, delegation of responsibilities to other physicians is permitted so long as all follow the QAPI process, supervised by the Medical Director.

With regard to time expectations, the regulations state that the Medical Director should “devote sufficient time” to carry out his responsibilities; and offers as a “guideline” that the job requires one quarter of his time. The number of hours this “guideline” is based on is not written; however most time-related guidelines are based on the assumption of a forty hour work week. The language addressing time expectations from the Interpretive Guidelines is provided below:

The medical director should devote sufficient time to fulfilling these responsibilities. As a guideline, the financial cost report each facility must file annually with CMS considers the medical director position to reflect a 0.25 FTE.

Common Duties of Medical Directors Not Included in the CFCs

Many companies expect contributions from the Medical Director with regard to business opportunities and may delineate these duties in contracts. These contributions may include but will not be limited to: business planning in general, addressing issues regarding certificate of need where applicable, participation in the construction and development of new facilities (including finding new land for the facility), and acting as an advisor intermediary in negotiations with other providers.

Medical Direction of Non-ESRD Facilities.

While the Conditions for Coverage comment on the duties and responsibilities of the dialysis facility Medical Director, they do not comment on the Medical Director’s role if the dialysis facility contracts with a hospital or a nursing home to perform dialysis services, where the patients being dialyzed are clearly not within the dialysis facility, but are, in fact, in-patients. The Medical Director will in all likelihood have parallel duties and responsibilities in this setting, especially in the area of the technical quality of the dialysis, the training and professionalism of the staff performing the contracted dialysis,

and in relationships with physicians prescribing and performing dialysis in that inpatient facility.

Medical Director Contracts

Contracts with dialysis organizations and other facility owners will contain language referencing the requirements listed above for ESRD facilities and perhaps those not listed by the government, including possibly separate contracts for medical direction of hospital and other non-ESRD facilities. The contract must not be linked in any way to the referral of patients. The size of the facility can be a determining factor for reimbursement. Reimbursement can be calculated at “fair market value” which is a mutually agreed value of the quality and importance of the services rendered. It does not necessarily derive from the number of hours devoted. But as noted above, there is an expectation that doing the job will require about 25% of a normal work week. Most federal references to a “normal” work week assume a 40 hour week. The contract may be with an individual physician or a physician practice. In both cases, a specific individual must be identified. Nephrologists should refer to the RPA position paper entitled “*Medical Director Agreements for Nephrologists*” for a more detailed discussion of the issues surrounding dialysis facility Medical Director contracts.

Medical Director Duties and Pay for Performance:

As part of the QAPI program for the facility and in conjunction with the ICT, the Medical Director is responsible for assuring that targets for clinical performance measures (CPMs) are achieved and maintained. As of April 2008, the evidence-based CPMs specified by CMS include elements of anemia management, dialysis adequacy, bone and mineral metabolism, vascular access for hemodialysis, influenza vaccination, patient education/satisfaction/experience of care, and survival. These CPMs form the basis for public reporting on the Dialysis Facility Compare website and may trigger state surveyor activities.

Additional CPMs may become the focus of QAPI activities within the facility based on internal quality assurance triggers. The Measures Assessment Tool (MAT), which is described in the Interpretive Guidelines and provided in Appendix B, specifies additional CPMs that are not evidence-based but, nonetheless, may become the focus of state surveyor interventions. In 2011, some CPMs will become the basis for payment for performance to dialysis facilities as specified in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. Which CPMs will be used and how they will be weighted have yet to be specified by CMS, but the role of the Medical Director in fostering the achievement of CPM benchmarks that will result in higher payment to the facility will be crucial. This may result in alternative Medical Director compensation arrangements that are tied to facility performance.

Ultimately, however, it is the medical staff that prescribes the processes that result in individual patient outcomes, and the Medical Director’s role is directed at process improvement through mentoring, quality improvement activities, and peer review. A

more robust data collection and reporting infrastructure, as envisioned in CROWNWeb (a federal data base for dialysis facilities still under development as this document is being drafted), will provide the tools for individual nephrologists to compare their patients' process and outcome data to those of their peers and to their own patients over time, fostering quality improvement. The Medical Director will be expected to review these data and target intervention activities to underperforming physicians. It is anticipated that the ESRD Networks will assist in providing Medical Directors with the tools needed to promote physician practice development.

