


Preparing for the New Medical Director Responsibilities Conditions for Coverage


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 October 21, 2008



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Disclosure


- I would like to disclose that I am employed as the Chief Medical Officer of FMC-NA and I receive an annual salary along with stock options in the Company. My presentation does not endorse any commercial interest, product or services.
- This presentation will not advocate for the off-label use of medications.



What Physicians Care About

- Excellent Patient Care
- Respect
- **Control**
- Fair Reimbursement
- **Efficiency/Time**

How will CfC affect these issues?




§ 494.80 Condition: Patient assessment
~~§ 494.90 Condition: Patient plan of care.~~
Interdisciplinary Teams

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian.

The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs.

The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.




Interdisciplinary Teams

When all in agreement – fine!

When in disagreement- how to resolve?


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Requires a process of escalation for resolution in patient's best interest when disagreement is frequent and unrelenting.



How does the Medical Director demonstrate his/her efforts?

How is this to be documented?



Medical Director Role in Interdisciplinary Team functions

- Medical Director is **not to assume the role of the patient's personal physician** nor to supersede the physicians decisions.
- Oversee and assure that all medical staff members, whether physician or physician extender **comply with requirement to see each patient and provide input to Interdisciplinary Team once monthly along with a progress note.**
- Assure that patient's physician or physician extender **sees each patient during dialysis at least quarterly.**
- Respond to requests from IDT to speak with and council physicians who do not **respond to the requirements of the IDT regarding patient outcomes.**
- Inform physicians of the outcomes of the **facility QAPI** and urge their involvement and engage them when their individual results have negative impact on QAPI outcomes.



§494.80 Condition: Patient Assessment V500

Condition level noncompliance should be considered if there are **serious and/or pervasive deficient practices** identified in the provision of individualized interdisciplinary comprehensive assessments of patients and their care needs. Examples of Condition level noncompliance include, but are not limited to:

- Assessments **not being completed for multiple patients** within the timelines required;
- One or more **professional members** of the interdisciplinary team (IDT) **not participating** in the patient assessment;
- A **pattern of general standardized assessment "findings"** without evidence that individual patient needs are assessed.



§494.80 Condition: Patient Assessment V501

The comprehensive patient assessment must demonstrate a **congruent integration of the evaluations completed by each team member**, identifying the patient's individual needs and allowing for planning for necessary care and services. Team members may choose to conduct **one-on-one interviews** with the patient or **may opt to set up team meetings** which would include the patient in order to collect the appropriate assessment information.

This assessment may be **incorporated into one document or composed of sections developed by each team member.**



§494.80 Condition: Patient Assessment V502

Non-physician practitioners, i.e., advanced practice registered nurses or physician assistants, functioning in lieu of physicians may conduct medical portions of this evaluation, in accordance with State law and facility policy.

While copies of histories and physicals (H&P) from hospital admissions may be included, the assessment should address the patient's current presentation and health status, including the patient's medical condition related to his/her kidney disease.



§ 494.80 Condition: Patient assessment (a) *Standard: Assessment criteria*

- (1) Evaluation of current health status and medical condition, including co morbid conditions.
- (2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.
- (3) Laboratory profile, immunization history, and medication history.
- (4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis stimulating agent(s).
- (5) Evaluation of factors associated with renal bone disease.
- (6) Evaluation of nutritional status by a dietitian.
- (7) Evaluation of psychosocial needs by a social worker.
- (8) Evaluation of dialysis access type and maintenance (for example arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).



(c) *Standard: Assessment of treatment prescription*

The adequacy of the patient's dialysis prescription must be assessed on an ongoing basis as follows:

- (1) *Hemodialysis patients.* At least **monthly** by calculating delivered Kt/V or an equivalent measure.
- (2) *Peritoneal dialysis patients.* At least every **4 months** by calculating delivered weekly Kt/V or an equivalent measure.



**(c) Standard: Assessment of treatment prescription
V518**

The recommended method stipulated for drawing blood samples to measure Kt/V included the following:

- Pre- and post- samples are drawn at the **same treatment**;
- Pre sample is drawn **just prior to the start of treatment**;
- **Slow flow or stop pump technique** is used for the post sample; staff should slow the blood pump speed to 50-100 mL/min for 15 seconds before drawing blood; in the event the equipment in use does not allow for "slow flow," then "stop flow" may be substituted;
- After 15 seconds, staff should draw the post dialysis BUN sample from the arterial port closest to the patients.

