Network 8, Inc.

Preface

This document was created as an educational resource for dialysis staff regarding the ESRD Conditions for Coverage, released 4-15-2008, and has been reviewed by CMS. The document contains information from each area of the Conditions, focusing both on newly added information as well as "old" information that is critical to ensure safe delivery of dialysis. This document is meant to serve as a guide to the Interpretive Guidance document, not as a stand-alone document. It is in no way meant to be a substitute for the entire document published in the Federal Register, April 15, 2008 or the entire Interpretive Guidance document released 10-3-08. Information contained in this document was obtained from:

(1) Part 494 Conditions for Coverage for End-Stage Renal Disease Facilities Interpretive Guidance, Interim Final Version 1.1 (released 10-3-08);
(2) Compendium of Comments and Responses Related to the Interpretive Guidance—Comments from ESRD Interpretive Guidance Distributed 8/4/2008, Interim Final Version 1.0;
(3) Questions and Answers from ESRD Update: New Conditions for Coverage, Dallas, TX and Cherry Hill, N.J., September 2008

The text of this document has been edited for clarity and brevity only when absolutely necessary—in general, text is taken verbatim from all three resources. The bulleted text is taken from the Interpretive Guidance document and information followed by (IG) is taken from the Interpretive Guidance column while information followed by (Reg) is taken from the Regulation column of the document.

The analyses upon which this publication is based were performed under Contract Number HHSM-500-2006-NW008C entitled "End Stage Renal Disease Network Organization Number 08", sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services. The conclusions and opinions expressed, and methods used herein, are those of the authors of the original materials produced by CMS (items 1-3 above). The editor of this publication assumes complete responsibility for the accuracy and completeness of the ideas reproduced in this document.

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Infection Control

Infection control section has incorporated two CDC documents as regulation, which means these recommendations must be followed.

1) "Recommendations for Prevention Transmission of Infections Among Chronic Hemodialysis Patients"—MMWR, Vol. 50, No. RR05, pages 18 to 28 (April 27, 2001).
2) "Prevention of Intravascular Catheter-Related Infections"—MMWR, Vol. 51, No. RR-10, pages 16-18 (August 9, 2002)

**Both documents can be found on Network 8 website www.esrdnetwork8.org on the Conditions for Coverage page.

Highlights

- Hand washing sinks should be dedicated only for hand washing purposes and should remain clean. Avoid placing, cleaning, or draining used items in hand washing sinks. Used or contaminated items should be handled in designated utility sinks. (IG)
- The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment; this sink may also be used by staff for hand washing. (IG)
- PPE: a cover garment that provides an impervious barrier to fluids must be worn. This could be a lab coat, a gown, or an apron which incorporates sleeves. The protective garment should fully cover the arms and torso from the neck area to the thigh/knee area. (IG)
- Non-direct patient care staff (MD, NP, SW, RD) must wear a cover garment if they are providing service to any patient in the treatment area during a time of high risk, such as during initiation or termination of dialysis. Visitors must be provided impervious cover garments if they are in the treatment area during initiation or termination of dialysis. (IG)
- According to the CDC, any item taken to a patient's dialysis station could become contaminated. Items taken to a patient's dialysis station include those placed on the top or sides of dialysis machines and dialysis chairs. Items taken to 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. Unused medications or supplies taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. (IG)
- The patient treatment area should have designated "clean" and "dirty" areas. The CDC defines a "dirty" area as an area where there is a potential for contamination with blood or body fluids and areas where contaminated or "used" supplies, equipment, blood supplies or biohazard containers are stored or handled. A "clean" area is an area designated only for clean and unused equipment and supplies and medications. Staff must be aware of the separation of clean and dirty areas to prevent cross-contamination. (IG)
- Single use vials must be used for only one patient, should not be entered more than once, and if entered, may not be stored for future use. (Reg/IG)
- If the external tranducer protector becomes wet, replace immediately and inspect the protector. If blood is present on the side of the transducer protector that faces machine, qualified personnel must open the machine and check the internal transducer protector after the treatment ends to ensure that contamination of internal pathway has not occurred. (Reg)
- For each dialysis station, the completion of one patient's treatment and post-dialysis care must be separated by enough time from the initiation of the next patient's care to allow correct disinfection. If the previous patient remains in the treatment chair while the machine is prepared for the next patient, extreme caution must be employed to prevent cross-contamination. (IG) *Per personal communication with CMS, although no specific time period between patients is prescribed, the

CDC would prefer that the machine not be prepared for the next patient until the current patient leaves the station.

- The facility should have written policies and procedures covering the infection control program and practices including, but not limited to, isolation and any additional precautions for patients with communicable diseases with different modes of transmission such as tuberculosis, influenza, and multidrug resistant organisms. The facility must review practices and update policies and procedures as needed to ensure infection control practices are rigorously followed. (IG)
- The facility must have a mechanism in place to ensure expired medications are not available for use. Opened multiple-dose vials should be handled aseptically and used and discarded in accordance with the manufacturer's set time frames and/or other accepted standards for use (e.g., US Pharmacopeia). (IG)
- There should be a documented reporting mechanism for infection control issues. The nurse manager, administrator and medical director should each be able to describe the infection control program and reporting mechanisms. (IG)
- The reporting of incidences of communicable diseases should be documented and become part of the QAPI record. Clusters of adverse events should be promptly reported to the appropriate State or local public health authority. The QAPI process does not preclude the need to report serious adverse events to public health authorities in a timely manner. (IG)
- The use of catheters for hemodialysis vascular access is the most common factor contributing to bacteremia in dialysis patients and the relative risk for bacteremia in patients with a catheter is seven times the risk for patients with an AVF. (IG)
- Catheter insertion sites should be routinely assessed by staff at each treatment. (IG)
- The CDC advises that prophylactic antibiotic lock solutions be reserved for use only in special circumstances, e.g., in units where the rate of catheter-related bloodstream infection (CRBSI) has not decreased despite optimal maximal adherence to aseptic technique. (IG)
- Facility staff should follow guidance from the NKF K/DOQI Vascular Access Guideline (2006), which states "Airborne contaminants from both patients and staff are prevented best by the use of surgical masks when the catheter lumens or exit site are exposed. Wearing clean gloves and avoiding touching exposed surfaces further decreases the risk for infection. Aseptic technique includes minimizing the time that the catheter lumens or exit site are exposed." (IG)
- Both a surveillance log/database and the patient's individual medical record should contain detailed information on catheter infections and other adverse events. (IG) *See QAPI section for more information on adverse events.

Hepatitis information

- Routine testing and vaccination for Hepatitis B is required. (Reg)
- All new patients should be tested and their HBV serologic status known prior to admission for treatment. If the results of this testing are not known at admission because of an emergency situation, the patient should be tested immediately upon intake and results known within 7 days of admission. (IG)
- HBsAg positive seroconversions must be reported to the State or local health department as required by law or regulation. (IG)
- Regarding employees: if employee states that he/she has been vaccinated against Hep B, but records are not obtainable, the personnel record should include a statement attesting to the employee having received the vaccine with dates (or approximate dates) signed by the employee. (IG)
- According to the CDC, patients and staff that have been vaccinated for Hep B should be tested for antibodies 1-2 months after the last dose of the series. Patients and staff who do not respond should be revaccinated with a full course of vaccine and retested for response. (IG)
- "Adequate response" to vaccine is a result of $\geq$ 10 mIU/ml anti-HBs. Result of "positive" or "negative" is not sufficient. (IG)

- Patients who respond to vaccine should have antibody level checked annually. If the antibody level declines to < 10, patient should receive booster dose. Retesting immediately after the booster dose is not necessary. (IG)
- Staff members who initially respond to vaccine need neither booster doses of vaccine or periodic serologic testing. (IG)
- New facilities that have not obtained approval for all required building permits or have not completed the required plan reviews in a jurisdiction that does not require building permits prior to the effective date of these regulations (10-14-08), must either provide a separate isolation room by 2-9-09 or obtain a waiver of the requirement of an isolation room. (IG)
- Refillable concentrate containers must be surface disinfected at the completion of each treatment. Refillable concentrate containers may be kept in the isolation area and refilled at the door or removed for cleaning and disinfection. In the disinfection area, the "isolation" containers(s) and wand(s) / pick-up tube(s) must be segregated in a dedicated, designated area away from all other containers and pick-up tubes. If the container/pick-up tube is to be rotated out of the isolation area, it must be bleached before subsequent use. (IG)
- One staff person may care for one or more Hep B + patients and one or more immune patients at the same time but MAY NOT simultaneously care for Hepatitis B susceptible patients. Patients who require a booster dose of the HBV vaccine should not be assigned to a staff member concurrently caring for HBV + patients. (IG)

Infection Control Q & A

1) When is the catheter site assessed, before or after the treatment? Pre-dialysis assessments are expected to include the vascular access. With a catheter, this would include the catheter site.
2) Antibiotic lock prophylaxis: the Interpretive Guidance (IG) is confusing. The IG states that Vancomycin should be avoided and that antibiotic lock solutions should be used "only in special circumstances." Is there a prohibition here? The IG was developed in consultation with the CDC, and the CDC cautions about the use of antibiotic lock solutions. In surveying, a deficient practice would be if EVERY patient with a catheter in a facility were being given an antibiotic lock solution, even though there is not a recognized problem with infected catheters. Use of Vancomycin should be limited to those organisms that are only sensitive to it. Use of Vancomycin for all patients who are suspected of having an infection could be cited—you would need to interview the medical director about this practice.
3) Should staff change gloves between "setting up" the machine and initiating the patient? Yes. Initiation of treatment is a point where there is high risk for contamination of the vascular system. The staff member needs to use fresh, clean gloves when they initiate treatment with the patient.
4) Typically we see staff use one glove, held in their hand (not putting the glove on) to silence alarms: is this practice acceptable with the new regulations? Observe care: if the staff discard the glove and perform hand hygiene before proceeding to their next task, the practice is acceptable.
5) Must staff always change gloves and do hand hygiene when moving between a specific patient and that specific patient's machine? During initiation and termination of treatment, CMS realizes it may not always be possible to change gloves and do hand hygiene while protecting the patient's access and maintaining patient safety. The intent is to minimize contact with the patient with the same gloves that have contacted potentially contaminated surfaces, such as the patient's dialysis machine.
6) Can intravenous medication vials labeled for single use be used multiple times? No. CMS is following the guidance of the CDC, as published in the CDC's 2001 document on recommendations for dialysis facilities and the CDC's August 15, 2008 document that clarified their previous communication on parenteral medication vials.

7) Can a facility use a single syringe to enter two vials when drawing up a single dose for one patient? If both vials are single use and are discarded after the single entry into each, the same syringe may be used. If either vial is multi-use, a different syringe must be used for entry into each vial.
8) What is appropriate method of disinfection of the patient station between patient shifts? Clean all surfaces without visible blood following the low-level disinfection protocol using soap, detergent, or detergent germicide. For visible blood, follow the intermediate-level disinfection protocol: immediately clean the area with a cloth soaked with tuberculocidal disinfectant or 1:100 dilution of bleach (300-600 mg/L free chlorine) following the manufacturer's directions for contact time. Wear gloves and place the used cloth in a leak proof container. After cleaning up all visible blood, apply disinfectant a second time using a new cloth or towel.
9) We often see a PCT taking out needles and then using hand hygiene and proceeding to disinfect the exterior of the machine, while the patient holds pressure on his/her access sites with a gloved hand. Is this practice "okay" with the new regulations? Yes, as long as the PCT does not go back to care for the patient without changing their gloves and performing hand hygiene after beginning disinfection of the machine, or while setting up the machine for the next patient.
10) PPE: are staff supposed to use face shield, or is wearing glasses sufficient eye protection? The expectation is to protect the staff member's mucous membranes from possible contamination by spurts or splashes of blood or body fluids. The average pair of glasses does not provide protection from the side, or protection of the nose and mouth.
11) Must staff, such as dietitians, social workers, etc., wear gloves when in the patient treatment area, if they don't touch the patient? If these staff members wear lab coats, does that suffice as a gown for infection control? Gloves are not required for casual patient contact. Any staff members who touch any potentially contaminated surfaces are required to wear gloves. Lab coats, which are closed in front and cover the arms and the body to the knees, are acceptable PPE in lieu of gowns.
12) Can a staff member wear the same mask/shield all day long? Is it okay for staff to wear their masks under their chin so that it is available when they need it? The same shield may be worn unless it becomes soiled, then it would need to be cleaned before continued use. Masks are generally time limited in usefulness as they become wetted as the wearer breathes through them, thus becoming ineffective as a barrier.
13) Could facilities use a clipboard that would sit on top of the machine and be wiped down between patients? Yes, as long as the clipboard is cleaned and disinfected in between use for patients.
14) Can facilities place hand sanitizers on the side of dialysis machines? Yes, if the dispenser is included in the cleaning done between uses of the machines for different patients.
15) What concentration of bleach should be used to clean and disinfect surfaces such as the dialysis machine and treatment chair? According to OSHA, a dilution of 1:100 is sufficient for general cleaning. If a large blood spill occurs, the blood should be first be absorbed with pads and those discarded, then a 1:10 solution used to disinfect the area.
16) What contact time is required for bleach used to clean and disinfect surfaces, such as the dialysis machine and treatment chair? According to the CDC, the most important thing from an infection control standpoint during patient changeover at the station is having clear separation between one patient's treatment, the cleaning/disinfection, and the next patient's treatment (and making sure to cover all relevant surfaces). The CDC is researching the literature to recommend a minimum contact time for this process.
17) If a computer data entry station is located away from the hemodialysis machines, what are the infection control requirements? Staff leaving the patient stations should wash or sanitize hands before touching the computer station.
18) What should the facility do if the patient refuses to wash their hands or wear a glove to hold their sites? Educate the patient again regarding the reasons for the request. If the patient still refuses, do not allow the patient to hold his/her own sites.

