

ESRD Conditions for Coverage (CfCs) Final Rule Rollout

Frequently Asked Questions (FAQs)

1. Q. When must the initial comprehensive assessment be completed on new patients?
 - A. The initial assessment must be completed within the later of 30 calendar days or 13 outpatient hemodialysis sessions after the patient's first dialysis treatment. Adequacy of the dialysis prescription must be assessed monthly for hemodialysis patients, and every 4 months for peritoneal dialysis patients.

2. Q. What are the requirements of the Quality Assurance and Process Improvement (QAPI) program?
 - A. The new QAPI condition requires a dialysis facility to develop and implement a QAPI program of its own design that reflects the complexity of the facility's organization and services. The QAPI program requires facilities to achieve measurable improvements and reductions in medical errors by using appropriate indicators and performance measures. The facility is required to continuously monitor its performance and take actions that result in performance improvements over time.

3. Q. When are facilities required to submit data electronically?
 - A. Starting February 1, 2009, dialysis facilities will be required to submit data electronically to CMS's CROWNWeb system.

4. Q. Are the social worker and dietician required to complete their own initial social and nutritional assessments as in the past, or is it all part of the comprehensive assessment now?
 - A. The ESRD Final Rule considers the social worker and dietitian part of the interdisciplinary team. Therefore, as we have stated in the preamble of the final rule (73 FR 20395):

The entire interdisciplinary team is responsible for ensuring that each patient is individually assessed and his or her needs identified, as required at §494.80. We agree that in order to conduct a clinical assessment, the patient must have face-to-face contact with the other interdisciplinary team members. We expect all professional members of the interdisciplinary team to complete the portions of the comprehensive patient assessment that are within their respective scopes of practice. It is not necessary for each professional team member to individually complete the entire comprehensive assessment and thereby duplicate efforts. Professional interdisciplinary team members might choose to conduct one-on-one interviews with patients to complete the assessments. The team may also opt to set up team meetings, which would include the patient, in order to collect the appropriate assessment information. We expect facilities to determine the best

way to manage this process, and create policies and procedures to accurately obtain patient assessment information. The assessment information is used to develop the patient's treatment plan and expectations for care, and thus it is critical for the members of the interdisciplinary team to participate.

5. Q. With respect to 42 CFR 494.80, it appears as if care plans will have to be updated monthly if and/or when lab values are out of the goal range, even on stable patients. Is this a correct interpretation of the rule?

A. Lab values alone are not the only predictor of a change in a patient's status. We have set criteria for the unstable patient and have indicated in 42 CFR 494.80(d) (set out below) the parameters surrounding an unstable patient. We have also stated that the plan of care updates must occur when there is a change in the patient's status, moving them from stable to unstable, and back.

§494.80(d) *Standard: Patient reassessment.* In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted—
(1) At least annually for stable patients; and (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.

In addition, we will allow a 15-day time period for the facility to implement any patient plan of care revision due to completion of a monthly assessment (done for unstable patients) or an annual assessment (completed for stable patients) (42 CFR 494.90(b)(2)).

6. Q. Can the comprehensive re-assessment be a review of the initial assessment with changes made when appropriate, or does it need to be the entire initial assessment done again?

A. As CMS indicates in the preamble of the ESRD Final Rule at 73 FR 20399, the comprehensive reassessment process is part of a cycle. Accurate and timely patient information obtained through a patient assessment must be reflected in the plan of care. As the assessment changes, the plan of care must be revised accordingly. Once the patient is determined to be unstable, a monthly reassessment is necessary to update the plan of care appropriately. A patient is unstable if he or she has had extended or frequent hospitalizations, or a marked deterioration in health status, or a significant change in psychosocial needs. In addition, a patient is unstable when he or she is determined by the interdisciplinary team to have poor nutritional status, unmanaged anemia, and inadequate dialysis concurrently. Unstable patients must be reassessed in accordance with 42 CFR 494.80(d), which specifies use of the assessment criteria at 42 CFR 494.80(a)(1) through 494.80(a)(13). While a comprehensive reassessment for patients classified as unstable is required, it is possible that patient status may not change in all parts of the assessment. Patient status, whether changed or unchanged, should be clearly reflected in the new assessment. In addition, the entire team is responsible for reassessing the patient.

