New Conditions for Coverage will impose a host of new requirements on dialysis clinics

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On February 4, the Centers for Medicare & Medicaid Services issued a proposed rule that would substantially revise the existing Conditions for Coverage for Suppliers of End-Stage Renal Disease Services (the “Proposed Rule”). CMS is accepting public comment on the Proposed Rule until 5 p.m. on Thursday, May 5.

In the Proposed Rule, CMS indicates that revision of the Conditions for Coverage was motivated by a number of factors, including a move away from process-based regulations and toward rules that focus on patient outcomes, with emphasis on quality assessment and performance improvement. Another key consideration was the desire to incorporate the most recent medical and scientific guidelines, including guidelines from the Centers for Disease Control and Prevention, the Association for the Advancement of Medical Instrumentation, and the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative. This article is intended to highlight some of the more significant changes articulated by CMS in the Proposed Rule.

Facility Design

The Proposed Rule contains a number of provisions that relate to the design of a dialysis facility and the environment in which services are rendered. For example, newly opened hemodialysis units would be required to have isolation rooms for hepatitis B positive patients; existing units would need to have a separate area with dedicated staff and dedicated dialysis machines. The requirement that a facility have a nursing/monitoring station, from which adequate surveillance of patients receiving dialysis services would be conducted, is eliminated. The theory here is that monitoring is most effectively achieved through interaction between staff and patients on the dialysis floor.

Emergency Preparedness

Each dialysis facility must implement emergency preparedness procedures to manage non-medical and medical emergencies. These include fire, equipment and power failures, care-related emergencies, and any natural disaster that is likely to occur in the area the facility is located. Every facility would be required to review its emergency and disaster plan at least annually. Both patients and staff must be trained in the facility’s emergency procedures, and staff training must be evaluated annually. Currently, the Conditions for Coverage require only that a facility have a fully equipped emergency tray, with emergency drugs, medical supplies, and equipment. Under the Proposed Rule, a facility would be required to have certain emergency equipment on the premises for immediate use, including oxygen, suction, an artificial resuscitator ventilation bag, defibrillator, and emergency drugs. CMS is soliciting comments on whether small, predominantly rural facilities should be exempt from the defibrillator requirement.

Fire Safety

To ensure fire safety, CMS proposes to adopt chapters 20 and 21 of the National Fire Protection Association Life Safety Code for all outpatient dialysis facilities, regardless of size. Amongst other things, this would require one hour of fire separation between different tenants in a multi-tenant building; at least two emergency exits; a fire alarm system that provides automatic notification of a fire to emergency forces; compliance with rules regarding smoke compartmentation (unless a facility is under 5,000 sq ft and protected by an approved sprinkler system); conducting fire drills at least once every three months; and a number of additional requirements. Recognizing that older dialysis facilities and others may have difficulty satisfying all of the LSC requirements, CMS proposes that a waiver from particular requirements would be available on a case-by-case basis, if

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a waiver would not adversely affect patient health and safety; and it would impose unreasonable hardship on a facility to meet a specific LSC requirement. Waiver requests would be submitted to the state agency (e.g. the Department of Health); the state agency would recommend approval or disapproval to the CMS regional office, which would grant or deny the request.

Patients’ Rights

The existing regulatory language gives facilities an unspecified amount of time to inform patients of their rights and responsibilities. CMS proposes that patients receive this information as soon as they begin treatment and that the information is provided in an understandable manner. Under the Proposed Rule, a facility must inform each patient of the patient’s right to establish an advance directive, such as a living will or a durable power of attorney for health care. Such directives would need to be maintained by the facility for those patients who execute them. Patients must be informed regarding the facility’s internal grievance process as well as the external grievance process available to them. With respect to external grievances, patients must be made aware of every grievance option available to them, although a patient’s right to sue the facility in court does not appear to be included. Unless there is an immediate threat to the health or safety of other patients in the facility, a patient is entitled to 30 days advance notice prior to discharge from a facility. This requirement is consistent with the law in most states and unlike many of the other new rules, is unlikely to require most facilities to change their current practices.

Patient Assessment

Under the Proposed Rule, a comprehensive patient assessment must be completed for every patient within 20 calendar days of the date on which the patient receives his or her first treatment at the facility. The Proposed Rule prescribes all of the elements of the assessment, including evaluation of the following: the patient’s current health status, the appropriateness of the dialysis prescription, factors associated with anemia and renal bone disease, the patient’s nutritional status and psychosocial needs, the patient’s dialysis access type and maintenance, the patient’s interests, preferences and goals, the patient’s suitability for a transplantation referral, family and other support systems, current physical activity level, and vocational and physical rehabilitation status and potential. The patient’s laboratory profile and medication history must also be included in the assessment. An interdisciplinary team, including a physician, a registered nurse, a social worker, a dietitian, and the patient, at his or her option, must prepare the comprehensive assessment. For new patients, a comprehensive reassessment would need to be conducted within three months. Thereafter, comprehensive reassessments must be conducted annually for stable patients, and monthly for unstable patients. Since there are differing opinions in the renal community regarding the frequency of reassessments, CMS is specifically seeking public comment on the proposed three-month time frame for reassessments.