19) Do all dialysis staff members need the training listed at V132 for infection control or just “hands on” staff? All dialysis staff members that are at risk for occupational exposure to blood and body fluids are expected to have the required infection control training; generally this would include all staff members.
20) Can you give some direction for appropriate footwear in the treatment area: are sandals or “Crocs” okay? Expect facility policy to direct this practice; generally, closed toes shoes are required to protect the staff member’s feet from potential exposure to blood. Surveyors should wear closed toe shoes when surveying dialysis facilities.
21) Can clinical staff wear artificial nails? Facility policy should guide this practice. However, research is emerging regularly to indict the use of artificial nails as a source of microorganisms that are easily transferred to patients.
22) Is it acceptable for a facility to shred all of the biohazardous waste, including dialyzers, sanitize it, and then dispose of it in the regular trash? There is equipment on the market to do this: if the facility has this equipment, and follows the directions for use, the shredded “remains” can be disposed of in the regular trash.
23) Does a facility have to replace/remix the 1:100 bleach solution every 4 hours? Where is this reference? No reference was found that requires this.
24) Do patient education tools, such as flip charts, used by multiple patients, need to be disinfected between patients? If multiple patients use patient education tools during their dialysis treatments (items taken to the dialysis stations), those tools must be able to be disinfected between uses by different patients.
25) Can an oxygenator be used by multiple patients? This includes the humidifier bottle and filter. How often must the filter be changed? Oxygen concentrators may be used by multiple patients, if the outer casing is surface disinfected, and the humidifier bottle and tubing are changed. The filter should be changed per manufacturer’s directions for use.
26) If a staff member carries an item, such as a heparin syringe, to the dialysis station, but does not put it down (no contamination), can it be returned to the common supply area? Depends. If the staff member keeps the syringe in her/his hand, and hands are clean/sanitized and it did not touch any potentially contaminated surface, the syringe may be returned to the common area.
27) If a non-reuse dialyzer and lines are primed and the patient is a “no-show”, can the facility use this equipment for another patient? Yes, if the dialyzer is the same as is ordered for the other patient.
28) Is there any requirement for the discard of a new dialyzer if it has been primed for more than two hours but not used? Consult the dialyzer directions for use and the facility policy. There is no regulation to direct this.
29) TB testing for staff: what is required? CMS does not require TB testing for staff.
30) Does staff need to be tested for TB? Where is this in the ESRD CfCs if it is included on the personnel file review tool? There is no ESRD federal requirement for TB testing. The tool was constructed to allow use in many states that do require TB testing.
31) Are dietitians, social workers, physicians, NPs/PAs required to have HBV routine screening? There is no requirement for routine screening of any staff members. The only screening required of employees is after completion of the vaccine series. All staff members are required to be offered vaccine.
32) How does a facility maintain patient confidentiality of the HBV + patient if the education of the patients outlines for whom or why the isolation room would be used? The regulations require that all patients be informed of the isolation requirement; the risk of HBV infection takes precedence over the confidentiality issue.
33) If there are multiple HBV + patients, can they share a machine and an area or room? Yes. If there are multiple HBV + patients, they can use the same area/room and machine, with routine cleaning and disinfection of the equipment/treatment chair between patients. Some facilities may have multiple stations in an isolation room where they dialyze several HBV + patients at the same time.

34) Should facilities offer HBV vaccine to social workers and dietitians working in an ESRD facility? Yes. All staff working in a dialysis facility should be offered HBV vaccine.
35) Is there a CDC recommendation for HBV revaccination of staff that do not respond to a first series? In the CDC 2001 MMWR recommendations, if staff member does not respond to a first HBV vaccination series, another series of vaccination is recommended. If they do not respond to the second series, no additional vaccination is recommended.
36) How can you tell if patients/staff have responded to the Hepatitis B vaccine? The CDC defines an adequate response to vaccination as a laboratory result of $\geq$ 10 mIU/mL anti-HBs. The laboratory performing the testing for anti-HBs must be able to define a 10 mIU/mL concentration. Results should be reported as a numeric value; a result of "positive" or "negative" is not sufficient. Some manufacturers of anti-HBs assays consider a level of anti-HBs that is slightly higher than 10 mIU/mL to be protective. For these assays, the higher level of titer considered to be protective by the manufacturer of the kit should be used to determine whether or not the patient or staff member is immune.
37) When is an isolation room required for HBV + patient? When is an isolation area acceptable? How is an isolation area defined? Any facility constructed after February 9, 2009 is required to have an isolation room unless granted a waiver of this requirement by CMS. Existing facilities currently using an area may continue to use that "isolation area." Existing facilities that begin caring for HBV + patients after February 9, 2009 may designate an area for such use, unless they are expanding the physical location, in which case they must add an isolation room or obtain a waiver of the requirement. An isolation "area" is separated from other stations by a space at least equivalent to that of another dialysis station.
38) If an existing clinic does not have an isolation room, do they have to build one? No.
39) If an existing clinic currently uses an area (not a room) for HBV + patients, may they continue to use this, or do they have to add a room? They may continue to use the area, with the requirement that the HBV + treatment area be separated from other treatment stations by a space the width of a treatment station.
40) If an existing clinic that currently does not accept HBV + patient expands their physical capacity, do they have to include an isolation room? The facility expanding their physical capacity would need to either add an isolation room OR obtain a waiver of this requirement.
41) Can a clear barrier be used to define an isolation area rather than a space the width of a dialysis station? The requirement for using an area as an isolation room is to provide space between the HBV + station and other treatment stations at least the width of a dialysis station. While a clear barrier may be used, it would not substitute for the space requirement.
42) Does the isolation room have to have a door? Does the door have to be closed during treatment? Yes. The patient needs to be able to be seen at all times, so there would either need to be see-through walls (glass, Plexi-glass) or a staff member in the room. The door should be closed during times when blood spurting or spattering is possible, e.g., at initiation and termination of treatment.
43) Do you need 2 sinks in the isolation room? No, there is no requirement for 2 sinks, but there must be one sink immediately available for use in or adjacent to the isolation room. State licensing rules may be more stringent.
44) How should concentrate containers be handled for isolated HBV + patients? Refillable concentrate containers must be surface disinfected at the completion of each treatment. Refillable acid concentrate containers should be kept in the isolation area and refilled at the door. Refillable bicarbonate concentrate container may be removed for cleaning and disinfection. In the disinfection area, the "isolation" container(s) and wands must be segregated in a dedicated, designated area away from all other containers and wands. If the container wand (also called pick-up tube) is to be rotated out of the isolation area, it must be bleached before subsequent use.

45) If the HBV + patient runs only twice per week and the room is terminally cleaned and the machine removed, why can't the room be used for HBV – patients? How is this different from using that room after the patient is discharged from the facility? According to the CDC, the difference is the risk of inadequate cleaning. When the cleaning has to happen after each treatment, the risk of exposure of patient to HBV is greater. The regulation requires the room/ area to be reserved for HBV + patient use until there are no longer any HBV + patients on census.
46) HBV + patient isolation area and space for existing facilities: when do these requirements take effect? For existing facilities, the requirements for isolation are effective 10/14/2008.
47) Can a facility apply for a waiver to use their isolation room for patients who are not HBV +? No waiver is required to use a room or an area formerly reserved for a HBV + patient AFTER all HBV + patients have been discharged and none are any longer dialyzing in the facility.
48) Does "physically expand" mean adding stations? If a facility adds stations, will they need to add an isolation room? Existing facilities that expand by adding stations will be required to follow the isolation requirements as of the time of the expansion.
49) Isolation station requirement for an area say "separated from other stations by a space equivalent to the width of a hemodialysis station." What is that width? The AIA guidelines (2006) specify 4 feet. Is that what we should use? To determine this width, measure the width of the chair and the width of the machine. Add these together, that is the width of space that would need to be used to separate the HBV + area from other patients.
50) When an ESRD facility is acquired by another provider (change of ownership), do they need to have an isolation room? A change of ownership would not spur a reconsideration of the need for an isolation room. The need for a room depends on the parameters that are spelled out in the regulation and interpretive guidance.
51) If a facility has an isolation room, may they refuse to accept HBV + patients, so that the isolation room can be used as a regular station and used for all shifts? Each facility must have provision for isolation of HBV + patients. If a facility has no current HBV+ patients, they may use their isolation room for any patient. While the medical staff may choose to admit or refuse to accept a patient, a pattern of refusal to accept HBV + patients in these circumstances would not meet the intent of the regulations and could result in a complaint investigation and citations for not having the provision for isolation.
52) If a facility has an isolation room, but does not have any HBV + patients, can the isolation room be used for other patients? Yes. As long as the room is terminally cleaned and disinfected after the last HBV + patient is no longer treated in-center. If another HBV + patient is admitted, the isolation room must be used exclusively for that patient.
53) For the isolation room waiver, how close does the "same geographical area" mean for existing facilities? Criteria for the isolation room waiver are being developed.
54) Do the sinks in the treatment area have to be of the type that the water flow can be operated without the use of hands? No. While state laws may have some requirements in this area, the federal regulation does not address this issue. It would be expected that staff would avoid re-contamination of their cleaned hands when they turn the water off.
55) If all sinks have sensors or foot pedals, may every sink be used for hand washing (even the "dirty" sinks where saline bags are draining)? No. Hand washing sinks should not be used for discarding of saline from used bags, as the fluid is considered potentially contaminated by patient blood or body fluids.
56) Can "clean saline" be discarded in the hand washing sink as long as the saline bag is removed from the extracorporeal circuit prior to blood entry into the system? No.
57) Do sinks have to be labeled "clean" or "dirty"? No.
58) Can sinks that are used to drain saline bags, disinfect clamps and priming buckets, etc., be used for hand washing? No. Hand washing sinks should be dedicated for that purpose and remain clean.

Water and Dialysate Quality

Water and dialysate section has incorporated two Association for the Advancement of Medical Instrumentation (AAMI) documents as regulation, which means recommendations must be followed.

1) American National Standard for Dialysate for Hemodialysis 2004 (RD52:2004)
2) American national Standard for Water Treatment Equipment of Hemodialysis Applications (RD62:2001—selected sections)

Highlights

- Survey of the Condition requires inspection of the water treatment and dialysate preparation equipment and their distribution systems; interview of personnel responsible for day-to-day operation of those systems; and review of the records of operation and testing for those systems. (IG)
- CRITICAL to ensuring patient safety is the expectation that every survey visit include direct observation of water testing for chlorine/chloramine. (IG)
- For initial surveys, the facility should provide a copy of a chemical analysis with results within AAMI standards accomplished prior to starting any patient treatment in the new facility. For resurveys, there must be evidence of ongoing monitoring of the chemical quality of the water, and actions taken when levels were outside the AAMI standards. (IG)
- If the water supply for the facility is from a private well, annual analysis of the quality of the product water may not be sufficient to ensure the feed water requirements of the water treatment system in use are continuously met. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. (IG)
- If the water supply utility has notified the city that the source water is highly chlorinated due to a water main break, flooding, or bacterial contamination of the municipal system, the facility will need to do more frequent monitoring of chlorine/chloramines (i.e., every 30-60 minutes). (IG)
- Product water used to prepare dialysate or concentrates from powder and conventional dialysate shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL. *Same limits for water and dialysate. (Reg)
- Action level for the total viable microbial count in the product water and conventional dialysate shall be 50 CFU/mL and the action level for the endotoxin concentration shall be 1 EU/mL. *Same action level for water and dialysate. (Reg)
- AAMI recommends that the water treatment and distribution system be disinfected promptly any time the levels of bacteria or endotoxins in product water exceed the actions levels. (IG)
- If dialysate samples exceed action level, corrective measures such as disinfection and retesting should promptly be taken, inclusive of notifying the medical director of culture results. “Prompt” means within 48 hours of receiving the results of testing. (Reg/IG)
- Water purification and storage system should be located in a secure area that is readily accessible to authorized users. To ensure access is restricted, the delivery doors/loading dock must not be left unlocked, open, and unattended. (Reg/IG)
- The layout of the water system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance. The

operator should be able to describe and identify the various components and the distribution system. (Reg/IG)

- Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction. Piping should be labeled to indicate the contents of the pipe and direction of flow. Major water system components should be labeled in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range. (Reg)
- Water softeners
    - Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated. (Reg)
    - The timer box cover must have a clear window allowing the timers to be seen, or the cover must be removed when timers need to be viewed. (IG)
    - Facility policy should define the expected level of salt in the brine tank, with a minimum requirement that salt pellets fill at least half of the tank. (IG)
    - Total hardness of the water exiting the water softener should be measured at the end of each treatment day. This will indicate the overall effectiveness of the water softener under worst-case conditions and will ensure that the softener is sized properly. (Reg/IG)
- Carbon tanks
    - Removal of free chlorine to a maximum level of 0.5 mg/L and chloramine to a maximum level of 0.1 mg/L is necessary to protect patients from red cell hemolysis. (IG)
    - Two carbon beds shall be installed in series with a sample port following the first bed. A sample port shall also be installed following the second bed for used in the event of free chlorine or chloramine break-through. (Reg)
    - Exhausted carbon adsorption media shall be discarded and replaced with new media according to a replacement schedule determined by regular monitoring. The date of exchange should be documented on the tank and in the appropriate log. (Reg/IG)
    - Regenerated carbon shall not be used for hemodialysis applications. Carbon can be removed and replaced on site when tanks are off line. Granulated activated carbon (GAC) with a minimum iodine number of 900 must be specified when replacement carbon is ordered. Acid-washed carbon is recommended, as it will protect the RO from exposure to excess aluminum, but is not required. (Reg/IG)
    - Each carbon tank shall have an empty bed contact time (EBCT) of at least 5 minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes). (Reg)
    - Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set shifts, testing should be performed approximately every 4 hours. Samples should be drawn when the system has been operating for at least 15 minutes. (Reg)
    - More frequent monitoring may be appropriate during temporary operation with a single carbon bed, which can occur following breakthrough of the first bed. (IG)
    - Sampling for total chlorine (the sum of free chlorine and chloramine), allowing a maximum level of < 0.1 mg/L of total chlorine, is often simpler than analyzing for free chlorine and chloramine separately. (IG)
    - Test strips with color comparison charts that indicate a low level reading of zero and a first “number” of 0.5 are not sufficiently sensitive to detect levels as low as 0.1 and must not be used for testing product water for safe levels of chlorine/chloramine. An indication of “0” on the comparison charts does not suffice to demonstrate the strips are sensitive to “0”. (IG)

    - When samples from the first sampling port are positive for chlorine or chloramine, operation may be continued for a short time (up to 72 hours) until a replacement bed is installed, provided that samples from the second sampling port remain negative. The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds should be replaced. (Reg)
    - When facilities operate with one exhausted carbon bed for up to 72 hours, the log of testing should include the actual time testing was done rather than indicating "1st, 2nd, or 3rd" shift. (IG)
- Reverse Osmosis
    - All results of measurement of RO performance should be recorded daily in an operating log that permits trending and historical review. The medical director, nurse manager, and chief technician must be able to describe how trends in the RO function are monitored to detect problems. (Reg/IG)
    - Not all manufacturers incorporate a preset limit, which would activate an audible alarm when the quality of the product water diminishes, but all do offer a process for the user to follow in determining a limit to set. The medical director and the chief technician should be able to discuss how the set point was determined. (IG)
    - The determination of rejection rates may require staff to calculate this from data displayed. If the RO does not display rejection rates, expect any staff member assigned responsibility for monitoring the water treatment system to be able to calculate the percent rejection. The operator should know normal ranges. (IG)
    - In the absence of an automatic divert to drain valve for the RO, facility staff must demonstrate knowledge of the requirement to manually stop water flow to the dialysis machines and other dialysis related equipment should the water quality alarm sound. (IG)
    - Chemical analysis for contaminants should be done when the RO system is installed, when membranes are replaced, and at not less than annual intervals thereafter. Chemical analyses should be done when seasonal variation in source water suggests worsening quality or when rejection rates fall below 90%. (Reg)
- Deionizers
    - Deionizers shall be monitored continuously using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms. Resistivity monitors shall have a minimum sensitivity of 1.0 megohm-cm. Patients shall not be dialyzed on deionized water with resistivity less than 1.0 megohm-cm. Resistivity monitor readings should be recorded on a log sheet twice each treatment day. (Reg)
    - If DI tanks are available for back-up use, the facility must take action to counter the tendency of DI to contribute bacterial contaminants to the water. This may be accomplished by placing the tanks on line post RO so that there is a low flow of water through them, or flushing the DI tanks daily. DI tanks should not be stored "wet". (IG)
    - Exhausted DI tanks must be returned to the vendor for recharging. The date of exchange should be posted on the tank(s) and recorded in a log. (IG)
    - Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm. There must be an automatic divert-to-drain system for any DI system used in-center. (IG)
    - Feed water for DI systems shall be pretreated with activated carbon adsorption upstream of the DI to prevent formation of carcinogenic nitrosamines. (Reg)
    - If DI is the last process in a water treatment system, an ultrafilter or other bacteria and endotoxin-reducing device shall follow it. (IG)
    - Samples for chemical analysis should be drawn after the DI. Taking the sample from the last patient treatment station would also meet this requirement. (IG)

- Water storage tank
    - The facility must follow the manufacturer's guidance for the disinfection of the water storage tank. Tanks that fill from the top and drain from the bottom may, in fact, drain several times a day. The goal is to not have stagnant water. (IG)
    - To monitor the water storage tank, measure bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated. Action levels for bacterial growth are 50 CFU/mL and 1 EU/mL for endotoxins. Expect action to be taken for levels above 50 CFU/mL and 1 EU/mL. (IG)
- Water distribution system
    - Bacteria and endotoxin testing should be conducted at least monthly. New systems or changes to existing system (i.e., changes to the RO membranes or installation of a new storage tank) merit testing weekly for one month. (Reg/IG)
    - Samples should be taken from first and last outlets of the loop and from outlets supplying reuse equipment and bicarbonate mixing tank(s). (Reg)
    - Action levels are > 50 CFU/mL; for endotoxin > 1 EU/ML. (IG)
- Bacterial control strategies
    - To prevent or limit biofilm development, water distribution system must be disinfected at least monthly. All surfaces in the system must have sufficient contact time with the disinfectant prior to its being rinsed from the system. (IG)
    - Dialysis machine line (from the outlet of the water distribution system to the back of the machine) must be disinfected regularly. This may be done by rinsing the machine with water containing germicide or hot water (if the distribution system is disinfected with hot water) when the water distribution loop is disinfected. The hot water used for routine machine disinfection generally does not disinfect this line. If germicide is used for disinfection, each machine should be rinsed and tested afterward to ensure that germicide has been rinsed out completely. (IG)
- Concentrates/mixing systems
    - Acid concentrates supplied in 55-gallon drums are the responsibility of the manufacturer until delivered; after delivery, the facility is responsible for proper handling. If the acid storage system can be accessed via an outlet on the outside of the building, the facility must ensure that there are safety controls in place to prevent mix-ups, tampering, or contamination of concentrates. (IG)
    - Appropriate personal protective equipment, as recommended by the manufacturer, should be used when mixing concentrates. (Reg)
    - Concentrate preparation, inclusive of the number of bags or weight of powder and the amount of water used, must be recorded. (IG)
    - Facility must have records of the manufacturer's instructions for the sanitizing, maintenance and monitoring of the mixing system. (IG)
    - Individuals responsible for mixing concentrates must demonstrate competency in following the manufacturer's directions for use. (IG)
    - Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. Label should remain in place until tank is empty. (Reg)
    - Bulk storage or dispensing tanks should be permanently labeled to identify contents. (Reg)
    - Labels should be used to alert staff when ozone or bleach is in a tank or concentrate jug during disinfection. If a group of jugs are being disinfected at once, a label or sign marking the area in use could be used rather labeling each jug individually. (IG)
    - In addition to container labeling, there should be permanent records of concentrate batches produced. (Reg)
    - Mixing logs must demonstrate complete documentation of required information (formula produced, volume of batch, lot numbers of powdered concentrate packages, manufacturer

of the concentrate, date / time of mixing, any test results, person performing the mixing, person verifying the mixing and test results, and expiration date). “Test results” may include conductivity or specific gravity. Facility policy must stipulate the expected ranges for the test(s) used to verify correct mixing. The use of pH as an indicator for proper dissolution is inappropriate for both acid and bicarbonate concentrates. (Reg/IG)

- Facility policy and practice must ensure that acid mixing tank is completely emptied between mixing batches of concentrate (Reg/IG)
- Bicarbonate mixing tanks should have a tight-fitting lid and be designed to allow all internal surfaces to be disinfected and rinsed. Bicarbonate concentrates have been shown to support bacterial growth and additional precautions should be taken when preparing and handling bicarbonate concentrate to avoid excess growth of bacteria. (Reg/IG)
- Bicarbonate concentrates must be used or discarded within the manufacturer’s timelines. If facility staff combine concentrates from partially used jugs, there must be some system in place (such as discarding all bicarb at end of the day) to ensure that concentrate is not kept past the maximum storage time of oldest portion. (IG)
- Central delivery systems should be cleared of bicarbonate and rinsed clear each treatment day. (IG)
- Over-mixing of bicarbonate should be avoided as this results in loss of CO2. There must be a system in place to prevent such, which could include a timer integrated into the mixing system for automatic cut-off, or a policy to require staff to monitor the mixer and cut it off immediately when the time period for mixing is completed. (IG)
- When additives are used to increase concentration of specific electrolytes in the acid concentrate, mixing procedures shall be followed as specified by the additive manufacturer. (IG)
- The State nurse practice act must be considered in determining the appropriate staff allowed to use additives to change electrolyte levels in acid concentrate. Since concentrate is a prescription medication, many states require a licensed nurse to perform this task. (IG)
- “Spiked” acid concentrates (concentrate mixed with electrolyte additives) must be clearly labeled with the added electrolyte, the date and time added, and the name of the person making the addition. (Reg)
- Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes (wands) should also be rinsed with treated water and allowed to air dry at the end of each treatment day. (Reg)
- Facilities that reuse bicarbonate concentrate jugs should disinfect the jugs at least weekly. Jugs can be disinfected with household bleach solutions (1:100) with a contact time of about 30 minutes or another EPA-registered disinfectant according to the manufacturer’s instructions. (IG)
- If the facility uses less contact time than 30 minutes, there must be evidence of the use of dialysate culture results to determine the needed contact time. (IG)
- If more than one acid is centrally delivered to treatment stations, outlets must be clearly labeled with the acid type. (IG)
- Each machine must be tested for pH using a hand-held meter or other appropriate testing device (adequately sensitive testing strips) before every dialysis treatment and whenever a different composition of acid concentrate is used. (IG)
- If the dialysis machine manufacturer requires testing of conductivity, this must also be tested using an independent testing device prior to each treatment and before using a different composition of acid concentrate during the same treatment. (IG)

- Microbial monitoring

    - Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general the sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin-free container. Sample taps should not be disinfected. (Reg)
    - Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. (Reg)
    - Facilities may take samples of dialysate using a “clean catch” technique of the effluent from the Hansen connectors, use a needleless system to access the port on the dialysate line, or use a syringe and needle to aspirate a sample from the port on the dialysate line. (IG)
    - Samples must be collected in the “worst case” scenario. Samples must be collected before sanitization/disinfection of the water treatment system and dialysis machines. (Reg/IG)
    - Dip samplers may be used for bacterial surveillance. Colonies should be counted using a magnifying device. (Reg)
    - Facilities that use dip samplers must send duplicate samples to a laboratory at least annually to evaluate the accuracy of the dip samplers. (IG)
    - For LAL testing, at a minimum, two tubes should be run each time the assay is performed. The first tube contains LAL reagent and the sample to be tested. The second tube contains LAL reagent, a know amount of endotoxin, and the sample to be tested. The second tube acts as a positive control to confirm the absence of any interference that might lead to a false negative result. (Reg)
- Adverse events
    - In the event of chlorine/chloramine breakthrough, responsible staff must know how to prevent the water treatment system from continuing to make product water that empties into holding tank. (IG)
    - Responsible staff should list notifying the medical director as an action they would take immediately in the event of a chlorine or chloramine breakthrough. (IG)
    - Water and dialysate monitoring must be reported in the Quality Assessment and Performance Improvement (QAPI) materials and the medical director must be involved in analyzing and addressing test results outside of expected parameters. (IG)
    - The medical director must develop standard protocols which require blood and dialysate cultures and endotoxin levels be collected in the event of patient adverse reactions(s) during or following dialysis treatment. (IG)

Water Treatment Q & A

1) How should surveyor cite failure to test staff for color blindness if the facility has no policy for this? If the facility uses tests for water safety that require differentiation of color differences, the person assigned to do those tests (and make those determinations) must be able to discern color differences. We will revise the Interpretive Guidance to make it clear that the ability to discern colors is required for persons responsible for performing tests whose results are dependent on changes in color. *Interim Final Version 1.1 IG were revised to reflect this-- “The ability to discern colors is an essential job function for persons responsible for reading colorimetric tests. Depending on the test method used, staff assigned this responsibility must be capable of distinguishing between different shades of pink and other colors or a digital meter must be used.”
2) Our state office requires that when the city adds chlorine to the centrally supplied water, the facilities should perform both chloramine and total chlorine tests on RO water. What is CMS position on this? AAMI recommendations and the CMS regulations allow facilities to do one test for

the levels of chlorine and chloramine, if the test can detect chlorine levels lower than 0.1 ppm and if the facility sets their allowable limit for chlorine at less than 0.1 ppm.