Principles

- 1. RPA endorses the core principles that form the basis for the CMS Conditions for Coverage for ESRD Facilities.**
- 2. RPA supports the key roles established for the dialysis facility Medical Director as set forth in the Conditions for Coverage for ESRD Facilities.**
- 3. RPA understands that medical directors must possess and employ good leadership skills in order to maintain a high performing and safe dialysis facility.**
- 4. RPA emphasizes that the specialized cognitive and technical skills of nephrologists make them most the qualified individuals to serve as dialysis facility Medical Directors, and as such a nephrologist should serve as dialysis facility Medical Director whenever possible.**
- 5. RPA supports the use of the Quality Assessment and Performance Improvement (QAPI) process as an integral component of the delivery of high quality care in the dialysis facility and the leadership role of the medical facility Medical Director in the QAPI process.**
- 6. RPA understands that documentation of the patient's clinical indicators and the steps taken by the Interdisciplinary Care Team (ICT) to improve the patient's care are a critically important function of the dialysis facility and that these activities need to be under the supervision of the facility Medical Director.**
- 7. RPA believes that as facility surveys are being conducted, the application of the Measures Assessment Tool should account for each patient being considered on an individual basis.**
- 8. RPA underscores the principle that as facility surveys are being conducted, the goals for some patients may need to be different from predefined targets and then incrementally changed to a standard value as the patient outcomes improve.**
- 9. RPA believes that in those instances where a specific target is not met, if there is documented evidence of steps taken by the Interdisciplinary Care Team to improve the patient's care, the facility should remain in compliance with the CFCs.**

Appendix A:

Understanding and Implementing the “Quality Assessment Process Improvement” (QAPI) Process:

The fundamental concept of the QAPI process is that it must be an activity of the governing body of the facility acting through the Medical Director and ICT who champion and implement focused processes to improve functions in the facility. In the words of the interpretative guideline, used by the surveyor:

“The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven QAPI program with participation by the professional members of the ICT. The program must reflect the complexity of the organization and services (including those under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its QAPI program including continuous monitoring for CMS review.”

It is RPA’s belief that in fact most Medical Directors have already been regularly attending to processes intended to improve care. Traditionally these processes have been at times less than systematic; now it must be formal, and recorded in a standard fashion in order to be readily understood and scored by the surveyors. The target of a QAPI process should be focused, measurable and result in planning which the facility can address with meaningful activity. The plan must, in some sense, be reiterative, meaning that after the planned activity is undertaken, the outcome should be re-measured to assess the value of the activity. Unlike clinical research, QAPI does not require proof of efficacy based on statistical analysis. The RPA believes that QAPI should be conducted consistent with the ethical precepts set forth in the 2006 Hastings Center report *The Ethics of Using QI Methods to Improve Health Care Quality & Safety* (<http://www.thehastingscenter.org/Publications/SpecialReports/Detail.aspx?id=1342>).

The options for pursuit of a QAPI process are virtually countless. CMS does expect QAPI processes in the event of low percentage achievement of laboratory test results when compared with the Measurement Assessment Tool (Appendix B). For example, if a facility has only 40 percent of measurements of adequacy of dialysis (URR or Kt/V) meeting conventional targets, they will look to the Medical Director to have established a QAPI process with this as the focus. But other activities are equally amenable to the process. To name a few, these could be the frequency of infections, the frequency of failure to meet water quality goals, the frequency of staff not coming to work, the frequency of missed drawing of blood and so forth.

An example of the process may be useful. There are several formal methods extant which support the QAPI activity. The most common is called the Focus, Analyze, Select, Team identification (abbreviated “FAST”) initiation, followed by the “Plan, Do, Check, reAct” cycle, abbreviated “PDCA”. A standard format showing the “FAST-PDCA” steps could be used for any problem. For this example, we have chosen a *hypothetical*

situation recognized by a Medical Director: *medications are not being checked with adequate frequency in the facility*. The first step is to focus on a problem of limited breadth (this problem fits that requirement). The next step is to measure something and record the metric; in this case, for example, one might measure and then analyze (meaning to decide if this is a problem) the fraction of charts lacking a review of medicines in the last 3 months. The next step requires a team, to pick or select the causes. For this, one might pick such things as nursing availability and commitment, patient willingness to bring medicines for review etc. With the team in place, planning begins. The team might decide to do or use several tools to engage the patient so that more bring in their medicines and to charge only a few nurses with the responsibility. After a reasonable period of time, the team re-checks by repeating the original measurement looking for improvement. If there improvement, the reaction would likely be that this was effective response to the problem and that in a year, we plan to repeat the measurement to check for sustainability.