7. Q. Under Subpart D, condition 494.140 (personnel qualifications), standard d (social worker), will there be any exceptions or grandfathering for social workers who do not have their specialization in "clinical practice"?

A. The requirement for social workers to have a MSW from a school of social work accredited by the Council on Social Work Education with a specialization in clinical practice means that the social worker has to be skilled in assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes, and must be able to design interventions with the patient, the family, the medical team, and community systems at large to maximize the effectiveness of ESRD treatment. This training received by MSWs enables them to perform these complex professional tasks and ensure effective outcomes that have a direct relationship to morbidity and mortality. (See 73 FR 20423 and §494.140(d)(2)) CMS will be releasing surveyor interpretive guidance closer to the effective date of the ESRD Final Rule (10/14/08) which will further address this issue.

8. Q. Our hemodialysis unit receives many new patients who are admitted for short-term rehabilitation. The turnover in our clinic is unusually high. We have allowed our social workers to wait for the 30-day transient period to end before doing a comprehensive assessment and plan of care. Will CMS continue to allow this practice when the new conditions for coverage go into effect?

A. CMS recognizes that dialysis facilities may experience difficulties in conducting assessments on patients who face a wealth of challenges, including frequent hospitalizations; however, these difficulties should not outweigh the need to complete a comprehensive initial assessment within a reasonable period. If a patient has received dialysis for a 1-month period, or 13 hemodialysis treatments, that in-center patient has likely been physically present in the facility for at least 40 hours. Therefore, we believe that by allowing facilities 30 days or 13 hemodialysis treatments to complete the assessment (whichever is longer) we are providing a reasonable timeframe for every member of the interdisciplinary team to assess the patient before developing the treatment plan.

9. Q. Do renal technicians that do no nursing, medical, or patient care still have to be certified as patient care technicians?

A. If a technician were not providing any patient care, he or she would not need to be certified as a patient care technician (PCT). If they do provide any patient care, then they must be certified as PCTs, pursuant to §494.140(e). Please note that if these technicians perform monitoring and testing of the water treatment system, they must complete a training program approved by the facility's governing body and the medical director as specified at 42 CFR 494.140(f).

10. Q. Our attending physician and medical director fulfill both roles for 90% of our patients. How can we meet the requirement of having "both" physicians sign the discharge order?

A. The physician would sign the discharge order in both places on the order form. In this instance, the dialysis facility must have a policy and procedure denoting the roles and responsibilities of the physician, both as the attending physician and medical director.

11. Q. Can a physician extender be used in place of monthly physician visits or do patients have to be seen by a physician at least once a month? If so, can there be occasional exceptions to the one physician visit per month?

A. Our revised regulations do not require that patients be seen monthly by a physician. 42 CFR 494.90(b)(4) requires that 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. CMS has not identified exceptions to this requirement.

12. Q. Can we refuse to admit Hepatitis B-positive patients if it so states in our policy? If we do not have HBV patients, do we still have to have a separate isolation area?

A. Every ESRD facility must meet the requirements at 42 CFR 494.30(a), which include the ability to treat HBsAg-positive patients according to the CDC guidelines incorporated by reference at 42 CFR 494.30(a)(1)(i). Your facility may be exempt from maintaining a separate isolation room (either as an existing facility or as a new facility that has obtained a waiver under 42 CFR 494.30(a)(1)(ii)), but no facility is exempt from being able to treat HBsAg-positive patients appropriately.

As discussed on pages 20376-20377 of the final rule, any HBsAg-positive patient in an existing dialysis facility should be separated from hepatitis B-susceptible patients by a demarcated physical space at least equal to the width of one dialysis station. Separate dedicated supplies and equipment must be used to provide care to the HBsAg-positive patient. Note that "separate equipment" includes glucometers. Use of an "end of row" hemodialysis station can facilitate the separation of the area from the mainstream of the dialysis facility's activities and decreases the number of adjacent dialysis stations. If a facility does not have any HBsAg-positive patients, this space may be used by non-HBsAg-positive patients on a normal basis.