Recognize that obtaining the sample to measure adequacy for PD patients depends on their cooperation with bringing samples of dialysate effluent and urine. If a scheduled sample is not obtained, staff should document the missed test, reschedule the test (including obtaining a blood sample on the same date as the fluid samples are collected), and consider reminders and re-education of the patient.



**§ 494.80 Condition: Patient assessment
(a) Standard: Assessment criteria**

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- (6) Evaluation of nutritional status by a dietitian.
- (7) Evaluation of psychosocial needs by a social worker.
- (8) Evaluation of dialysis access type and maintenance (for example arteriovenous fistulas, arteriovenous grafts, Central Venous catheters and peritoneal catheters).



**§ 494.80 Condition: Patient assessment
(a) Standard: Assessment criteria**

- (9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes.
- (10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.
- (11) Evaluation of family and other support systems.
- (12) Evaluation of current patient physical activity level.
- (13) Evaluation for referral to vocational and physical rehabilitation services.



**§ 494.80 Condition: Patient assessment
V514**

The IDT comprehensive assessment must demonstrate that each patient is evaluated for suitability for transplantation referral, using selection/exclusion criteria provided by the transplant center.

The regulations for transplant programs require written selection criteria to be developed and provided upon request to patients and dialysis facilities. Selection criteria vary among transplant centers; if the dialysis facility refers patients to multiple transplant centers, the dialysis facility should have the selection criteria for each center on file and available to patients; patient are also free to select a transplant center other than the ones normally utilized by the dialysis facility for referrals.

If the assessment finds a patient is not suitable for transplantation, the reason for the non-referral should be documented as part of the comprehensive assessment.



**§ 494.80 Condition: Patient assessment
(a) Standard: Assessment criteria**

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- (12) Evaluation of current patient physical activity level.
- (13) Evaluation for referral to vocational and physical rehabilitation services.



(b) Standard: Frequency of assessment for patients admitted to the dialysis facility

An initial comprehensive assessment

- within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
- A follow up comprehensive reassessment must occur within 3 months



(b) Standard: Frequency of assessment for patients admitted to the dialysis facility V516

Patients returning to dialysis from a failed transplant or changing modalities are also considered "new" patients.

If the comprehensive patient assessment and plan of care for an experienced dialysis patient transferring from one dialysis facility to another is received with the patient in transfer, the receiving facility's IDT must conduct a reassessment within three months of the patient's admission to the new facility.



(d) Standard: Patient reassessment V519 and V520

A comprehensive reassessment of each patient and a revision of the plan of care must be conducted—

- (1) At least annually for stable patients
- (2) At least monthly for unstable patients including, but not limited to, patients with the following:
 - (i) Extended or frequent hospitalizations;
 - (ii) Marked deterioration in health status;
 - (iii) Significant change in psychosocial needs; or
 - (iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.



CMS Definitions of Unstable V520

The IDT members have the flexibility to use their professional judgment to develop more stringent policies regarding the definition of "unstable".

"Significant change in psychosocial needs" would include any event that interferes with the patient's ability to follow aspects of the treatment plan. Such events may include instability in one's own or immediate family member's employment, physical or emotional abuse, deterioration in mental or functional status, amputation, housing instability, death or major illness in the family, consideration of terminating treatment, and loss of emotional support. In addition, any patient considered at risk for involuntary discharge or transfer must be considered "unstable."



CMS Definitions of Unstable V520

"Poor nutritional status" would include failure to thrive symptoms, with loss of body weight and low serum albumin.

"Unmanaged anemia" would include continued lab findings of hemoglobin/hematocrit values which are out of range as defined by community-accepted standards or Centers for Medicare and Medicaid Services (CMS) Clinical Performance Measures (CPMs). Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical standards and current CMS CPMs.

"Inadequate dialysis" would include a trend of results for Kt/V or URR which do not meet minimum expectations as defined by community-accepted standards or CMS CPMs for a three month period of time. Refer to the MAT. Inadequate dialysis would also include symptoms related to fluid management such as volume overload or depletion; intradialytic symptoms such as syncope or congestive heart failure; hypertension; or the need for extra treatment(s) for fluid removal.



Definition of Unstable recommended by FMS, DaVita and RPA

■ Extended or Frequent hospitalizations CMS = 15 days

- Hospitalization of more than 30 days with discharge occurring within last 30 days
- More than 3 admissions in the last 30 days

■ Marked deterioration in health status – IDT 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



Definition of Unstable recommended by FMS, DaVita and RPA

■ 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

This is a different standard than the "targets" in the Plan of Care!