If there is not improvement, the PDCA process should ideally be performed again with presumably different elements. All of this should be recorded in such a fashion that another reader or the team itself a year later can understand what was identified as a problem and how it was handled. It is not yet clear what frequency of this process the surveyors will be expecting. However, it is clear that if the surveyors see glaring problems without any evidence that they are being addressed systematically and with documentation, important steps will likely be immediately required. Use of the QAPI process by medical directors to establish a systems approach in areas that had previously only been addressed informally, and adoption of the habit of seeking areas to improve care should facilitate successful compliance with the CFCs.

Appendix B: The Measures Assessment Tool

At the end of the Interpretative Guideline Document used by the surveyor is a detailed table of “expected targets”, called the Measures Assessment Tool, which is provided on the following pages. The clinical measures outlined on the MAT include, but are not limited to, specific parametric items such as Kt/V, albumin, hemoglobin, parathyroid levels etc. Also listed are other indicators such as access status, volume status, rehabilitation status. This table is extremely detailed and could be interpreted to mean that that all values are expected to be met. However, the introduction to the tool itself notes that:

In using the MAT for individual patient assessments and plans of care, patient target levels should be assessed using the MAT. However, each patient should be treated individually and when a specified target is not met, either the plan of care should be adjusted to achieve the community-accepted standard or an explanation should be provided by the interdisciplinary team member of the group. Initially, goals for some patients may need to be different from these targets and then incrementally changed to the standard value as the patient outcomes improve.

Accordingly, both the surveyor and the governing body of the facility must understand that the expected target values are not a requirement for every patient. Where a target is changed for an individual patient, this choice must be found in the documentation. The Medical Director should familiarize himself with both this table and the introductory comments.

MEASURES ASSESSMENT TOOL (MAT)

494.40 Water and dialysate quality:					
V196 V196 V178 V180	Water quality	Max. chloramine (must determine) Max. total chlorine (may determine) Action / Max. bacteria – product water / dialysate Action / Max. endotoxin – product water / dialysate	≤0.1 mg/L daily/shift ≤0.5 mg/L daily/shift 50 CFU/mL / <200 CFU/mL 1 EU/mL / <2 EU/mL (endotoxin units)	AAMI RD52	Records
494.50 Reuse of hemodialyzers and blood lines (only applies to facilities that reuse dialyzers &/or bloodlines)					
V336	Dialyzer effectiveness	Total cell volume (hollow fiber dialyzers)	Measure original volume Discard if after reuse <80% of original	KDOQI HD Adequacy 2006; AAMI RD47	Records Interview
494.80 Patient assessment: The interdisciplinary team (IDT), patient/designee, RN, MSW, RD, physician must provide each patient with an individualized & comprehensive assessment of needs					
V502 V503 V504 V505 V506 V507 V508 V509 V510 V511 V512 V513 V514 V515	<ul style="list-style-type: none"> - Health status/comorbidities - Dialysis prescription - BP & fluid management - Lab profile - Immunization & meds history - Anemia (Hgb, Hct, iron stores, ESA need) - Renal bone disease - Nutritional status - Psychosocial needs - Dialysis access type & maintenance - Abilities, interests, preferences, goals, desired level of participation in care, preferred modality & setting, outcomes expectations - Suitability for transplant referral - Family & other support systems - Current physical activity level & referral to voc & physical rehab 	<ul style="list-style-type: none"> - Medical/nursing history, physical exam findings - Evaluate: HD every mo; PD first mo & q 4 mo - Interdialytic BP & wt gain, target wt, symptoms - Monitor labs monthly & as needed - Pneumococcal, hepatitis, influenza; med allergies - Volume, bleeding, infection, ESA hypo-response - Calcium, phosphorus, PTH & medications - Multiple elements listed - Multiple elements listed - Access efficacy, fistula candidacy - Reason why patient does not participate in care, reason why patient is not a home dialysis candidate - Reason why patient is not a transplant candidate - Composition, history, availability, level of support - Abilities & barriers to independent living; achieving educational & work goals 	Refer to Plan of care & QAPI sections (below) for values	Conditions for Coverage KDOQI Hypertension & Anti-Hypertensive Agents in CKD 2004 (BP) KDOQI HD Adequacy 2006 (volume)	Chart

