Medicare Updates Its Dialysis Facility Requirements: 2008 Final ESRD Conditions for Coverage

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On April 15, 2008, CMS released the long delayed final rule for end-stage renal disease (ESRD) conditions for coverage. [1] The final rule completely revises and updates the conditions, which were last revised in 1976. The conditions are moved in the new rule from 42 C.F.R. part 405, subpart U, to a new 42 C.F.R. part 494. The new conditions became effective October 14, 2008.

In the preamble to the final rule, CMS emphasizes that the new conditions reflect a shift from a process-oriented to a patient-centered approach. In that spirit, the new conditions establish three central requirements: (I) patient safety, (II) patient care, and (III) administration.[2] Additionally, throughout the new conditions we see a trend toward incorporating standards and guidelines from outside expert organizations. In this article we will take a brief look at each of these sections, highlighting the most salient new requirements and noting the provisions which received the most numerous comments during the notice and comment period.

I. Patient Safety

a. *Infection Control*

The final rule incorporates by reference the CDC publication "Recommended Infection Control Practices for Hemodialysis Patients."[3] The CDC guidelines require that items taken into the dialysis station must either be dedicated to a single patient or disinfected before entering a common clean area or being used on another patient.[4] The new rules also incorporate by reference the HICPAC guidelines for catheter- related infections.[5]

In addition, the new rules require a separate isolation room for dialyzing hepatitis B surface antigen (HBsAg) positive patients, using separate equipment.[6] Staff may not care for HBsAg-positive patients and hepatitis B susceptible patients during the same shift. Given the potential need for structural renovations, CMS is giving facilities extra time to comply with the isolation room requirement.[7] The new rule includes a waiver provision for new facilities being

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[1] 72 Fed. Reg. 20370 (Apr. 15, 2008).
[2] *Id.* at 20372.
[3] *Id.* at 20376 (except Hepatitis C screening not incorporated by reference).
[4] *Id.* (adhesive tape and blood pressure cuffs must be dedicated to the patient).
[5] *Id.* at 20378.
[6] *Id.* at 20376.
[7] The effective date is February 9, 2009. *Id.*

built in geographic areas which already have sufficient isolation rooms to serve the local population.[8]

The new conditions remove the requirement for an infection control officer; infection control is monitored by the QAPI program discussed below.[9]

b. *Water Quality*

The new rules incorporate by reference the 2004 AAMI guidelines for water and dialysate.[10] The guidelines establish "action levels" at which the facility must take steps to prevent contaminants from reaching unsafe levels. The guidelines also establish a schedule for how frequently water and dialysate must be tested. The testing requirements impose a significant burden on facilities; chlorine/chloramine testing, for example, must be performed at the start of each day and then at the beginning of each shift (or every four hours, whichever is shorter).[11] The new rule added endotoxin testing to the blood and dialysate culture requirement.[12] And all samples must be tested within 24 hours otherwise CMS does not consider them an accurate reflection of contamination.[13]

CMS received many comments regarding the carbon tank requirements. The new rule requires at least two carbon tanks or equivalent components.[14] Although the new conditions impose high standards for water quality, CMS stopped short of requiring ultrapure dialysate.[15]

c. *Physical Environment*

The new rules attempt to allow facilities more flexibility. For example, the new rules no longer require a "nursing station," rather patients must be in view of the staff during treatment.[16] The new rules continue to grandfather in existing facilities from the sprinkler system requirements, but all new facilities or facilities which move locations must meet the updated sprinkler standards.[17] The new rules also require facilities to provide privacy to patients when they are examined or treated.[18] In addition, the rules require facilities to possess either a defibrillator or an automated external defibrillator on the premises.[19]

The new rules impose a duty upon facilities to create emergency preparedness plans. Staff must instruct patients of where to go during an emergency, and facilities must establish an alternate phone number if the main line will not be answered during an emergency. Furthermore, each facility must contact its local disaster management agency annually to ensure that the agency knows of the dialysis facilities particular needs in emergency situations.[20]

II. Patient Care

a. *Patient's Rights*

The new conditions require that patients be informed of their rights to have advanced directives, of all facility policies, including discharge policies and grievance mechanisms, and of all modality choices (including home hemodialysis).[21] Under the new rules, patients must receive the

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[8] *Id.* at 20377.
[9] *Id.* at 20378.
[10] *Id.* at 20379.
[11] *Id.* at 20380.
[12] *Id.*
[13] *Id.* at 20381.
[14] *Id.*
[15] *Id.* at 20381.
[16] *Id.* at 20385.
[17] *Id.* at 20387.
[18] *Id.* at 20385.
[19] *Id.* at 20386.
[20] *Id.*
[21] *Id.* at 20387 (throughout the preamble to the final rule, CMS emphasizes making patient's aware of the option of home hemodialysis, *see* p. 20396).