3) What are the acceptable levels of chlorine and chloramine in water used for dialysis treatment? Are free chlorine and total chlorine the same thing?
   - The allowable level for total chlorine is 0.5 ppm; the allowable level for chloramine is 0.1 ppm.
   - Free chlorine is different from total chlorine; tests for total chlorine include free chlorine. If the facility were using two tests, they would test for total chlorine and free chlorine, and subtract the result for free chlorine from the result for total chlorine to determine the result for chloramine.
   - If only one test is performed, the test must detect both total chlorine and free chlorine, and be sensitive to levels less than 0.1 ppm. If only one test is performed, the facility must set the target value as less than 0.1 ppm.
4) Is it acceptable for facilities to use the powder or tablet reagents to test water for chlorine/ chloramine rather than the testing strips? Yes. The expectation is that facilities use a testing method that is approved by the FDA for testing of water for chlorine/chloramine and they use a test method that is sensitive to the levels required. The DPD methods using tablets/powders would meet this requirement.
5) What if the facility is using a qualitative method for testing water chlorine levels? Is this an immediate jeopardy citation? Depends. For some test strips, there are two testing methods: one, the qualitative method which only provides a positive or negative result; and two, the quantitative method, which provides a numerical value for the result. If the staff member is performing the test correctly and there are no other issues related to the level of understanding of the responsible staff member, and the test result is negative, cite the need to use the quantitative method as a standard deficiency at V196. If the staff member is not performing the testing correctly, or there are other issues related to the level of understanding of the staff member, this could result in an immediate jeopardy finding.
6) What is the maximum allowable level for total chlorine and chloramines? The maximum allowable level for total chlorine (the free and bound chlorine combined) is $\leq$ 0.5 mg/L, and $\leq$ 0.1 mg/L for chloramines. If the only test the facility is doing is for total chlorine, then $\leq$ 0.1mg/L must be used for the maximum allowable level, to ensure patient protection from chloramines exposure.
7) Is there a regulation stating where in the water treatment system the water should be tested for chlorine/chloramine? Yes. V192 requires 2 carbon tanks/banks with a sample port between them for the daily and each shift testing for chlorine/chloramine. It also requires a sample port after the second carbon tank/bank for testing if the first test exceeds limits.
8) When the facility is going to be using the water in the storage tank at the start of the day, does the water system have to be run for 15 minutes before testing? Yes. The purpose for running the water system before testing is to guard against sampling water that has been in the carbon bed for an extended period. Testing the water being “made”, even if the water in the storage tank is currently being used, ensures water safety as the “new” water fills the tank.
9) How many dialysis machine/dialysate cultures must be done each month? Two dialysis machines per month and each machine must be cultured annually, at a minimum.
10) When should water and dialysate cultures be taken in relation to disinfection? Cultures and endotoxin levels of the water and dialysate should be taken prior to disinfection of the water system/dialysis machines (i.e., in the “worst case” scenario—V254).
11) For initial surveys of water/dialysate systems, what is required for microbial monitoring for verification of the systems? To validate new water systems, bacterial and endotoxin testing should be done at least weekly for one month to demonstrate levels within AAMI limits (V213). Dialysate mixing and distribution systems should be validated per manufacturer’s directions for use. Dialysate/machine cultures should be taken weekly until a pattern of acceptable levels is established. (V253)

12) How often must a water system without a holding tank be disinfected? All water distribution systems must be disinfected at least monthly, or more often if the manufacturer's directions for use dictate.
13) The regulation states that the results of routine monitoring of water storage tanks for bacteria and endotoxin levels should be recorded on a log sheet. Are there acceptable alternatives for recording? Yes. Laboratory-generated reports are an acceptable alternative to recording results in a log is there if a provision for an aggregate report allowing multiple monthly reports to be easily compared for trends.
14) Should dialysate cultures be collected at the end of dialysis? Cultures of water and dialysate should always be taken at "worst case" time: product water samples taken prior to disinfection, dialysate samples from the dialysate port of the dialyzer at the end of dialysis. **Note that interpretive guidance states that dialysate samples may also be taken from Hansen connector or from port on dialysate line.
15) Is there any problem with using chloramine for disinfecting? Generally the facility will not use chloramine: chloramine is used by city water treatment systems to extend the "life" of the chlorine; using chloramine allows chlorine to still be in the water system at the end of the city's water distribution system. There is no need to extend the "life" of chlorine in the dialysis facility, as the distribution systems are limited in length. Since chloramine = chlorine and ammonia, using chloramine for disinfection in the facility would also result in a need to safely dispose of the ammonia released when the chloramine disassociates.
16) Is it okay to have a contract service (such as the water company that installed the system) monitor the facility for alarms, times, etc.? The facility could contract with a water vendor for the service of water treatment. It is unlikely that outside staff would be available during all treatment times to monitor the function of the system; but the contract staff could ensure there were alarms, that the timers were visible, that filters were changed as needed, etc. Facility staff would need to be trained and responsible for monitoring the system when the water contractor was not on-site.
17) Are facilities required to test the water system alarms for water quality and low tank level? The requirement is that the alarm sound in the treatment area. In order to know if the alarm sounds, the alarm must either be tested or the facility staff must note when the alarms sound during operation. **Clarification: regulations do not require a low tank level alarm.
18) For an RO: is an alarm that is located in another location, but is audible in the patient treatment are acceptable? Yes. RD 62 which is incorporated into RD 52 at V186 requires that the RO include an audible alarm which can be heard in the treatment area. The requirements for DI are more stringent and specify the alarm must be audible and visible in the treatment area.
19) When must machines be tested for conductivity and pH? Each machine must be tested for pH using a hand-held meter or other appropriate testing device, e.g. adequately-sensitive testing strips, before every dialysis treatment and whenever a different composition of acid concentrate is used. If the dialysis machine manufacturer requires testing for conductivity, there must also be testing using an independent testing device prior to each treatment and before using a different composition of acid concentrate in the same treatment.
20) Can pre-packaged (by the manufacturer) bicarbonate concentrate jugs be "topped off" when partially empty? No. Topping off partially filled bicarb jugs is rarely appropriate, due to the high propensity for microbial growth, and combining pre-packaged liquid medications, which could have different lot numbers, is not an acceptable nursing practice.
21) With bicarbonate, what is over mixing? Why would it be a problem? Where is the time limit for mixing specified? Each manufacturer of bicarbonate powder for use in making the bicarb concentrate for dialysis specifies the mixing time. Mixing longer can result in off gassing of the bicarbonate, which will change the pH of the mixture, and can result in the formation of a precipitate, lowering the calcium level of the concentrate, and potentially causing the patient's serum calcium to drop.

22) Must the bicarbonate concentrate in elevated tanks be emptied daily, even if it risks air locks in the distribution system? Expect that the manufacturer's direction for use of the elevated tanks be followed. Recognize that bicarbonate is a very good growth media and that the manufacturer's guideline for bicarb regarding length of storage must be followed.
23) If individual one gallon acid concentrate jugs, supplied by the manufacturer, are used, must these be labeled with the patient's name? If the same concentrate is being used for multiple patients, the jug would not have to be labeled with the patient's name. If the jug of concentrate was specifically prepared for one patient, the labeling must include the name of the patient. In all cases, the label on the container must match the dialysis prescription for that patient.
24) How long following dialysis can patient reactions occur and still be considered as potentially related to the water? Would water/dialysate cultures need to be taken if the reaction occurs after the patient leaves the facility? Generally, reactions occurring up to four hours after treatment can be considered as potentially related to the treatment. Pyrogenic reactions to the water used for dialysis, such as fever and/or chills, are generally sudden and occur during the patient's dialysis treatment, and the facility is expected to take action as described at V275. If multiple patients report similar reactions within several hours of discharge from their treatments, the facility should evaluate the occurrences for possible trends and act upon them as indicated, which could include culture collection.
25) If one of the two carbon tanks has been exhausted, can the facility operate with one carbon tank until the exhausted carbon tank is replaced? V197 allows dialysis to continue with one exhausted carbon tank for up to 72 hours as long as testing after the remaining functional tanks remains below the accepted limit of < 0.1 ppm of chloramine.
26) If the primary carbon tank is exhausted, and the total chlorine reading after the secondary tank is at 0.1 mg/L, can patients still be dialyzed? If the primary carbon tank is exhausted, dialysis may continue up to 72 hours, as long as the reading after secondary carbon tank is < 0.1 mg/L chloramines. If the only test the facility is doing is total chlorine, the level must be < 0.1 mg/L. More frequent testing after the secondary carbon tank would be expected and the exact times the tests were done recorded.
27) If the facility rebeds the carbon tanks on-site, what precautions must be taken? If the carbon tanks are rebedded at the facility, the carbon must be disposed of in accordance with the local waste management requirements. The manufacturer's guidance should be followed for PPE which might be required.
28) Can test strips sensitive to 0.5 be used to test for residual bleach after rinsing? Yes.
29) What about KDF (Kinetic Degradation Fluxion: high-purity copper-zinc granules that reduce contaminants in water using an oxidation/reduction [redox] reaction) and UV for chlorine removal from water? The use of other methods of chlorine removal may be required in some situations, but in each case would need to be in addition to the requirement for two carbon tanks. Guidance at V192 addresses some alternatives.
30) Is a 510K approval required for a new facility's water treatment system that is built by the facility? Yes. Since 1997 all water treatment components are required to have a 510K approval.
31) Are water systems installed before 5/30/1997 subject to these regulations? 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 5/30/1997 are required to have FDA 510K approval. However, all water treatment systems in use for Medicare certified dialysis programs are required to be in compliance with CMS rules.
32) Does the language at V274 mean that AAMI updates can be automatically adopted as regulation, without having to go through the whole "process"? No. When publications/standards from non-government entities are adopted as regulations, subsequent updates are not automatically included. Each update must go through the rulemaking process to be adopted as regulation.

Reuse of Hemodialyzers and Bloodlines

Reuse section has incorporated AAMI "Reuse of Hemodialyzers, third edition, ANSI/AAMI RD47: 2002/A1: 2003 by reference as regulation.

Highlights

- The observation of actual practice of reprocessing and reuse is critical to the survey of this Condition, as are interviews with the staff responsible for reprocessing and reuse. Additionally, records of the reprocessing process and medical records of patients included in the reuse program must be reviewed. Surveys of facilities that participate in centralized reprocessing programs require on-site visits at the reprocessing site, on a rotating basis, as part of the survey process. (IG)
- Examples of condition-level citations: (IG)
  - Staff members assigned responsibility do not demonstrate competency;
  - Less than sufficient concentration of germicide is in use;
  - Direct care staff do not test for residual levels of germicide prior to reusing a dialyzer or the testing methods in use are not sufficiently sensitive;
  - Reprocessing a dialyzer of a HBV+ patient.
- Hepatitis B positive patients must be excluded from any reprocessing/reuse program. (Reg)
- Any dialyzer included in the reprocessing/reuse program must be labeled by the manufacturer for multiple use. (IG)
- Record keeping
  - Reprocessing records must be complete, legible, and protected from unauthorized access. The record of use of a dialyzer may be included in the patient record, in computer listings, and in separate records of reprocessing. The history of each dialyzer from first use to discard must be able to be followed. (IG)
  - The overall dialyzer reuse procedure documentation includes reference materials, procedures, and policies, some of which may be distributed in the facility for operating purposes. The other records serve to document aspects of the reuse procedure for each dialyzer, along with quality control (QC) and quality assurance (QA) measures, so that a complete history of the reprocessing of each dialyzer and QC/QA procedure exists. (IG)
- Training program
  - The dialysis facility's physician or director shall establish a training course for the persons performing hemodialyzer reprocessing. The curriculum should include at least the following information (Reg):
    - Facility procedure for reprocessing, including rationale for each step;
    - Basic documentation requirements of the program;
    - Operation and maintenance of equipment used for reprocessing dialyzers, and if appropriate, the dialysis systems and components;
    - Microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infection hazards;
    - Risks and hazards of multiple use of dialyzers;
    - Consequences of not performing tasks properly;