13. Q. Does the RN present in the facility have to meet the requirements of a charge nurse if you have an LPN that does meet those requirements?

A. The RN present in the facility does not necessarily have to meet the requirements of a charge nurse. However, the RN present in the facility must meet the requirements for a RN, which includes the ability to meet the practice requirements in the State in which he or she is employed. In addition, as we state at 42 CFR 494.140(b)(3), the charge nurse responsible for each shift must:

(i) be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

- (ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and
- (iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

14. Q. Why does the CDC *Morbidity and Mortality Weekly Report* document require dialysis staff to wear long-sleeved gowns? We believe this requirement would take us back to the early 1990s when people wore long-sleeved scrubs. Many facilities use aprons that are impervious to blood. Blood on forearms can be seen immediately and washed off.

A. As we state on page 20377 of the final rule, staff scrubs or uniforms are sufficient attire within the dialysis unit, except for times when one might expect to be exposed to a blood spattering. Cover gowns primarily serve to protect a staff member from exposure to blood within the dialysis unit. This is addressed on page 22 of the RR05 CDC document (“Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,” developed by the Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, volume 50, number RR05, April 27, 2001, pages 18 to 28). This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to:
http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.

15. Q. Is a physician required to visit a home peritoneal dialysis patient monthly?

A. 42 CFR 494.90, Condition: Patient Plan of Care, requires an appropriate plan of care for each patient based upon medically indicated needs, treatment, and services. Patient needs identified in the plan of care should drive the frequency of home visits of the interdisciplinary team members, including the physician. Regular contact with facility staff offers the patient an ongoing support service and an avenue for communicating questions and concerns. Our regulations at 42 CFR 494.100, Condition: Care at Home, require periodic monitoring and home visits by a team member as part of the patient plan of care; they are necessary in order to protect patient health and safety. We expect that each home care patient, in addition to being visited, would have regular contact with dialysis facility staff. The dialysis facility should ensure that care being provided to home-care patients is equivalent to care provided to other facility patients. We note that 42 CFR 494.90(b)(4) requires that 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. We have not specified that patients must be seen at home. If appropriate, they may be seen at the dialysis facility or at a physician's office.

16. Q. How do we qualify a Medical Director that was previously Internal Medicine Board–eligible but never took the boards to be certified? Is there a Grandfather clause? In addition, if a Medical Director has not renewed his or her Internal Medicine Certification but has kept his or her Nephrology Board Certification current, which is under the Internal Medicine Board, does he or she still qualify to be Medical Director?

A. Our goal is to improve quality of care via the revised Conditions for Coverage and to ensure that the medical director has the appropriate qualifications. Therefore, we require that the medical director be “board-certified” in internal medicine or pediatrics by a nationally recognized professional board, per our regulations at 42 CFR 494.140(a). We did not include the term “board-eligible,” as it is no longer used, defined, or recognized by the American Board of Internal Medicine (ABIM) (http://www.abim.org/cert/policies_ssneph.shtm). A physician who does not meet the requirements at 42 CFR 494.140(a)(1) may only serve as the medical director when a qualified physician is not available, and when approved by the Secretary as provided for in 42 CFR 494.140(a)(2).

CMS recognizes that there is some confusion surrounding this requirement as well as ABIM’s requirements for re-certification for board certification in internal medicine. Therefore, we are working to develop a solution that recognizes the value of having physicians as medical directors that are board-certified in internal medicine, pediatrics, *or nephrology*. We intend to recognize board-certified nephrologists as meeting the certification requirement for medical directors. We will provide more information and direction about this issue when the revised Interpretive Guidance is issued.