information about their rights within the first three treatments at the facility.[22] But the rules do not specify the level of detail, the format (*i.e.* audiovisual, oral, or written), or what type of staff person must deliver the information.[23]

In addition, the rules do not mandate that facilities discuss "end of life" options or assist in advance directive planning; facilities must only inform patients of their right to have a directive, document the existence of patient directives in the medical record, and communicate to the patient the facilities' policy toward such directives.[24]

Patients must be informed about all treatment modalities and all scheduling options, even those modalities or options not offered at the facility.[25] Facilities must inform patients of other facilities that may accommodate the patient's schedule or choice of modality.[26] The preamble to the final rule states that it is sufficient for facilities provide the patient with an informational handout regarding their options or give patients the information on Medicare's DCF website (which posts a list of providers).[27]

b. *Patient Assessment*

The new rules place great emphasis on the role of the "interdisciplinary team." The team must be composed of at least: the patient (or patient's designee), a registered nurse, a physician, a qualified social worker, and a registered dietician.[28] Patient participation, while encouraged, is not mandated.[29] The role of the social worker on the team, and addressing the psychosocial status of the patient, is discussed repeatedly throughout the preamble to the final rule.[30] Additionally, while the medical director is not a required member of the interdisciplinary team, he/she is responsible under the new conditions, for the delivery of patient care and outcomes in the facility and so, in this role, the medical director may choose to be a member of the interdisciplinary team.

Each patient is entitled under the new conditions to a individualized, comprehensive assessment of their needs performed by such a team.[31] Each member of the team must assess the patient and complete the assessment within 30 days or 13 treatments (whichever is later).[32] Stable patients require a follow-up comprehensive reassessment 3 months after the initial assessment and annual reassessments thereafter.[33] The team is also responsible for referring patients to appropriate external sources for care (*e.g.* for transplant or rehabilitation).[34]

c. *Patient Plan of Care*

The new rules eliminate the requirement for short-term and long-term care plans.[35] After the initial assessment is complete, the team must create a written, individualized, comprehensive plan of care, which is updated as the patient's condition changes and includes measurable expected outcomes. The care plan must include vascular access monitoring.[36] In addition, the team must assess each patient's unique needs for anemia management, but the new rules do not include specified target levels for hemoglobin/ hematocrit.[37] Under the new rules, patients are must receive at least one

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[22] *Id.* at 20388.
[23] *Id.*
[24] *Id.* at 20389-90.
[25] *Id.* at 20390.
[26] *Id.* at 20391.
[27] *Id.* at 20390 (it is not necessary for facilities to identify specific alternative providers in the geographic area).
[28] *Id.* at 20393 (pharmacists are not required on the team, *see* 72 Fed. Reg. at 20427).
[29] *Id.* at 20394.
[30] *Id.* at 20396, 20397, 20406.
[31] *Id.* at 20393.
[32] *Id.* at 20398.
[33] *Id.* at 20398-9.
[34] *Id.* at 20397.
[35] *Id.* at 20399-20400.
[36] *Id.* at 20403 (limited to clinical observation, auscultation, and palpitation of the access).
[37] *Id.*

monthly visit by their physician or a "physician extender" (e.g. nurse practitioner, clinical nurse specialist, or physician assistant).[38]

The new rules require the ESRD facility to reform transplant referral tracking.[39] The team must be aware of whether the patient has been evaluated for transplant, is wait-listed, or is awaiting donation.[40] Moreover, the team must contact the transplant center annually, as well as inform the transplant center about changes in the patient's condition.[41]

Patients are part of the interdisciplinary team and where the patient is not able to meet the plan of care goals, the plan should be adjusted. However, if a patient is non-compliant, the facility must intervene.[42] If such intervention fails, the facility must document the intervention, the results, and the new plan for care given the patient's behavior.[43]

d. *Care at Home*

The new conditions both consolidates requirements for home dialysis that were previously sprinkled throughout the ESRD conditions, as well as add new requirements to make the rules governing home dialysis more robust. The new rules make clear that home dialysis services must be at least equivalent to the services provided to in-facility patients.[44] The standards for home dialysis are broken down into three component parts: training, monitoring, and support services.