    - Risks and hazards associated with toxic substances used in reprocessing, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances;
    - Use and location of protective eyewear, respirators, masks and special clothing;
    - Emergency procedures as required by the facility;
    - Principles of dialysis with emphasis on dialyzer characteristics and effect of reuse on such.
        - Each person who is assigned dialyzer reprocessing must complete all the components of the training and demonstrate competency. Personnel files should include (IG):
        - Evidence the medical director/designee has certified that each of the reprocessing personnel has successfully completed the required training;
        - Annual competence review and applicable retraining;
        - Retraining for any major change in the reuse program, such as a change in equipment or germicide.
- Medical issues
    - Health screening of personnel is dependent on the germicide in use. (IG)
    - At the time of this writing (9-9-08), the CDC does not object to reprocessing and reusing dialyzers from patients with hepatitis C or patients with known HIV infection because of the low viral burden and transmission efficiencies. Standard precautions should be used in the reprocessing of all dialyzers—gowns, masks, and gloves. Each facility should be aware of the hazards of infection and set policies accordingly. (IG)
    - Facility reuse policies must specify which patients would be excluded from reuse program. (IG)
    - Orders for treatment must include whether or not the patient will participate in reuse. (IG)
- CMS does not require specific written patient consent [for reuse], but does require that patients be informed that the facility does reprocess dialyzers and about that process. (IG)
- Water monitoring
    - All water that comes into contact with the fluid pathways for blood or dialysate must be of AAMI quality. (IG)
    - Water samples for microbial and endotoxin testing must be routinely taken each month from the water supplying each reprocessing system, as close as possible to the point where the dialyzer would be connected to the system. If more than one automated reprocessing system is in use, the water supply to each system must be monitored monthly. (IG)
    - New facilities or facilities which add dialyzer reprocessing must validate the safety of the water supply to the reprocessing system by testing for bacteria (microbial content) and pyrogens (endotoxins) weekly for at least 3 months, and at least monthly thereafter. (IG)
- Reprocessing basics
    - The pressure of the water used for reprocessing should be monitored. There should be a pressure gauge in the water line of any sink used for dialyzer rinsing, with defined parameters for the accepted pressures to use during that procedure. (IG)
    - Reprocessing area should be designed to maintain acceptable ambient concentrations of harmful substances. Although the equipment for air testing may not be kept on-site, it should be available for use if staff or patients complain about germicide vapors. (Reg/IG)
    - There should be a schedule for routine air-level testing for germicide vapors, along with references describing the safe exposure levels, and if there are any circumstances that would require an unscheduled test. (IG)
    - “Clean” and “dirty” dialyzers must be stored separately; the status (in the reprocessing cycle) of any dialyzer must be clearly apparent at all times. Stock must be organized to allow rotation

and prevent use of out-of-date materials. Reprocessed dialyzers in storage should be protected from unauthorized access to prevent tampering and to protect the confidentiality of the patients involved in the reuse program. (IG)
    - Reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded. Note that testing strips may require dating when opened with discard based on the number of days since opened. (Reg/IG)
    - If heat disinfection is the reprocessing method, records of each batch of dialyzers processed must include an indicator, such as an automated time/temperature recording log, that the dialyzers were exposed to the appropriate temperature for the time required. If a chemical, such as citric acid, is used to enhance heat disinfection, a presence test for citric acid is also required before clinical use of the dialyzers. (IG)
    - If an incubator or oven is used to raise the dialyzer storage temperatures, a recording thermometer should be in use to assure sufficient temperature is consistently maintained. Records should document that these devices functioned as expected. (IG)
    - A permanent record (paper or electronic) must be maintained to enable tracking each dialyzer's history and performance testing; information recorded on the dialyzer label must also be recorded either in a log or in the patient record, as the labels are discarded with the dialyzer. (IG)
- Dialyzer labeling
    - When a patient is provided a new dialyzer that is to be reprocessed, that dialyzer must be labeled with the patient's name before or at the first use. Dialyzers that are used without being labeled with the applicable patient's name must be discarded. (IG)
    - At a minimum, each reprocessed dialyzer must be labeled with the patient's name, the number of previous uses, and the date and time of the last reprocessing. (IG)
    - For patients with similar names, a warning is necessary to alert staff and prevent dialyzer errors. Dialyzers in use must demonstrate use of warning labels if there are two or more patients with similar names on census. (IG)
- Dialyzer transportation and handling
    - Dialyzers not reprocessed within two hours should be refrigerated and not allowed to freeze. (IG)
    - Personnel should wear appropriate PPE to handle used dialyzers until reprocessing is complete. Per the CDC, "Place all used dialyzers and tubing in leak-proof containers for transport from station to reprocessing or disposal area." (IG)
    - If used dialyzers are transported in a common carrier, such as a basket, the potential for cross-contamination must be eliminated (i.e., exteriors must be free of visible blood and all ports capped or each dialyzer contained in a sealed bag). (IG)
    - If used dialyzers are refrigerated prior to reprocessing, facility policy must define and personnel must be aware of maximum refrigeration times, temperature ranges, and quality controls in place to assure the practice is safe. (IG)
- Process Information
    - According to the CDC, if the header caps are removed for cleaning, only a stream of AAMI quality water may be used to clean blood clots, etc. from the exposed ends and the header caps. (IG)
    - While one chemical may be used as a cleaning agent and a second chemical used as a germicide, the first chemical must be rinsed from the dialyzer before the next chemical is added, unless it has been demonstrated that mixing of the two chemicals is safe and effective. (IG)
    - If bleach is used as a cleaning agent, a procedure must be in effect to limit the time the dialyzer may be exposed to bleach, as prolonged exposure may damage the dialyzer membrane. (IG)
    - The acceptable total cell volume (TCV) is at least 80% of the original TCV. (Reg)

    - Every dialyzer to be reprocessed must have its original TCV measured prior to the first use. “Dry pack” dialyzers must be discarded and not reprocessed. (IG)
    - All staff that reprocess or reuse dialyzers must demonstrate understanding that a drop in TCV to less than 80% of original volume requires discard of that dialyzer. Staff must also be aware of other criteria dialyzers must meet for continued reuse (e.g., limit on number of times a dialyzer may be reused, reasons for discard). (IG)
    - A membrane integrity test such as an air pressure leak test shall be done between uses. (Reg)
    - No realistic procedure exists whereby a dialysis center can monitor the effectiveness of the disinfection procedure (this would require the use of specialized equipment and highly-trained microbiologists). Instead, facility should adhere rigidly to established protocols for quality control and quality assurance. Testing the germicide’s final-use concentration, as well as verifying each dialyzer was filled with germicide, should be a part of the facility’s quality control program. (IG)
    - CMS requires that dialyzers not be subjected to multiple germicide solutions because of possible combined actions of the germicides on the dialyzer membrane. (IG)
    - To prevent injury, staff members shall take care to not mix reactive materials such as sodium hypochlorite [bleach] and formaldehyde. (Reg)
    - Reuse staff must be knowledgeable about the germicide used and the risks this germicide presents to him/her and to patients. (IG)
    - Containers of germicide should be dated to indicate dilution and discard dates. (IG)
    - If a manual reprocessing system is in use, the blood and dialysate compartments must be filled with a volume of germicide equal to three times the total volume of the blood and dialysate compartments of the dialyzer (to equal three compartment volumes) in order to reach at least 90% of the prescribed germicide concentration. (IG)
    - Used and new port caps must be disinfected prior to use. The reuse tech should be knowledgeable about the minimum germicide contact time required for port cap disinfection. (IG)
    - If the germicide is diluted on-line, the concentration in a dialyzer from each reprocessing system must be checked immediately after reprocessing at least monthly. (IG)
    - The exterior of each dialyzer must be cleaned after reprocessing steps are complete. Spraying the dialyzer with germicide is generally unsatisfactory, unless all the surfaces of the dialyzer are covered with the spray. Dialyzers may be dipped or allowed to soak in a germicide solution, or wiped with a disposable cloth saturated with a germicide solution. (IG)
    - There may be occasions when reprocessed dialyzers are stored for extended periods of time. There must be a system for ensuring that dialyzers are not stored longer than the maximum time limit specified by the germicide manufacturer and facility policy without reprocessing. (IG)
- Safety-related
    - When checking for the presence or concentration of the germicide in the dialyzer, do not place anything into the blood or dialysate ports to withdraw the sample. Doing so may damage the fibers of the dialyzer and lead to blood leaks during dialysis. (IG)
    - Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and other appropriate identifying information correspond to the identifying information on the patient’s permanent record. If possible, one of the persons checking identification should be the patient. (Reg)

- Standard of practice requires the final check be done when the patient is present for that treatment. (IG)
- If the extracorporeal circuit is prepared ahead of time, staff must repeat the residual germicide test just prior to treatment initiation to allow detection of any “rebound” of germicide. This is particularly a concern if fluid circulation through the circuit and dialyzer is stopped. (IG)
- If facility practice is to discard the priming solution by “bleeding patients on,” policy and practice must reflect a requirement that a staff member constantly attend that patient while the venous line is open as blood fills the extra corporeal circuit, to prevent accidental blood loss. (IG)
- Fever (temperature over 100° F) or chills as well as unexplained pain in the blood access arm on initiation of treatment, should be reported to the physician, advanced practice registered nurse, or physician assistant. (Reg)
- Patient temperature must be checked pre and post treatment and signs of infection must be evaluated for any potential relationship to reprocessing/reuse. (IG)

- Quality related
  - Facility must maintain a record of dialyzer complaints (deviation from expected outcome, such as dialyzer failure, patient reaction, blood leak). Each complaint should be investigated, and any reuse incidents reported in the Quality Assessment Performance Improvement (QAPI) records with corrective actions as indicated. (IG)
  - Facility staff must comply with the FDA’s Medical Device User Reporting requirements. (IG)
  - Dialyzer blood leaks should be recorded in a log kept in the complaint investigation record file. (Reg)
  - Criteria chosen as the internal standards for quality shall be documented in policy/ procedure manual. Process review should be part of the activity of the individual carrying out the [reuse] process and another staff member should oversee that review to confirm or improve the process. Final oversight is the responsibility of the medical director. (Reg)
  - Facility must have a standardized procedure to ensure blood and dialysate cultures and dialysate endotoxin testing are obtained in the event of a patient reaction possibly related to dialyzer reprocessing and/or reuse. (IG)
  - Responsible staff (chief tech, area technical manager, medical director) must be able to describe actions to be taken if a group of patients experience adverse reactions potentially related to reprocessing/reuse. (IG)
  - Facility is responsible for reporting any adverse outcomes potentially related to reprocessing/reuse, to Federal, State, or local government agencies as required by law. Facility policy should address adverse occurrence reporting. (Reg/IG)

Reuse Q & A

1) Can an advanced practice registered nurse or physician assistant sign treatment orders for whether or not a patient will participate in the reuse program? Can the APRN or PA evaluate patient symptoms which could potentially be related to incorrect dialyzer reprocessing? Yes. These are appropriate roles for the APRN or PA functioning in lieu of a physician.
2) If dialyzer reuse labels are affixed to individual patient reprocessing records, must those logs be filed in the patient’s medical record? The reprocessing records have to be treated as a medical record, but may be maintained separately. When the patient is no longer

treated at the facility, the facility might choose to combine these records with the other records of that patient's care.

3) Do the dialyzers of patients who are on single use (not reuse) need to be labeled for the patient? No. Single use dialyzers do not need to be labeled with the patient's information.
4) When a dialyzer must be replaced mid-treatment, can a pre-processed dialyzer be used? Yes, as long as the pre-processed dialyzer is labeled with that patient's name and the original TCV of the dialyzer is known.
5) Are there some types of dialyzers that require the end caps to be removed and the header spaces cleaned? No. If the facility opts to remove dialyzer end caps and perform header space cleaning, it must be done within the guidelines at V334.
6) Is there a requirement that dialysate port caps be used only for the same dialyzer they were removed from (after being disinfected)? No. After dialysis, the dialyzer ports must be capped for transportation to the reprocessing area. Port caps may be reused for any reprocessed dialyzer, after being disinfected for the appropriate contact time as per disinfectant manufacturer's directions for use. (V340)
7) Is it a safe practice for the facility to periodically reprocess (refill with fresh germicide) the dialyzer for a patient who is away from the facility for an extended period of time (4-5 months)? The facility must follow the germicide and dialyzer manufacturer's directions for use for maximum storage time of reprocessed dialyzers. While the practice might meet the directions for use, it is unlikely that such a practice would be cost efficient.
8) Does the reuse room have to have a door? No. The AAMI guidelines allow reuse to be done within the patient treatment room. The reuse room must be protected from access by unauthorized persons and designed to maintain acceptable air levels of germicide vapors (V318).
9) Does the air quality need to be tested for peracetic acid? Peracetic acid is the compound of acetic acid and hydrogen peroxide. As there is no identified permissible exposure limit (PEL) for peracetic acid, it is expected that a facility using this chemical would test the air levels for acetic acid and hydrogen peroxide. (V318)
10) What testing must be done to ensure there is sufficient concentration of Renalin (peracetic acid) in reprocessed dialyzers? Why do some facilities do the testing before they store the dialyzers and others do the testing before they use the dialyzers? Because there are two requirements for this testing:
    - To verify that the reprocessed dialyzers have sufficient germicide concentration immediately after reprocessing and prior to storage. If the germicide is diluted on-line by the automated reprocessing system, this germicide concentration verification test must be done on at least one dialyzer for each reprocessing system once a month (V341).
    - Every Renalin (peracetic acid) reprocessed dialyzer must be tested for the presence of sufficient germicide concentration prior to rinsing the germicide before use (V350).
11) Why must the ESRD surveyors inspect the centralized reprocessing center, if they are an unrelated company? Centralized reprocessing sites are not certified separately, but are considered a part of the ESRD facility that uses the facility for the reprocessing of their dialyzers. The ESRD facility retains the responsibility for compliance with the Conditions for Coverage.
12) When multiple dialysis facilities use a centralized reprocessing center, does the review of the reprocessing procedures have to be conducted at the centralized reprocessing location with every recertification survey of the dialysis facilities? No. The survey agency(ies) that are responsible for the oversight of the user facilities should review the operation of the reprocessing center at selected times: a visit to the reprocessing center is not expected each time a user facility is surveyed.