17. Q. Does a patient care technician (PCT) need to keep renewing his/her certification on a continual basis? If there is proof of certification from one of the three listed certifying boards will a PCT qualify indefinitely? If the answer is that he/she has to recertify, which of the following takes precedence—the State’s Board of Nursing where he/she may be certified once only (and continue to receive a certificate from the Board of Nursing) or the CMS Conditions of Coverage?

A. We require at 42 CFR 494.140(e)(4) that patient care dialysis technicians be certified under a State certification program or a national commercially available certification program as follows: “(i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician, or (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.”

National commercially available certification programs include those of the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners Nursing and Technology (BONENT), and the National Nephrology Certification Organization (NNCO). If the State has a certification and competency-testing program (which includes standardized tests reflecting the content listed in the regulation, administered in a proctored environment unrelated to any dialysis facility) in place that is specific to dialysis PCTs, then State certification also satisfies this requirement. In other words, if a PCT is currently certified, as noted above, to practice by the State in which he or she is employed as a PCT, then he or she meets the requirements at 42 CFR 494.140(e)(4).

18. Q. Is the intent of the October 14, 2008, implementation date to have all revised care plans and assessments completed on each patient, or to have all policies and procedures in place and begin using the new rules on admissions, dates of care plan reviews, etc... on October 14, 2008?

A. It is the intent of the final rule that ESRD facilities will have all necessary policies and procedures in place on October 14, 2008, to begin following the new rules including those relating to admissions, dates of care plan reviews, etc. As existing patients' plans of care are revised after that date, they would then be revised as per the new regulations.

19. Q. Do the facilities have to have a totally separated isolation room, or a designated area in the clinical area?

A. As discussed on pages 20376-20377 of the final rule, any HBsAg-positive patient in an existing dialysis facility should be separated from hepatitis B-susceptible patients by a demarcated physical space at least equal to the width of one dialysis station. Separate dedicated supplies and equipment must be used to provide care to the HBsAg-positive patient. Note that "separate equipment" includes glucometers. Use of an "end of row" hemodialysis station can facilitate the separation of the area from the mainstream of the dialysis facility's activities and decreases the number of adjacent dialysis stations. If a facility does not have any HBsAg-positive patients, this space may be used by non-HBsAg-positive patients on a normal basis.

20. Q. Do LPNs have to be certified as dialysis techs?

A. No, as stated at 42 CFR 494.140(b)(4), "Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed."

21. Q. The timelines for completing both the assessment and care plan are stated as 30 days or 13 treatments—isn't there a somewhat longer time for the care plan, as it must be developed from the assessment?

A. No, as stated at 42 CFR 494.90(b)(2), the plan of care must be implemented within the latter of 30 calendar days or 13 hemodialysis sessions. That means that the assessment must have been completed and the plan of care developed within that time period.

22. Q. Are long-term care plans still required when the new conditions go into effect?

A. The long-term care plan for current ESRD patients would continue only until patients are assessed under the new Conditions and a new patient plan of care is developed according to the requirements at 42 CFR 494.90. After October 14, 2008, all unstable patients and all stable patients with long-term care plans that have expired must be assessed and have their plans of care developed under the new regulations.

23. Q. Are blood pressure covers going to be mandatory for all dialysis machines? We do not wish to wipe down cuffs as the process eventually ruins the Velcro.

A. The RR05 CDC infection control precautions (incorporated into the regulations by reference at 42 CFR 494.30(a)(1)(i)) state that items taken into the dialysis station should be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. Items that cannot be cleaned and disinfected (for example, adhesive tape or cloth-covered blood pressure cuffs) should be dedicated for use only on a single patient. Blood pressure cuff covers may be more cost effective and may be used for blood pressure cuffs that cannot be decontaminated easily between patients. In contrast, rolls of tape cannot be decontaminated and can serve as a source of contamination for both facility personnel and patients. Tape rolls must be dedicated to a single patient, or disposed of after patient use.

24. Q. How does CMS plan to address all the drug-related needs of dialysis patients without pharmacist participation on the interdisciplinary team?