494.90 Plan of care The IDT must develop & implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs as identified by the comprehensive assessment & changes in the patient's condition, & must include measurable & expected outcomes & estimated timetables to achieve outcomes. Outcome goals must be consistent with current professionally accepted clinical practice standards.

V543	(1) Dose of dialysis: volume	Management of volume status	Euvolemic & BP 130/80 (adult); lower of 90% of normal for age/ht/wt or 130/80 (pediatric)	KDOQI HD Adequacy 2006	Chart
V544	(1) Dose of dialysis (HD adequacy)	Adult HD <5 hours 3x/week Adult HD 2x/week, RKF <2 mL/min HD 4-6x/week	Kt/V ≥1.2; Min. 3 hours/tx if RKF <2ml/min Inadequate treatment frequency Min. Kt/V ≥2.0/week	KDOQI HD Adequacy 2006	DFR
V544	(1) Dose of dialysis (PD adequacy)	Adult PD patient <100 mL urine output/day Pediatric PD patients, low urine urea clearance	Min. delivered Kt/V _{urea} ≥1.7/week Min. delivered Kt/V _{urea} ≥1.8/week	KDOQI PD Adequacy 2006	Chart
V545	(2) Nutritional status Monitored monthly	Albumin Body weight Other parameters in Patient assessment V509	≥4.0 g/dL bromcresol green (BCG) method % usual weight, % standard weight, BMI, estimated % body fat	KDOQI Nutrition 2000 KDOQI CKD 2003	Chart
V546	(3) Mineral metabolism & renal bone disease	Calcium Phosphorus Intact PTH q 3 months	All: >8.4 mg/dL & <10.2 mg/dL All: 3.5-5.5 mg/dL Adult: 150-300 pg/mL (16.5-33.0 pmol/L) Pediatric 200-300 pg/mL	KDOQI Bone Metabolism & Disease 2003	Chart
V547 V548 V549	(4) Anemia Monitor Hgb/Hct monthly Monitor iron stores routinely	Adult & pediatric Hgb on ESAs Adult & pediatric Hgb on ESAs Adult & pediatric Hgb off ESAs Adult & pediatric Hgb on ESAs Adult & pediatric: transferrin saturation Adult & pediatric: serum ferritin	Hgb: <12.0 g/dL ³ Hgb: 10-12.0 g/dL ⁴ Hgb: >10 g/dL ⁴ Hgb: 10-12.0 g/dL, <13.0 g/dL ⁵ >20% (HD, PD), or CHr >29 pg/cell ⁶ HD: >200 ng/mL; PD: >100 ng/mL ⁶ rds =Facility Records Interview =PatientHD/ PD: <500 ng/mL or evaluate if indicated ⁶	³ =FDA "black box" warning ⁴ =Medicare reimbursement policy ⁵ =KDOQI Anemia 2007 ⁶ =KDOQI Anemia 2006	DFR