13) Is it required for a surveyor to observe the entire reuse process during an initial certification? If the facility has initiated reuse at the time of the initial survey, then the surveyor should observe the process. Many times the planned reuse program has not yet been initiated, as the number of patients being treated is too small to make a reuse program cost efficient. If the reuse program has not been initiated, review the policies and procedures, the qualifications of the person(s) who will be responsible for doing reprocessing and interview that individual as well as clinical staff about the training they have received related to the plan for reuse and reprocessing of dialyzers.
14) What is the cost of a new dialyzer? The cost of new dialyzers vary from around $7-$40, depending on the number of dialyzers purchased, and the relationship between the ESRD facility and the dialyzer manufacturer.

Physical Environment

Incorporated by reference: NFPA 101: Life Safety Codes, 2000 edition (chapters 20 and 21)

Highlights

Building and Equipment

- Facility must be designed, constructed, equipped, and maintained to provide a safe, functional, and comfortable environment. (Reg)
  - "Safe environment" means that there are no obstacles which would present risks for trips and falls, such as loose floor tiles; no areas that would pose infection control risks, such as broken work surfaces; and no outside doors that remain propped open, allowing entry of unauthorized individuals and animals or creating a hazard in the event of fire. (IG)
  - Systems to assure patient safety must be in place, such as a method for patients to call for help from the restrooms and exam rooms. Access to patient treatment areas, reprocessing areas, water treatment systems, supply storage and dialysis equipment must be restricted to authorized personnel only. Access limitation does not preclude visits or tours by individuals(s) authorized and supervised by facility personnel. (IG)
  - The use of "dummy" drip chambers is acceptable only for machine maintenance purposes and only for use outside of the patient treatment area. (IG)
  - The presence and availability of "dummy" drip chambers in the patient treatment area is considered an immediate and serious threat to patient health and safety. (IG)
  - Maintenance of refrigerators should include the monitoring of temperatures to assure these are appropriate for the items stored. (IG)
  - If a generator is present, documentation should be available regarding testing and maintenance per manufacturer's instructions. (IG)
  - Records should be available regarding the daily cleaning and testing and periodic calibration of pH and conductivity meters as recommended by the manufacturer. (IG)
  - Documentation of periodic calibration of patient scales, blood pressure devices, blood volume monitors, and laboratory equipment, as applicable, should be available. (IG)
  - Patient treatment chairs, facility wheelchairs, and waiting area chairs must be maintained to allow effective cleaning/disinfection. (IG)
  - Torn upholstery must be repaired or replaced; broken mechanisms (footrests, reclining levers) must be repaired or the equipment removed from use. (IG)

Environment

- Space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff. (Reg)
- "Sufficient space" for needed care would allow space for: (IG)
  - All dialysis equipment, supplies and items for each patient;
  - Caregivers to provide emergency care, including CPR, the use of emergency equipment, stretcher and emergency personnel; and
  - Provision of personal privacy when needed.
- "Sufficient space" to prevent cross-contamination would allow space to: (IG)
  - Prevent blood or body fluid spatters from one patient or station to another;
  - Prevent contact between machines, chairs, and other equipment;
  - Reasonably accommodate patient belongings;

    - Provide privacy and aseptic care of catheters, including dressing changes;
    - Safely dispose of bodily wastes/fluids and hazardous waste; and
    - Readily access hazardous waste receptacles.
- The space allowance should take into consideration the space taken up by patients' dialysis chairs when reclined with foot rests up. (IG)
- The facility must develop an acceptable plan to determine the temperature in the patient treatment area. An "acceptable plan" could be to set the thermostat for a reasonable temperature, inform patients and staff of the set temperature, and suggest patients may want to bring a blanket. It is not acceptable to allow the temperature to be randomly raised or lowered, dependent on one person's comfort level. (IG)
- If patients choose to use a blanket or other covering, their vascular access site, bloodline connections, and face must be visible throughout the treatment. A head covering on a patient is acceptable, as are gloves. (IG)
- There should be sufficient number of privacy screens or other methods of visual separation available and used to afford patients full visual privacy when indicated. Arrangement for private conversations may need to be outside of the patient treatment area in a private location. (IG)
- Each patient, including his/her vascular access site and bloodline connections, must be able to be seen by a staff member throughout the dialysis treatment. Allowing patients to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes. (IG)

Emergency preparedness

- Each facility must have a facility-specific disaster/emergency plan and be able to respond accordingly. Disaster/emergency plans should address failure of basic systems such as power, source water, air conditioning or heating systems, as well as treatment specific failures such as the facility water treatment system or supply delivery. (IG)
- Responsible staff and patients should be knowledgeable regarding the emergency plan should the facility be non-operational after a disaster. (IG)
- Non-expired emergency/evacuation supplies, including site dressings, saline, IV tubing, should be available to accommodate evacuated patients. (IG)
- Staff emergency preparedness training must be provided and evaluated at least annually and include ensuring that staff have sufficient knowledge to inform patients of: what to do, where to go, whom to contact if emergency occurs when patient is not in the facility, and how to disconnect from machine. (Reg)
- Medical records should include evidence of education in emergency evacuation and emergency preparedness, to include some measure of patient understanding, such as return teaching or demonstration. (IG)
- The facility should have a system in place to identify patients who will need assistance in disconnection and evacuation during an emergency. (IG)
- All direct patient care staff (i.e., nurses and patient care technicians) must have current basic CPR certification. (IG)
- Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. (Reg)
- If a traditional defibrillator is present, written protocols approved by the medical director and a staff member trained and competent to use that equipment should be present whenever patients are dialyzing in the facility. (IG)
- All members of the facility staff must be able to demonstrate knowledge of how to obtain emergency medical assistance, e.g., 911 system, or equivalent for the locality. (IG)

- Facility must evaluate annually the effectiveness of the emergency and disaster plans and update them as necessary. (Reg)
- The facility must conduct drills or mock emergencies at least annually in order to determine the staff's skill level/educational needs and effectiveness of their plan. (IG)
- The facility must contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency. (Reg)
- Effective 2-9-09, dialysis facilities must comply with Chapter 20 (for new facilities) or Chapter 21 (for existing facilities) of the 2000 edition of the Life Safety Code (LSC) for Ambulatory Health Care Occupancies of the National Fire Protection Association (NFPA), 101. (Reg)
- If a dialysis facility is located in a building with other tenants, it must be separated from the other tenants on the same floor by a one-hour firewall. (IG)
- If the dialysis facility is located within a hospital, but not separated from the hospital by 2-hour firewall construction, the dialysis facility must meet the hospital LSC requirements. (IG)
- Facilities participating in Medicare as of 10-14-08 utilizing non-sprinklered buildings on such date may continue to use such facilities if buildings were constructed before January 1, 2008 and State law so permits. (Reg)
- Facilities that are new, relocated, undergoing major renovation or an existing facility (participating in Medicare) constructed after January 1, 2008, must comply with the LSC provisions for sprinklered buildings. (IG)

Physical Environment Q & A

1) AED requirement: if a hospital-based unit is located in the hospital, may the hospital CPR team respond to a cardiac emergency? Would the dialysis unit need an AED? The facility would need to determine the average response time of the CPR team, and if that response time were less than approximately four minutes, the dialysis facility would not need to have a separate AED. If the average time were longer, then the dialysis unit would need to get an AED.
2) Do the medical director, other physicians, and the APRN and PA have to have current CPR certification? The regulations do not require certification for these individuals.
3) Emergency drugs: If the medical director states no drugs are needed, what is the recourse? Is there a minimum number or list of emergency drugs that must be available? V411 requires that the nursing staff be trained in the use of emergency drugs. V413 requires emergency drugs be present. The emergency drugs to be present may be defined by the medical director and cannot simply be "no drugs are required". Minimally, the drugs expected to be available include Benadryl, 50% dextrose, epinephrine, Solu-Medrol and other drugs as indicated for medications that could result in anaphylactic reactions.
4) Can medications be drawn up the night before for the first shift of patients the next day? No.
5) What are the expectations for refrigerators for medication storage? V403 addresses equipment maintenance. This requires that medication refrigerators are clean and have evidence that the required temperature for the medications being stored is maintained.
6) How long should dialysis machine disinfection logs be maintained? Dialysis machine disinfection logs are considered as part of patients' medical records, since the routine disinfection of the machines is significant to the safety of the patients who are dialyzed on them. The logs do not have to be kept with patients' records, but should be maintained and accessible per medical record retention requirements.
7) Is a Life Safety Code survey required for all initial and recertification surveys? A Survey and Certification Letter will describe the relationship between the LSC survey and the ESRD survey. The LSC will be conducted either by a fire specialist from the State Agency or by a local fire marshal contracted by the State Health Department. Generally, the LSC surveys will be done

separately from the ESRD survey. The LSC survey is expected to be within a reasonable time of the initial or recertification survey.

8) If a dialysis center is located in a hospital, what LSC requirements apply? Hospital LSC are more stringent than those in these regulations, and an ESRD facility located in a hospital must be in compliance with the hospital LSC.
9) Will a freestanding home dialysis training unit be required to meet the requirements of the LSC for Ambulatory Health Care facilities? Yes. The home dialysis training unit must meet the new ESRD Conditions of Coverage, which include Life Safety Codes.
10) Is there a square footage requirement for dialysis stations? For minimum distance between dialysis stations? The ESRD Conditions for Coverage do not specify a square footage requirement. V404 includes a requirement to provide "sufficient" space for delivering care and services to patients, prevent cross-contamination, and accommodate emergency medical equipment. It is also expected that the space would be sufficient to allow needed privacy. State or local regs may include square footage requirements.
11) Is an emergency generator required? CMS regulations do not require ESRD facilities to have an emergency generator. Some states may require these.
12) If an existing facility uses video monitoring for their isolation room, may they continue to use that? Why can't providers use video monitoring to visually observe patients? At V407, the regulation specifically states that patients must be in view of staff during hemodialysis and that video surveillance will not meet this requirement.
13) Does the "no video surveillance" apply to nocturnal dialysis? Yes, if nocturnal dialysis is occurring in the dialysis facility, the patients must all be visualized by staff throughout the treatment and video surveillance cannot be substituted. This requirement does not apply to home hemodialysis patients on nocturnal dialysis.
14) Are mirrors to visualize patients during dialysis acceptable? While mirrors may be used as an adjunct, they may not replace frequent, direct observation of the patient.
15) What if patients refuse to keep their vascular access uncovered? Is having the patient sign a waiver acceptable? Patients have the right to refuse aspects of their treatment plans. If the patient refuses to keep his/her access uncovered, the facility would be expected to educate the patient about the risks associated with covering the access during dialysis, assess the patient's reasons for the decision, and develop a plan of care to address the issue. Having a patient sign a waiver does not remove the responsibility of the facility to monitor the patient's access.
16) Can you discuss why the use of "dummy drip chambers" presents an immediate jeopardy situation? At V403, the interpretive guidance discusses the issues with using a "dummy" drip chamber to bypass the air detector. While the intent may be to speed up the set up of machines, unintentional failure to remove this "dummy" drip chamber from the air detector places the patient at risk for life threatening air embolism. Using a "dummy" drip chamber to prime the machine is contrary to every machine manufacturer's directions for use and presents the opportunity for a patient injury or death. There have been patient deaths associated with the use of these.