A. During the ESRD Notice of Proposed Rulemaking's comment period, pharmacists fully supported a role for the pharmacist on the interdisciplinary team, while other commenters supported an optional role for pharmacists in dialysis facilities. Therefore, due to a lack of consensus among commenters, we did not require dialysis facilities to include pharmacists as members of the dialysis interdisciplinary team. However, we have encouraged dialysis facilities to use pharmacist expertise as appropriate. In addition, the facility policies and procedures referred to at 42 CFR 494.150(c)(1) must include medication policies and procedures that adequately protect patient safety.

25. Q. What is an "abbreviated involuntary discharge procedure?" Who determines what is contained in an abbreviated involuntary discharge procedure? Are facilities required to help patients find a new facility if this abbreviated involuntary discharge procedure is used?

A. The regulations state that in the case of an "immediate severe threat" to the health and safety of others, the facility may utilize an abbreviated discharge procedure instead of following the required procedures for an involuntary discharge. An "immediate severe threat" is considered to be a threat of physical harm. For example, if a patient has a gun or a knife or is making credible threats of physical harm, this would be considered an "immediate severe threat." An angry verbal outburst or verbal abuse is not considered to be an immediate severe threat. In instances of an "immediate severe threat," facility staff may determine to use "abbreviated" involuntary discharge or transfer procedures. These immediate procedures may include taking immediate protective actions, such as calling "911" and asking for police assistance. In this scenario, there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer. After the emergency is addressed and staff and other patients are safe, staff must notify the patient's physician and the medical director of these events, notify the State and Network of the involuntary discharge, and document this contact and the exact nature of the "immediate severe threat" in the patient's medical record.

26. Q. What is the definition for “clinical nurse specialist?” Is this a “Certified Nephrology Nurse?”

A. A “Certified Nephrology Nurse” (CNN) may or may not qualify as a “Clinical Nurse Specialist” depending upon the qualifications of the CNN. A CNN is a certification status that is granted by the National Nephrology Certification Commission (NNCC), which is affiliated with the American Nephrology Nurses Association. The CNN is awarded to nurses who pass the CNN test and who qualify to take the test through their experience and background. A person must be at least an RN with 2 years of experience to take the test. On the other hand, a “Clinical Nurse Specialist” (CNS) and a “Nurse Practitioner” (NP) are both classified as “Advance Practice Nurses.” A CNS has at least a master’s degree and specialized training. The ESRD regulations recognize that some CNSs and some nurse practitioners, both of whom are classified as “non-physician practitioners” by Medicare, may perform certain limited functions normally performed by physicians. A CNN who also meets CNS qualifications, may function as a CNN/CNS. Likewise, a CNN who also meets NP qualifications may function as a CNN/NP.

27. Q. How is CMS going to reconcile the CfC home patient visit requirement vs. the home patient Medicare Capitated Payment (MCP) guidance?

A. The MCP sets a specific rate to reimburse physicians who manage ESRD home patients as a single monthly rate, regardless of the number of face-to-face physician or practitioner visits. Although a frequency of required visits does not apply to home patients in the MCP, the CfCs require equivalent care among facility-based and home patients. A monthly visit either by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care would meet the CfC’s care at home periodic monitoring requirement.

The CfC requires that the facility make visits to the home in accordance with the plan of care. Monitoring probably will differ for stable and unstable patients; thus, facility personnel need to be aware of a patient’s level of need in order to adequately carry out its monitoring responsibility.

28. Q. Are there “acceptable reasons” for a home patient not being periodically monitored?

A. While patient choice is a hallmark of these regulations the interdisciplinary team should determine the most appropriate oversight while trying to comply with patient desires. This should be documented in the plan of care.

29. Q. Are water systems installed before May 30, 1997, subject to these regulations?

A. Yes. Regardless of when a water treatment system is installed, the system must yield water and dialysate that meets AAMI standards and must be monitored and maintained in accordance with the ANSI/AAMI RD52 guidelines, as incorporated by reference in these guidelines. Under FDA regulations, only water treatment devices installed after May 30, 1997, are required to have FDA 510(k) approval. However, all water treatment systems in

Medicare-certified dialysis programs are required to be in compliance with CMS rules regardless of when they were installed.