In light of the comprehensive assessment requirements, CMS has eliminated the requirement that a facility develop a “long term care plan” for each patient. Individualized short term care plans are still required, however, and must be completed within 10 days of the facility’s completion of the comprehensive assessment, or within 30 calendar days of the date a patient begins dialysis.

Home Dialysis

The Proposed Rule expands the role of the dialysis facility with respect to home patients, with the goal of ensuring that the quality of care received by home patients is at least equivalent to that received by in-center patients. The existing regulations simply require that a facility provide a training program for self dialysis and home dialysis patients. The Proposed Rule lists 10 discrete topics that must be covered by a home training nurse as part of a patient’s home training program. These include the nature and management of ESRD, the full range of techniques associated with the patient’s modality, nutritional planning, achieving emotional and social well-being, detecting and reporting complications, access and use of support services, monitoring health status, emergencies, infection control, and proper waste storage and disposal.

Once training is complete, the dialysis facility must 1) record who received the training and indicate that the patient or caregiver demonstrated comprehension of the training; 2) retrieve and review self-monitoring data from patients or caregivers every two months; and 3) maintain this information in the patient’s medical record. The goal of the information collection requirements is to allow the facility to determine if a patient needs to be retrained and if a patient remains a suitable candidate for home dialysis. If a home dialysis patient receives equipment and supplies from a Method II supply company, the supplier must report to the facility, every 30 days, all services and items furnished to the beneficiary so that the information can be documented in the patient’s medical record.
Nursing Home Dialysis

In the Proposed Rule, CMS iterates the existing requirements for nursing home dialysis, as follows: 1) the nursing home must be the patient’s permanent home (this condition would not be met by a rehabilitative stay or a brief recovery time stay); 2) the patient and caregiver must complete home dialysis training; 3) the patient must have a dedicated machine, equipment, and supplies; and 4) support services must be furnished by a certified facility. The Proposed Rule does not set forth any additional requirements for nursing home dialysis but, instead, identifies a number of issues for which it is seeking public comment.

CMS believes there should be a written agreement between all parties providing care to a nursing home dialysis patient that delineates each party’s responsibilities. (Because the survey guidelines issued in March 2004 and updated in July 2004 already require a coordination agreement, it seems highly likely that this requirement will become part of the revised Conditions for Coverage.) CMS is considering whether it should require a nursing home that provides home dialysis care to comply with all of the Conditions for Coverage, with limited exceptions. CMS would also like to require that a registered nurse be available during multiple simultaneous nursing home dialysis treatments, and is considering whether this individual should be a nursing home employee trained by the dialysis facility or an employee of the dialysis facility. CMS recognizes that trained caregivers will participate in the treatment, but is soliciting comments on whether there should be patient-caregiver ratios and whether the supervising RN’s scope of responsibilities should be limited to dialysis care.

In continuing with its theme of expanding the role of the dialysis facility, CMS would require that the certified facility provide training to the nursing home staff and all caregivers who will be working with ESRD patients, including nursing home staff and any caregivers that may be furnished by the Method II supply company. The dialysis facility would be required to periodically assess the competency of the caregiver staff; retrieve and review all patient data, including laboratory values, clinical data, outcome data, and interdisciplinary team notes; monitor the care of patients; and monitor whether the nursing home dialysis program is negatively impacting the care provided to other nursing home residents. Thus, in contrast to the current paradigm, in which a dialysis facility is not held responsible for the actions or omissions of individuals (other than its own employees) who provide staff-assistance in a nursing home setting, the Proposed Rule would render a dialysis facility accountable to Medicare for the performance of these caregivers. In light of the challenges associated with supervising and monitoring clinical personnel who are rendering services at an off-site location, ascribing this level of responsibility to an outpatient dialysis facility may create a barrier to the expansion of nursing home dialysis programs.

Quality Assessment and Performance Improvement

Under the Proposed Rule, CMS would require all dialysis facilities to collect and analyze clinical data, on a systematic basis, about the components of their care processes. Facilities are expected to set goals, track their performance, and intervene where necessary to achieve improvements in outcomes and patient satisfaction. A facility’s QAPI program must address the following areas:

- adequacy of dialysis
- nutritional status
- anemia management
- vascular access
- medical injuries and medical errors identification
- hemodialysis reuse program, if applicable
- patient satisfaction and grievances

CMS expects a facility whose treatment outcomes vary significantly from accepted standards to identify the reasons for the poor outcomes and take actions that result in performance improvement. Finally, CMS is considering imposing minimal clinical standards that would serve as “external stimuli” for further improvements in the quality of dialysis services.