Appendix C: Definition of Unstable Patient from the CFC Interpretive Guidelines

- Extended or Frequent hospitalizations
 - Hospitalization of more than 15 days with discharge occurring within last 30 days
 - More than 3 admissions in the last 30 days
- Marked deterioration in health status – ICT to identify and document the specific reasons.
 - Change in ambulation severe enough to interfere with the patient’s ability to follow aspects of the treatment plan.
 - Hypotension, restlessness, pruritus or other symptoms severe enough to prevent completion of majority of dialysis treatments.
 - Sudden onset of recurrent cardiac arrhythmias;
 - Recurrent infections [not requiring hospitalization],
 - Chronic congestive heart failure with chronic hypotension,
 - Advanced or metastatic cancer or other organ system disease which interferes with the patient’s ability to follow aspects of the treatment plan,
 - Chronic or recurrent peritonitis
- Significant change in psychosocial needs
 - Change in mentation or psychosocial needs severe enough to interfere with the patient’s ability to follow aspects of the treatment plan and may include situations related to immediate family members.
- Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis
 - Albumin < 3.4 for any modality or weight loss > 10% dry body weight in 3 months *plus*
 - Hb < 10 for any modality for 3 months *plus*
 - Kt/V meeting the following criteria for 3 months
 - $eKt/V < 1.0$
 - $SpKt/V < 1.2$ for incenter HD on 3x/week
 - $stdKt/V < 2.0$ for > 3x/week (Incenter or HHD)
 - $Kt/V < 1.7$ for PD

Appendix D: Model Waiver Letter and Procedures for Medical Director Personnel Requirements

MODEL LETTER FOR ESRD WAIVER: Qualifications for Medical Director

Date

State Survey Agency
Survey & Certification, ESRD Program

Street Address

City, State, Zip code

Dear ESRD Specialist,

We are writing to request a waiver of the requirement for Board certification, completion of 12 months training program in nephrology, and/or 12 months experience providing care to patient on dialysis for the medical director of our facility, name, address, and CMS certification number.

Our medical director, name, has been medical director at this facility since date. A brief resume is attached. A qualified physician is not available to serve as the medical director of this facility for the following reason(s): stated reason(s).

We understand that a facility may apply for a potentially renewable, time-limited waiver if one or more of the qualification requirements listed above for medical director are not met. We also understand that facility-based outcomes will determine the length of time of the applicable waiver. We understand that the facility-based outcomes will consist of a composite ranking drawn from the most recent twelve-month period for which CMS has facility-specific, statistically-developed and rank-ordered outcome data. The composite ranking will be generated by the Kidney Epidemiology and Cost Center of the University of Michigan.

We appreciate your consideration of this request and await your response.

Sincerely,

Name

Contact information, including mailing address, email address, and phone number

<p>V683</p>	<p>Waiver: <u>Medical Director Qualifications</u></p> <p>If a qualified physician is not available to serve as medical director of a certified dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.</p> <p>Potentially renewable, time-limited waivers for the qualifications of a medical director will be granted to dialysis facilities based upon facility outcomes. Because the medical director is responsible for the care and outcomes in the dialysis facility, outcomes are an important part of the waiver process. If a medical director is transferring to a new facility, outcomes of both the former and the current facility will be considered.</p>	<p>A “qualified medical director” is a physician who meets the following qualifications:</p> <p>(1) Is Board-certified in Internal Medicine/Pediatrics: According to the website of the American Board of Internal Medicine (ABIM) and the American Board of Pediatrics (ABP), a physician does not need to maintain certification in internal medicine or general pediatrics to recertify in nephrology or pediatric nephrology. Therefore, a medical director certified in nephrology or pediatric nephrology does not need to maintain current certification in internal medicine or general pediatrics. CMS accepts the position of the ABIM and ABP and accepts current board certification in internal medicine, pediatrics, nephrology, or pediatric nephrology as meeting this requirement;</p> <p>(2) Has completed a board-approved training program in nephrology; and</p> <p>(3) Has at least 12 months of experience providing care to patients receiving dialysis.</p>	<p>A facility may request a waiver to appoint (or retain) as medical director a physician who does not meet one or more of these qualifications if a physician who does meet these qualifications is not available to direct the dialysis facility. <u>The request (with a brief resume of the physician and an explanation as to why a physician meeting the board certification requirement is not available) should be submitted to the applicable State Survey Agency.</u> A model letter is attached.</p> <p>Waivers will be time-limited but potentially renewable. The time period will be driven by patient outcomes information from the most recent twelve-month period for which CMS has outcome data. Facilities whose outcomes are in the lowest quintile of all ESRD facilities ($\leq 20\%$) may receive a one-year waiver for the qualifications of their medical director. Facilities whose outcomes are in the upper four quintiles (21-100%) may receive a three-year waiver.</p> <p>The State Survey Agency will communicate information regarding the waiver to the applicable CMS Regional Office. The CMS Regional Office will inform the facility about the decision regarding the waiver.</p>
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