The finalized conditions make clear that training must be provided by a facility that is approved to provide home dialysis services.[45] The new conditions also specify that the training of the home dialysis patient, the designated caregiver, or self-dialysis patient must occur and the patient's competency assessed before the initiation of home or self-dialysis, and whenever the caregiver or modality changes. The training must be provided by the training RN, and it must be overseen by the interdisciplinary team responsible for that patient's assessment, and the development of the patient's plan of care. In the preamble to the final rule, CMS notes that other members of the clinical staff may assist in providing training, however, ultimately the RN is responsible for ensuring that the standard for training is met. Similar to the old Conditions, the final conditions do not address the location of home dialysis training.

The conditions state that training must address the specific needs of the patient in each of the following areas:

- The nature and management of ESRD;
- The full range of techniques associated with the selected modality, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective use of erythropoiesis-stimulating agents (if prescribed) to achieve and maintain a target level of hemoglobin or hematocrit;
- How to detect, report, and manage potential dialysis complications, including water treatment problems;
- Availability of support resources and how to use those resources;
- How to self-monitor health status and record and report health status information;
- How to handle medical and non-medical emergencies;
- Infection control precautions; and
- Proper waste storage and disposal procedures.[46]

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[38] *Id.* at 20408 (CMS repeatedly makes references to the use of physician extenders throughout the preamble to the final rule).
[39] *Id.* (rule does not specify which staff member must do said tracking).
[40] *Id.*
[41] *Id.* at 20409.
[42] *Id.* at 20402.
[43] *Id.*
[44] *Id.* at 20409.
[45] *Id.* at 20410; 42 C.F.R. § 494.100.
[46] 42 C.F.R. § 404.100(a)(3).

The final conditions provide that the "home dialysis facility must furnish (either directly, under arrangement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company."[47] CMS notes that the intent of the final Conditions is to allow maximum flexibility for facilities to carry out the support services requirements.[48]

The final Conditions modify the list of required support services:

- Periodic monitoring of the patient's home adaptation, including visits by interdisciplinary team members and facility personnel in accordance with the patient's plan of care;
- Coordination of the patient's care by a member of the interdisciplinary team;
- Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes specified in the Conditions;
- Patient consultation with members of the interdisciplinary team, as needed;
- Monitoring of the quality of water and dialysate used by home hemodialysis patients including onsite evaluation and testing;
- Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment prescribed by patient's physician; and
- Identifying a plan and arranging for emergency back-up dialysis services when needed.[49]

In addition to all of the above support services requirements, the facility must maintain a recordkeeping system that ensures continuity of care and patient privacy.

The final conditions specifically require the ongoing monitoring of home dialysis patients. Every two months the facility must collect and review the patient's self-monitoring data and maintain that information in the patient's medical record.[50] CMS notes in the preamble that if a patient is non-compliant and does not maintain their self-monitoring data, it is the facilities responsibility to intervene.[51] The facility must document any such interventions, the results of such interventions, and the plan to protect patient safety within the limitations of poor compliance.

In the new rules, CMS briefly addresses the provision of home dialysis services provided in a long term care facility ("LTCF").[52] CMS recognizes the difficulties and issues associated with applying the "care at home" conditions in a LTCF setting. However, CMS opted to consider the subject in a separate rulemaking, and so made no changes to its current policy.

e. *Quality Assessment and Performance Improvement (QAPI)*

Another theme woven through the new rules is the emphasis on measuring outcomes. The new conditions require the facility to develop, implement, maintain and evaluate a data-driven QAPI program.[53] The program is to include nutritional status, anemia management, vascular access, medical injuries and error identification, hemodialyzer reuse program, patient satisfaction, and grievances.[54] If a facility's outcomes vary significantly from acceptable standards, the facility is expected to indentify

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[47] 42 C.F.R. § 494.100(c).
[48] 73 Fed. Reg. at 20412.
[49] 42 C.F.R. § 494.100(c)(1).
[50] 42 C.F.R. § 494.100(b).
[51] 73 Fed. Reg. at 20411.
[52] *Id.* at 20413
[53] *Id.* at 20481.
[54] *Id.* at 20414.

the source of the discrepancy and take steps to rectify the problem.[55] The new rules, however, did not issue facility-level performance standards.[56]

III. Administration

a. *Personnel Qualifications*

The new rules regarding personnel qualifications received the most comments of any of the conditions.[57] The new rules include stricter requirements for medical directors. Medical directors must be a physician board certified in internal medicine or pediatrics, as well as nephrology, and have at least twelve months experience caring for dialysis patients.[58]

In addition, a RN is required to be present at the facility whenever patients are being treated in the facility.[59] The nurse manager must be a full-time employee of the facility.[60] Registered nurses are required to have twelve months of nursing experience as well as three to six months of dialysis experience.[61] An LPN may act as a charge nurse only under the supervision of an RN.[62]