§ 494.90 Condition: Patient plan of care
 (a) Standard: Development of patient plan of care.

- (1) *Dose of dialysis*
- (2) *Nutritional status*
- (3) *Mineral metabolism*
- (4) *Anemia*
- (5) *Vascular access*
- (6) *Psychosocial status*
- (7) *Modality*
 - (i) *Home dialysis*
 - (ii) *Transplantation status*
- (8) *Rehabilitation status*




Measures Assessment Tool (MAT)
V540

Use the **Measures Assessment Tool (MAT)** during review of records for a ready reference of the current professionally-accepted clinical practice standards which facilities should be using to establish targets for individual patient's clinical outcomes.

Recognize that the standards included in the **MAT** are targets. Each patient should be treated individually. When a specified target is not met, the plan of care should either be adjusted to achieve the target or to provide an explanation by the IDT in areas where the targets are not able to be achieved.

Examples of Condition level non-compliance would include, but not be limited to:


- **Serious and/or pervasive deficient practices** identified in the development or implementation of individualized plans of care;
- **A pattern of failure to revise** the applicable portion of the plans of care when the current plan did not result in achieving or sustaining the intended outcome;
- **A pattern of failure in updating the plans of care** when indicated by the patient's condition.



Measures Assessment Tool (MAT)
V540

The written patient plan of care may be one document or composed of separate sections, but must be congruent and reflect the integration of the comprehensive assessments contributed by all the members of the IDT.

To ensure the development of a congruent, integrated patient plan of care, the facility **may conduct IDT conferences or use another mechanism that ensures the development of an integrated plan**. A substitute mechanism for a team conference needs to **facilitate discussion** among team members about the information gathered from the comprehensive patient assessment and provide the opportunity for team coordination and development of an effective, individualized plan of care for the patient to ensure the desired outcomes are achieved. To facilitate full team participation in conferences, any member, including the patient, **may participate through telecommunication**.



§ 494.90 Condition: Patient plan of care.
V560

The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

The patient may see the practitioner in the dialysis facility (before, during or after treatment), or in the physician's office if the record of care for that visit is incorporated into the dialysis facility medical record.

"Periodically while the hemodialysis patient is receiving in-facility dialysis" is meant to refer to in-center patients and should generally result in at least quarterly practitioner visits at the dialysis center during dialysis treatment.

At a minimum, monthly medical progress notes should document that a physician or that a non-physician practitioner (i.e., advanced practice registered nurse or physician assistant) who functions in lieu of the physician, has seen each patient and addressed the status and plan for that patient's renal and active comorbid problems.



(7) Modality.
(i) Home dialysis
V553

The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

Patient records must demonstrate that each patient was informed about all available dialysis modalities and locations for home dialysis training if that service is not available at this facility.

If the patient declined or was determined not suitable for home dialysis, the IDT must document their rationale for this decision.



(7)Modality (ii) Transplantation status
V554

The patient record must show evidence that the patient was informed about transplantation as an option, living and deceased kidney donation, area transplant center(s) and each transplant center's selection criteria.

Each patient's record must reflect the IDT's determination about the patient's suitability and whether the patient accepted or declined referral for transplantation and reason for non-referral.

If a patient was determined as suitable for transplantation referral, the IDT must document making the referral and providing applicable information to the transplant center as appropriate or when requested.



Patient Plan of Care

(c) Standard: Transplantation referral tracking V561

The interdisciplinary team must—

- (1) **Track** the results of each kidney transplant center referral;
- (2) **Monitor** the **status** of any facility patients who are on the **transplant wait list**;
- (3) **Communicate** with the transplant center regarding patient transplant status at least annually, and when there is a **change** in transplant candidate **status**.



(d) Standard: Patient education and training V562

The patient care plan must include, as applicable, **education and training** for patients and family members or caregivers or both, in aspects of the **dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types**.



b. Responsibilities of the Medical Director (Proposed § 494.150) **In Preamble but not Interpretive Guidelines**

The governing body could develop a **process to improve the medical director's performance**. A facility's governing body could also contact the appropriate authorities, such as the **Network Medical Advisory Boards, State Licensing Boards, State Professional Boards, and any other suitable agencies or organizations**.

If the **medical director** is **unsuccessful** in achieving medical staff compliance or managing disciplinary issues involving attending physicians and has exhausted all options, we expect that the matter would be referred to the governing body, the **ESRD Network** or other appropriate authorities, such as the **state agency and state licensing boards**.