30. Q. Must a dietitian have at least one year of experience in a clinical setting?

A. Yes. The dietitian must have one year of clinical experience to be categorized as the qualified dietitian required at each dialysis facility. A dietitian with less than one year of clinical experience cannot meet the patient assessment, plan of care, QAPI program review, or care at home requirements of the regulations. The facility may define other tasks for the dietitian with less than one year of experience in a clinical setting.

31. Q. Must the assessments, for example, nutritional, psychosocial, medical history, be in one document or can they be in separate forms?

A. The assessments may be either in one document or in separate documents. The regulations do not specify. However, the assessments should be readily accessible to team members.

32. Q. The new regulations mention NFPA's Life Safety Code 2000. The code has been updated in 2006. Will CMS utilize this newer version or stay with the 2000 version?

A. CMS will use Chapter 20 (for new dialysis facilities) and chapter 21 (for existing dialysis facilities) of the 2000 edition of the NFPA's LSC for Ambulatory Health Care Occupancies.

33. Q. Can the Life Safety Code be uniformly waived for dialysis providers? If enforced, compliance with the LSC would result in significant financial hardship on smaller facilities.

A. Through regulations, CMS has the authority to waive specific provisions of the LSC. A waiver may be granted if a specific facility is unable to comply with a certain requirement of the LSC, and if complying with that requirement would cause an "unreasonable hardship" for the facility. The waiver will only be granted if it is determined that the health and safety of the dialysis facility's patients are not adversely affected by the waiver. In many cases, the waiver may be limited to a specific time period.

34. Q. Can a facility continue to follow the CDC statement from 2002 that allowed the multiple use of single-use vials?

A. CMS has incorporated by reference into these regulations the CDC guidelines issued on April 27, 2001, which only allow single use of single-use vials, at §494.30(a)(1)(i). CDC requires the single use of vials designated for single-use across the health-care spectrum of providers. The 2002 letter will not apply once our new regulations are effective on October 14, 2008.

35. Q. The CfCs require that facilities need to document reasons why patients cannot receive care at home. How extensive does the documentation need to be?

A. The rules do not specify the mechanism for the documentation. The intent of this regulation is to ensure that each patient receives information about the modalities of home dialysis, and that each patient who is capable of doing home dialysis is given the opportunity to choose home dialysis if he/she desires. If a facility does not provide the option of home dialysis, patients have the right to know about other facilities that offer this option. The survey process will expect to find that patients receive information on the home dialysis option; and to find that eligible patients are offered a choice of home versus in-center dialysis.

36. Q. When will Interpretive Guidance for this rule be available?

A. A draft version of the Interpretive Guidance was distributed for public comment earlier in 2008. CMS plans to distribute a revised draft of the Interpretive Guidance (IG) for the ESRD regulation prior to September 2008, pending Office of Management and Budget (OMB) review. CMS has received extensive input from the renal community about the content of the IG, and CMS looks forward to further comments. We expect that final version 1.0 of the IG will be available by the effective date of the regulation, October 14, 2008.

37. Q. Can a facility have more than one medical director?

A. The regulations state that each facility can only have one medical director. Having one medical director is required because the facility's medical director is responsible for tracking data trends and monitoring the actions of various components of the facility through the required Quality Assessment and Performance Improvement (QAPI) program. If a facility chooses to have multiple directors responsible for different components of the facilities operations (for example, home dialysis, financial operations), then the facility can designate a facility-generated group of "directors" for facility purposes with a lead director for overall coordination and management purposes. Under the regulation and for CMS purposes, one person needs to be responsible as medical director to coordinate and oversee the care of the facility and the QAPI review.

38. Q. If a facility has an old water distribution system without a conical tank, which was installed before 1997, does the facility have to replace the water tank?

A. If existing facilities with older storage tanks can demonstrate a history of water and dialysate cultures being below action levels established by the Association for the Advancement of Medical Instrumentation (AAMI), replacement of the tanks is not required.