Patients' Rights

Highlights

- The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. (Reg)
- "When they begin their treatment" means within the first six treatments after admission to the facility. (IG)
- In all verbal and nonverbal communications, patients must be treated with respect, dignity, and sensitivity. Rude, abrupt, or demeaning behavior, physical or mental harassment, punishment, or the use of restraints or involuntary seclusion are not acceptable and must not be imposed for purposes of discipline or staff convenience. (IG)
- Physical or chemical restraints may be imposed only upon the written, specific order of a physician or other licensed practitioner permitted by the State and facility to order restraints. The need for restraints should be reassessed at each treatment. (IG)
- If restraints are used routinely on a patient, staff should address this practice in the patient's plan of care. A restraint does not include a personal escort or orthopedic device, surgical dressing or bandage, a protective helmet, or other method to hold a patient while conducting routine aspects of the dialysis treatment. (IG)
- Patients have the right to receive all information in a way that he or she can understand. (Reg)
- The interdisciplinary team comprehensive assessment and plan of care must assess patient needs for information and barriers to receipt of that information, and develop ways to address those barriers. There should be a reasonable facility plan for communicating information in various languages if there is a need. (IG)
- Patients have the right to privately discuss their condition and treatment. Staff should allow the patient to direct where discussions of sensitive topics should occur, and ask the patient if he/she wants to schedule a time to discuss a sensitive issue away from the treatment area. (IG)
- Patients have the right to privacy and confidentiality in personal medical records. Patients' health records must be protected from casual access. Hard copy medical records should be stored in a secure location when not in use. (Reg/IG)
- A signed release is not required by HIPAA to share protected health information for continuity of care, such as, but not limited to: providing emergency care; contacting other dialysis facilities as part of the protocol for involuntary discharge; termination of treatment; or when asking the police to help locate a patient so he/she can receive dialysis. (IG)
- Patients have the right to know about and participate in their care and treatment to the extent they desire. The facility must encourage patient participation in care planning. Examples of ways to promote this participation include, but are not limited to, offering the patient the option to participate in interdisciplinary team care planning or to attend a planning meeting in-person or by teleconference from home. "Chair-side" review of the plan of care is also acceptable, if sufficient privacy can be provided. (IG)
- Patients must be notified of changes to their dialysis prescription and the reason for those changes. Patients have the right to refuse the change without fear of discharge. (IG)
- Patients have the right to refuse any aspect of treatment, to refuse to participate in experimental research, and to discontinue their dialysis treatments completely. (I

- Patients have the right to be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives. (Reg)
- Advance directives include written documents such as living wills and durable powers of attorney for health care decisions (also called a health care proxy or medical power of attorney) as recognized by State law. (IG)
- If the facility's policy does not allow the honoring of a patient's advance directive, there must be a protocol in place for facilitating the patient's transfer to a facility that will honor the advance directive, if the patient so chooses. (IG)
- Facility staff must inform patients regarding facility policies related to patient care, including the isolation of patients with infectious diseases [also includes policy regarding eating in unit]. (IG)
- Patients must be made aware of charges for any services that may not be covered under Medicare. If a facility plans to bill a patient for items and/or services which are usually covered by Medicare, but may not be considered reasonable and necessary in a particular situation, the patient must be informed and be offered an Advanced Beneficiary Notice (ABN). (IG)
- Facility staff should inform patients about what is expected of them while receiving services at the facility. Some examples: treating others with mutual respect, following the plan of care, keeping appointments, notifying the facility of changes in residence and contact information, and providing information on payers and changes in insurance. (IG)
- Facility staff must inform patients about the internal grievance process and the steps to follow for filing an internal grievance. (IG)
- Facility must establish a procedure for informing patients about seeking external help to resolve grievances that cannot be resolved internally or if patients are not comfortable using the internal process. The facility staff must inform each patient/designee how to contact the appropriate external entity to file a grievance including the ESRD Network and the State survey agency. (IG)
- Patients must be given information about the facility policies for routine and involuntary discharges. (IG)
- The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD Network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients. (Reg)

Patients' Rights Q & A

1) The regulation at V451 states facilities "must inform patients . . . (of their rights) when they begin their treatment." Is allowing facilities 6 treatments to inform patients of their right contradicting the regulation statement? The regulation does not define "when they begin their treatment." CMS has the authority to define this in the interpretive guidance.
2) Can a large dialysis organization use the list of patient rights in the interpretive guidance for all their clinics or does each facility need to tailor their list of patient rights to include any additional rights specified by their applicable Network? The patient rights listed in the regulation must be posted in each facility. The Networks or the State licensing rules may include additional rights. Each facility must provide their patients with information on all applicable rights.
3) Does the patient right to privacy prohibit conducting chair-side care planning with the patient if other patients can hear what is being said? The interdisciplinary team should ask the patient if he/she wishes to have the plan of care in a private space or in the treatment area. If the patient agrees to have the care planning session in the treatment area, it would not violate HIPAA or privacy in this regulation.

4) What rights do patients have relative to their own medical records? Patients have the right to read their own medical record, to have corrections made to their record, and to obtain a copy of their record, for which a nominal fee may be charged.
5) Under HIPAA rules, is a facility permitted to contact another entity about a patient that the facility is trying to place following an involuntary discharge without permission of the patient? A signed release is not required by HIPAA to share protected health information for continuity of care, such as, but not limited to, providing emergency care, contacting other dialysis facilities as a part of the protocol for involuntary discharge, termination of treatment, or when asking police to help locate a patient so that he/she can receive dialysis.
6) How does the dialysis staff monitor physical restraints in the dialysis unit, for example, for the nursing home patient? At V452, the use of restraints is addressed. Restraints should rarely be used, there must be a specific physician's order for them if used, and the plan of care must address the use of restraints if used for more than a single occasion.
7) How should patients be informed of charges for services that are not covered by Medicare? If a facility plans to bill a patient for items and/or services which are usually covered by Medicare but which are not considered "reasonable and necessary" in a particular situation (according to section 1863 of the Social Security Act), the patient should be informed and be offered an Advance Beneficiary Notice (ABN) to sign pursuant to section 1879 of the Social Security Act.

Patient Assessment

Highlights

- Compliance with this Condition is determined by observation of practices, interviews of patients, personnel, and medical staff; and review of medical records. 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. (IG)
- 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. (IG)
- This assessment may be incorporated into one document or composed of sections developed by each team member. (IG)
- Comprehensive assessment must include, but is not limited to: (Reg)
  - Evaluation of current health status/medical condition, including co-morbid conditions;
  - Evaluation of the appropriateness of the dialysis prescription;
  - Blood pressure and fluid management needs (* for pediatric patients weighing less than 35 kg, blood volume monitoring during hemodialysis should be available in order to evaluate body weight changes for gains in muscle weight vs. fluid overload—IG);
  - Laboratory profile;
  - Immunization history, and medication history
    - Should include whether patient has received pneumococcal, hepatitis, and influenza vaccines and whether patient has been screened for TB. CDC recommends that all dialysis patients be tested at least once for baseline TB skin test results and re-screened if exposure is detected. CXR may be used if skin test is not an option. CDC also recommends that all dialysis patients be offered influenza and pneumococcal vaccine. (IG)
    - Medication history should include a review of the patient's allergies and all medications, including over-the-counter medications and supplements the patient is taking. The assessment should demonstrate that all current medications were reviewed for possible adverse effect/interactions and continued need. (IG)
  - Evaluation of factors associated with anemia, such as H/H, iron stores, and potential treatment plans for anemia, including erythropoiesis-stimulating agent (ESA) administration;
  - Evaluation of factors associated with renal bone disease;
  - Evaluation of nutritional status by a dietitian;
    - Before interviewing family members or caregivers, the dietitian should seek the patient's permission to interview the relevant individual(s). If the patient is a resident of a long-term care (LTC) facility, the dietitian should contact the staff or the LTC facility as part of the assessment and to provide continuity of care. (IG)
    - Recognize this area is critically important in pediatric patients. The dietitian must consider the special nutritional needs of these patients. (IG)
  - Evaluation of psychosocial needs by a social worker;
  - Evaluation of dialysis access type and maintenance;
  - Evaluation of the patient's abilities, interests, preferences, and goals; the preferred modality and setting, and the patient's expectations for care outcomes;

    - If a patient is determined not suitable for or declines home dialysis therapy, the reason must be documented in their plan of care (IG)
  - Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s)
    - 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. (IG)
  - Evaluation of family and other support systems;
    - Pediatric patients present special situations. Facilities that treat pediatric patients must have policies that address the need to evaluate the family and other support systems of the pediatric patient. (IG)
  - Evaluation of current patient physical activity level;
  - Evaluation for referral to vocational and physical rehabilitation services;
    - Pediatric patients may also warrant rehabilitation services. Pediatric patients should be encouraged to attend school full-time if possible. If school attendance is not possible, other options should be offered for school-age children to obtain education. (IG)
- Frequency of assessment—an initial comprehensive assessment must be conducted on all new patients (all admissions to a dialysis facility) within the latter of 30 calendar days or 13 dialysis sessions, beginning with the first session. (Reg)
  - Applies to all new dialysis patients, regardless of modality. (IG)
  - 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 team must conduct a reassessment within three months of the patient's admission to the new facility. This also applies to transient patients received with an assessment and plan of care. (IG)
  - The transfer in of a large number of patients at once (such as opening a new facility or due to disaster impacting the functionality of the transferring facility) may impact the staff's ability to complete this requirement within the mandated timeline. If this is the case, the facility should develop a plan to ensure completion of the assessments of the transferred patients promptly and a method to triage patients' need for assessment. (IG)
- A follow-up comprehensive reassessment must occur within 3 months after the completion of the initial assessment. (Reg)
- A comprehensive reassessment of each patient and a revision of the plan of care must be conducted at least annually for stable patients and at least monthly for unstable patients. (Reg)
  - "Unstable" includes, but is not limited to:

  (1) extended or frequent hospitalizations (extended: longer than 15 days; frequent: more than 3 hospitalizations in one month);

  (2) marked deterioration in health status (may include events such as a change in ambulation severe enough to interfere with patient's ability to follow aspects of the treatment plan; hypotension, restlessness, pruritus or other symptoms severe enough to prevent completion of the majority of dialysis treatments; sudden onset of recurrent cardiac arrhythmias; recurrent infections; chronic CHF 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; and/or chronic or recurrent peritonitis);

  (3) significant change in psychosocial needs (instability in one's own or immediate family members' employment, physical or emotional abuse, deterioration in mental or functional status, amputation, housing instability, death or major illness in the family, consideration of termination of treatment, and loss of emotional support, as well as any patient considered at risk for involuntary discharge or transfer); or,

(4) concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis (failure to thrive symptoms with weight loss and low albumin; continued lab findings of h/h values out of range; trend of results for Kt/V or URR that do not meet minimum expectations as defined by community-accepted standards or CMS CPMs for a three month period of time). (Reg/IG)

Patient Assessment Q & A

1) What is the difference between a "multidisciplinary" assessment and an "interdisciplinary" assessment? "Multidisciplinary" team members work sequentially and use the medical record as the chief means of communication. "Interdisciplinary" team members work collaboratively with regular meetings to discuss patient status and the evolving plan of care. Interdisciplinary teams work together toward common goals, pool their expertise, and use one another as a forum for problem solving.
2) Do all existing patients need to have a comprehensive assessment and plan of care in place on 10/14/08? No. Every facility is to make a plan for completing this new process for all its existing stable patients by 10/14/09. Unstable patients require monthly assessments, so the first of these would be due in November 2008.
3) What rules apply to staff talking with family/support members about a patient? While the IDT may not discuss a patient's protected health information (PHI) with family member/others without the patient's permission, it is not a violation of HIPAA for staff to ask family members/others for information that would help the IDT provide care for the patient. HIPAA does not prohibit a staff member from educating a family member or other support person about how to help the patient with diet, medications, and coping with kidney disease.
4) Can the medical director substitute for the "treating physician" in the IDT? The regulation expects "a physician treating the patient" to be a member of the IDT. If the medical director were not one of the physician's treating the patient, he/she would not be allowed to routinely substitute on the IDT.
5) What documentation of the IDT work will we expect to see? For individual patients: look at the patient assessment, the plan of care, progress notes, physician orders, treatment records; for home patients, review clinic visit reports as well. For the facility, expect to see participation of the IDT in QAPI program.
6) Is there any specific format required to document the patient assessment and plan of care? Can these both be included in one form? There is no specific format required: both the assessment and the POC can be included in the same form.
7) What is the difference between "initial" assessments and "comprehensive initial interdisciplinary" assessments? "Initial" assessments are described under the Condition of Responsibilities of the Medical Director at V715. An "initial" assessment must be done by a member of the medical staff, i.e. MD, APRN, or PA, before the initiation of the patient's first dialysis treatment in the facility. The "initial" assessment includes the creation of medical orders and prompt recognition of and action to address urgent patient needs (e.g. anemia with hgb < 10 gm/dL, fluid overload, hyperkalemia). The "initial" assessment also requires a patient evaluation by a registered nurse for any immediate needs. The initial medical assessment can be accomplished by review of medical records and consultation with the referring physician without medical staff "seeing" the patient in the facility prior to the first treatment. "Comprehensive initial interdisciplinary assessments" are described in detail at the Condition of Patient Assessment.
8) Please expand upon the initial assessment requirement. When a new patient is admitted, a member of the medical staff must assess the patient, provide treatment orders, and identify any needs for immediate action. In addition, an RN is expected to make a nursing assessment of the patient prior to the first treatment (V715).