In assessing the burden created by these new QAPI requirements, CMS focused on the fact that the five largest dialysis providers already monitor 14 different clinical performance measures. Individual providers, however, may not have the computer systems and programs to collect and efficiently analyze this data. The Proposed Rule does not provide a waiver from the QAPI obligations for independently-owned dialysis facilities or rural dialysis facilities.

Personnel and Staffing Requirements

Medical Director

The Proposed Rule would not materially change the qualifications or the scope of responsibilities of the medical director, except that the medical director would be responsible for implementing a facility’s QAPI program, ensuring adherence

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1. This section of the Proposed Rule appears to relate exclusively to home hemodialysis. Requirements for patients who receive peritoneal dialysis in a nursing home setting are not addressed.
2. This requirement would actually be more stringent than the current Conditions for Coverage, which require only that a licensed health care professional, which may be a physician, a registered nurse, or a licensed practical nurse, be on duty whenever patients are being dialyzed.
to patient care policies and procedures, and ensuring that the facility’s interdisciplinary team follow discharge and transfer policies. While these responsibilities are not specifically assigned to the medical director under the current conditions, most medical directors currently participate in these activities. Nonetheless, by specifically ascribing these responsibilities to the medical director, the Proposed Rule would provide a basis upon which a third party, including a patient, a family member, a payer, or the facility itself, could seek to impose legal liability upon a medical director in the event of non-compliance. Finally, CMS is soliciting comments on whether the revised Conditions for Coverage should detail the obligations of the medical director when there is a quality problem attributable to a particular attending physician.

Registered Nurse

CMS is proposing that an RN be on the premises of the dialysis facility at all times when patients are being treated. (The current Conditions for Coverage require that a facility hire a full-time RN, but they do not mandate that the RN be on the premises at all times during treatment.) This proposal is based on the concern that dialysis technicians and LPNs may not have the expertise to properly react to critical medical emergencies.

Social Worker

The Proposed Rule would require that the social worker of a dialysis facility have a master’s degree in social work. Currently, there is an exemption from this requirement for any social worker that was employed in a dialysis facility or transplantation setting as of 1975. According to CMS, a master’s degree is necessary to give the social worker knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness necessary to serve the needs of patients and their families.

Dialysis Technician

CMS considered the adoption of a national certification requirement for dialysis technicians, but ultimately declined, for a host of reasons, including long-standing congressional policy not to interfere with state control over health care professionals, cost, and insufficient evidence that national certification is necessary to ensure quality. However, CMS would require that all dialysis technicians who participate in patient care 1) meet all applicable requirements for the education, training, and credentialing of dialysis technicians under the law in the state where the technician is employed; 2) have a high school diploma or its equivalent; and 3) complete at least three months of on-the-job training under the direct supervision of an RN, following completion of the facilities technician training program. The Proposed Rule would also mandate that every dialysis facility have a written and approved training program specific to dialysis technicians, and would require that the program cover certain specified topics. Despite CMS’ decision not to create a national certification program for dialysis technicians, the Proposed Rule, if adopted, would largely define the manner in which dialysis technicians are trained and the skills they must possess.

Medical Records Supervisor; Medical Records

CMS is proposing to eliminate the requirement that a dialysis facility designate a medical records supervisor. Separately, the Proposed Rule would require that, in the absence of a state law requirement, patient medical records would need to be maintained for five years from the date of discharge for adults and three years from the date of discharge, or until the patient reaches the age of majority under state law, whichever is longer, for minors. Under the Proposed Rule, a facility would have one working day to transfer a patient’s medical records in the event that a patient transfers to a new dialysis facility.

Finally, the Proposed Rule would modify the obligations of a dialysis facility to submit data to CMS, and would specifically require that data be submitted in an electronic format and at such intervals as is specified by the HHS Secretary. The data will include cost reports, ESRD administrative forms, patient survival information, existing clinical performance measures, and any future clinical performance standards developed in accordance with the National Technology Transfer and Advancement Act, as adopted by the HHS Secretary.

Conclusion

Throughout the proposed rule, CMS repeatedly states that its goal is to reduce the federal regulatory burden on dialysis facilities, eliminate unnecessary procedural requirements, revise the Conditions for Coverage to be more outcome oriented, and protect the basic rights of ESRD patients. While we certainly agree that the Proposed Rule is focused on protecting patients, we believe this summary illustrates that the Proposed Rule, as currently drafted, would not ease the regulatory burden on dialysis facilities. For every process or procedure that has been eliminated, there appear to be two or three new required procedures. Moreover, the Proposed Rule more closely regulates the clinical decisions and activities of the patient’s nephrologist. However, unless CMS receives a strong indication from the provider community that it is dissatisfied with particular aspects of the rules, they are likely to be implemented as proposed.