The new conditions include a new type of staff member: patient care dialysis technicians ("PCTs").[63] PCTs must be certified either under a State program or a nationally commercially available certification program.[64] PCTs must acquire certification within 18 months of being hired (or within 18 months of publication of the new rule).[65] PCTs must work under the direction of an RN.[66]

Registered dieticians ("RD") must have one year professional work experience in clinical nutrition.[67] A RD may use a dietetic technician to provide assistance under supervision, but the RD is required to meet the conditions for the interdisciplinary team.[68]

Social workers are required to possess a Masters degree as well as a specialization in clinical practice.[69] The new rule preserves a limited exception to grandfather in social workers who practiced at least two years before 1976. Both social workers and RDs may be shared between facilities so long as each facility has adequate staff to meet their needs.[70]

The new rules do not include qualification standards for chief executive officers, medical record practitioners, or transplantation surgeons.[71]

b. *Responsibilities of the Medical Director*

The new conditions emphasize that the medical director is responsible for the delivery of patient care and patient outcomes in the facility.[72] The medical director is held accountable to the governing body for the quality of patient care. It is the director's responsibility to ensure that all people who treat patients at the facility adhere to the policies and procedures. Medical directors also have the operational responsibility for the QAPI program.

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[55] *Id.* at 20415.
[56] *Id.* at 20416-17 (CMS intends to develop such standards through a process of voluntary consensus and will publish them as a proposed rule in the Federal Register).
[57] *Id.* at 20419.
[58] *Id.* at 20420.
[59] *Id.* at 20421.
[60] *Id.*
[61] *Id.* at 20420.
[62] *Id.* at 20421.
[63] *Id.* at 20419.
[64] *Id.* at 20425.
[65] *Id.*
[66] *Id.* at 20426.
[67] *Id.* at 20422.
[68] *Id.* at 20423.
[69] *Id.*
[70] *Id.* at 20424.
[71] *Id.* at 20419.
[72] *Id.* at 20427.

c. *Medical Records*

The new conditions eliminate many of the old specific requirements for medical records to allow the facility greater flexibility. For example, the medical records supervisor requirement has not been included in the new rules.[73] The new rules do not specify state what information must be included in the medical records.

d. *Governance*

The new conditions retain the requirement that the facility be under the control of an identifiable governing body or person (CEO or administrator) with full legal authority and responsibility for the governance and operation of the facility. The rules clarify that it is the roll of the governing body to ensure that there is an adequate number of qualified staff.[74] In the spirit of increased flexibility, CMS did not pronounce staff to patient ratios in the new rule, instead "adequate staff" is interpreted broadly to mean sufficient staffing to provide quality care.[75]

The new rules provide significant freedom in crafting a grievance procedure. The facility must have a procedure which allows patients to submit an oral or written grievance without fear of reprisal.[76] However, the rules do not cover how the facility must make the grievance process known.[77]

A new provision creates a permissible condition for involuntary discharge of a patient.[78] Involuntary discharge is intended to be a last resort, and the rules include many conditions for discharging non-compliant patients.[79] Among other requirements, the facility must notify the patient as well as the Network thirty days before discharge, contact an alternative facility and attempt to place the patient, and notify the State survey agency of the efforts to resolve the problem.[80]

Lastly, following the theme of increased outcomes measurement, the new conditions require facilities to electronically submit administrative and ESRD clinical performance measures ("CPM") data to CMS.[81] The new rules implement a new electronic web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), which is designed to collect and analyze clinical performance measures data.[82] The CROWNWeb system will have the capacity to produce reports comparing facilities based on CPM data.[83] The requirement to use the new CROWNWeb system is delayed until February 1, 2009 to allow facilities time to adopt the new technology.[84]

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This article merely touches on the high points of the hundreds of pages the new regulation. The new ESRD conditions for coverage dramatically depart from the requirements of the old conditions. The new conditions reflect CMS's intent to enhance facility flexibility, increase outcome data collection and transparency, and improve the rules to adequately cover current technologies and standards of practice.

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[73] *Id.* at 20430-31.
[74] *Id.* at 20433.
[75] *Id.* at 20434.
[76] *Id.* at 20437.
[77] *Id.*
[78] *Id.* at 20438.
[79] *Id.* at 20439.
[80] *Id.* at 20439-40.
[81] *Id.* at 20441.
[82] *Id.* (CMS no longer plans to use the VISION software, *see* p. 20443).
[83] *Id.* at 20442.
[84] *Id.* at 20442-43.