9) Do transfer and transient patients need an initial comprehensive IDT assessment in 30 days/ 13 treatments? Each patient new to dialysis must have an initial comprehensive IDT assessment within 30 days or 13 treatments after admission. This requirement applies to all new dialysis patients, without regard to the modality of treatment. If the comprehensive 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 patient's IDT must conduct a reassessment within three months of the patient's admission to the new facility. This same provision, completion of a reassessment within 3 months of admission, applies to transient patients who are received with the sending facility's comprehensive assessment and plan of care.
10) Does an acute patient who dialyzes in an outpatient facility require the full assessment and care plan process (patient has been discharged from a hospital and is coming to the outpatient facility until kidney function is regained)? Every patient is expected to receive the same level of care. If the acute patient were treated in the outpatient facility longer than 13 treatments/30 days, the assessment/plan of care would be expected to be completed.
11) When an existing patient changes modalities, what is the assessment/plan of care requirement? Whenever an existing patient changes modalities, the patient is treated as a "new" patient and must have a comprehensive reassessment and plan of care within 30 days, or 13 HD treatments, whichever is later.
12) Discuss the mechanics of updating an assessment: what would the document look like, a series of assessments? If a patient is stable, but does not achieve or maintain the goal for one or more areas in the plan of care, the facility would need to update that portion of the plan of care. This could be done on the assessment form, or in the progress notes of one or more of the IDT members. The form of the documentation is not specified.
13) Can the physician/APRN/PA use a history and physical from a hospital discharge rather than completing another one? If the H&P is current and addresses ESRD and the patient's co-morbid conditions, it could be used as part of the IDT patient assessment.
14) Can an H&P from a previous ESRD facility be used instead of the physician/APRN/PA conducting another one? When an experienced dialysis patient transfers from one unit to another, if the patient assessment/plan of care from the previous facility is transferred with the patient, the expectation is that the IDT at the new facility conducts an assessment and develops a plan of care within 3 months of the patient's admission. At that time, the previous H & P could be used as part of the data reviewed, but a new assessment is expected to be done.
15) Can the annual reassessment for a home dialysis patient who lives a great distance from the facility be done in the physician's office, if the IDT meets there and the documentation is sent to the dialysis facility? If the required members of the IDT meet at the physician's office, and fulfill the requirements for the comprehensive interdisciplinary reassessment and plan of care revision for the patient, the information can be sent to the ESRD facility for the medical record.
16) What criteria from a transplant center are supposed to be used to screen patients as potential transplant candidates? Transplant centers are required to develop "selection criteria" and share this on request with potential candidates and dialysis facilities. These often read like "exclusion criteria" as they list diagnoses or conditions that would exclude a patient from consideration for transplantation.
17) How often are social workers and dietitians required to see patients and document progress notes? There is no requirement for frequency of SW and RD contacts with patients and progress notes. The documentation by the SW and RD should be as needed to show assessment, planning and implementing care to meet the patient's individualized needs.
18) Who is qualified to evaluate psychosocial needs? A "qualified social worker" as defined by the Conditions at V691, is the IDT member who is qualified to evaluate psychosocial needs.

19) Where can the psychosocial assessment survey too “KDQOL-36” be found? http://gim.med.ucla.edu/kdqol is the web address for this tool.
20) At V520, does a patient have to have all 4 characteristics described, to be considered unstable, or only one? If a patient meets any of the characteristics described in this tag, they would be considered unstable.
21) What is meant by “concurrent poor nutritional status, etc.” for classifying a patient as unstable? Concurrent here means the patient has all three of these conditions simultaneously: poor nutritional status, unmanaged anemia, and inadequate dialysis.
22) Would a visit to the hospital emergency department qualify as a hospitalization for the purposes of classifying the patient as unstable? For the unstable definitions included in these regulations, the hospitalizations listed are “extended” or “frequent.” A trip to the ER would not equal unstable due to hospitalization, but could cause the patient to be classified as unstable, depending on the cause of the trip to the ER.
23) The Conditions require that facilities need to document reasons why patients cannot receive care at home. How extensive does the documentation need to be? 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 that eligible patients are offered a choice of home versus in-center dialysis.
24) What documentation is expected for medication review? A list of the medications with evidence of review for possible adverse effects/interactions and need for continued use.
25) What does “respond promptly” to laboratory results mean? The IDT must evaluate lab results as they become available and take action, as indicated.
26) Can an alternative to the tuberculin skin test be used to test for tuberculosis? The CDC recommends that all dialysis patients be tested at least once for baseline TST results. For individuals who are unable to tolerate use of the TST, chest x-rays may be used to test for tuberculosis.
27) What procedure is used to draw blood samples for calculating dialysis adequacy or Kt/V for HD patients? The facility must ensure that the method/procedure for drawing the blood sample to measure Kt/V will produce accurate results. At the time of publication of these regulations, the stipulated method for drawing blood samples to measure Kt/V included the following:
    - Pre and post samples are drawn during the same treatment;
    - Pre sample is drawn just prior to the start of treatment;
    - Slow flow/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”, “stop flow” may be substituted;
    - After 15 seconds, staff should draw the post dialysis BUN sample from the arterial port closest to the patient.

    All staff should be using the same method as described above. Home HD patients should be instructed to draw their samples in the same way.
28) Are there new Kt/V guidelines for PD? Yes. According to KDOQI PD Adequacy 2006, the latest Kt/V measure for adequate peritoneal dialysis is a weekly Kt/V of 1.7.
29) Is it a deficient practice for all patients in the facility to be on the same model dialyzer? Depends. Each patient must be assessed for individual care needs, care planned and delivered to meet those individual needs. Using the same model of dialyzer and dialysis prescription for all of the facility patients may not represent individualized assessment and care.

Patient Plan of Care

Highlights

- This Condition is directly related to the Condition for Patient Assessment, as the plan of care is built upon the assessment. The individual plan of care is revised after each patient assessment, and portions of the plan of care must be updated if the target goals for each area are not achieved or not sustained. (IG)
- Plan of Care reviews individual patient outcome data and addresses the goals and plans set for individual patients while the Quality Assessment and Performance Improvement (QAPI) program reviews aggregate data for trends and commonalities and addresses facility-wide goals and improvement plans. (IG)
- 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 cannot be achieved. (IG)
- If a patient chooses to use a designee (for participation in planning care), there must be written authorization from the patient for sharing of protected health information (PHI) with the designee. (IG)
- 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. (IG)
- To facilitate full team participation in conferences, any member, including the patient, may participate through telecommunication. (IG)
- The care plan must address, but not be limited to, the following: (Reg)
    - Dose of dialysis—Achieve and sustain HD Kt/V of at least 1.2 and PD weekly Kt/V of at least 1.7 (or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy) and manage the patient's volume status.
        - Each patient should be weighed before and after each treatment. (IG)
        - Patients' BP must be monitored pre, during and post treatment and abnormally high or low values must be addressed. (IG)
        - If the patient shortens treatments, misses treatments, or gains excessive fluid between treatments, the prescribed dose of dialysis may not be able to be delivered. Ultimately, the patient can choose to continue behaviors that result in lessened treatment results. With documentation of educational efforts, the patient's choice can be an explanation on a plan of care for not achieving standard treatment results. (IG)
    - Nutritional status—IDT must provide the necessary care and counseling services to achieve and sustain an effective nutritional status.
        - Facility must have established target goals for patients' albumin levels, and monitor each patient's body weight trends. (IG)
        - In the event the patient has a wasting disease, cachexia, or chronic inflammation contributing to a poor nutritional state, the plan of care should acknowledge these as limiting factors in achieving and sustaining the goal for nutritional status. (IG)
    - Mineral metabolism—Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

    - Expect the facility to have established target goals for patients' calcium, phosphorus, and PTH levels. (IG)
    - If the facility is using a medication algorithm/protocol for managing CKD mineral and bone disorder, the care for each patient must be individualized. (IG)
    - Facilities treating pediatric patients should have specialized methods for monitoring and management of CKD mineral and bone disorder. (IG)
- Anemia—Must provide the necessary care and services to achieve and sustain the clinically appropriate h/h level (must be measured at least monthly). Must monitor BP and iron stores on a routine basis.
    - If protocols/algorithms are used, must ensure that the care for each patient is individualized. (IG)
    - In the event of hyporesponse, there must be evidence that the patient was evaluated as to the possible underlying cause(s) and that the plan of care was revised accordingly. (IG)
- Vascular access—Must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. HD patient must be evaluated for appropriate vascular access type. Access must be monitored for symptoms of stenosis.
    - Medical record must include evidence of the evaluation and the basis for the decision for placement of the current vascular access. (IG)
    - If the vascular access is not an AVF, the record should indicate why the patient was determined to not be a candidate for a fistula. (IG)
    - If the patient has been dialyzed with a central venous catheter for > 90 days, there should be an active plan in process for the placement of a more permanent vascular access or information in the record to demonstrate that a catheter is the most appropriated vascular access for that patient. (IG)
    - Some patients may not be candidates for a fistula or graft; each patient has the right to make an informed choice. (IG)
    - Facility must have an on-going program for access monitoring and surveillance. (IG)
        - Monitoring strategies may include the physical exam of the vascular access, observance of changes in adequacy or in pressures measured during dialysis, difficulties in cannulation, or difficulties in achieving hemostasis after needle removal.
        - Surveillance strategies include device-based methods such as access flow measurements, direct or derived static venous pressure ratios, duplex ultrasound, etc.
- Psychosocial status—Must provide the necessary monitoring and social work interventions. Includes services/referrals to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.
        - Facilities may choose to use the KDQOL-36 from the implementation date of these regulations in order to have more comparable data once the KDQOL-36 is mandated (date undetermined). Pediatric patients should be assessed using an age appropriate assessment tool. (IG)
        - "At regular intervals" means that the assessment survey is administered by the time of the first reassessment (within 4 months of initiating treatment), and repeated at least annually. (IG)
- Modality—IDT must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis. If the patient is a transplant referral candidate, the IDT must develop plans for pursuing transplantation.
        - 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. (IG)

        - If the patient declined or was determined not suitable for home dialysis, the IDT must document their rationale for this decision. (IG)
        - 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 facility's selection criteria. (IG)
    - Rehabilitation status—IDT must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients.
        - Pediatric patient services should address normal growth and development needs, education needs, and age-appropriate activities, especially if dialysis treatments take place during hours when the child would normally be in school. (IG)
        - The IDT must provide and document assistance (education, encouragement) and referrals, if indicated, which were aimed at enabling patients to maintain or return to their desired level of functioning at work, school, home, and in their community. (IG)
- Implementation of the plan of care—must be completed by the IDT (including the patient if he/she desires), and must be signed by the team members, (including patient). (Reg)
    - The patient's signature is to acknowledge the information in the plan. If the patient chooses not to sign their plan of care, the reason for refusal must be documented. (IG)
- Plan must be implemented within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient dialysis sessions, beginning with the first outpatient session. (Reg)
- Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments. Monthly updates of the plan of care are required for unstable patients while annual updates are acceptable for stable patients. (Reg/IG)
- If the expected outcome is not achieved, the IDT must adjust the plan of care to achieve the specified goals. There must be evidence that barriers to achievement of the goals were identified and that the plan was reviewed and revised, as indicated. (Reg/IG)
    - This requirement is not met if the only reason documented for failure to achieve goal(s) is "patient non-compliance" or "non-adherence." If the team believes the cause of the failure to reach the goal is non-adherence, the IDT efforts should focus on identifying potential causes of the non-adherence and addressing those causes. The IDT must recognize each patient has the right to choose less than optimal care when the patient determines optimal care would negatively impact his/her quality of life. (IG)
    - The Condition does not "require" a patient to meet every goal. Any member of the IDT, including the patient, may document why goals are not met or cannot be met. (IG)
- Facility must ensure that MD, APRN, Clinical Nurse Specialist, or PA sees all patients at least monthly and periodically while patient is receiving dialysis treatment. "Periodically" means at least quarterly practitioner visits at the dialysis center during dialysis treatment. (Reg/IG)
- The requirement for patient to be seen at least monthly by a physician, APRN or PA also applies to home dialysis patients. (IG)
- Any patient may choose not to be seen by a physician every month. However, if there is a pattern of a patient consistently missing physician visits, the IDT should determine whether or not the patient is unstable, according to these regulations, and should address the lack of medical oversight with the patient in the plan of care. (IG)
- The IDT must track the results of each transplant referral, monitor the status of all patients on the transplant wait list, and communicate with the transplant center regarding patient status at least annually and when there is a change in status. (Reg)
    - A "change in status" refers to a medical or psychosocial event that could either temporarily or permanently change a transplant patient's status. Examples of "change events" are

cardiac events, weight loss, cessation of smoking or identification of a new potential living organ donor. (IG)

- The patient care plan must include 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. (Reg)
  - The patient's medical record must demonstrate the provision of patient education and training in all of the listed subject areas. There may be a single form or section of the medical record for information on patient education or it may be located in various parts of the record, such as the progress notes. (IG)

Patient Plan of Care Q & A

1) Is there any specific format required to document the patient assessment and plan of care? Can these both be included in one form? There is no specific format required: both the assessment and the POC can be included in the same form.
2) Should the plan of care be one shared document or can each discipline have its own plan or care? The written plan or care can be one document or composed of separate sections, but must be congruent and reflect the integration of the comprehensive assessments contributed by all members of the IDT.
3) What documentation of the IDT work will we expect to see? For individual patients: look at the patient assessment, the plan of care, progress notes, physician orders, treatment records; for home patients, review clinic visit reports as well. For the facility, expect to see participation of the IDT in QAPI program.
4) Are facilities required to hold care plan meetings with all disciplines and patients at the same times as opposed to passing around the document and each person signing off on it? The patient assessment and plan of care are required to be developed by the IDT, which includes the patient. These can be accomplished many ways; best practice would be to have face-to-face meetings of the team, including the patient; other options would be to accomplish part of the assessment/POC during chair-side rounds, having each discipline work with the patient and collaborate with their finding. The plan of care must demonstrate collaboration and congruence, which is not likely to happen if a piece of paper is just passed around among the team.
5) When the IDT develops the plan of care, is it expected that all members be present and document their presence? The IDT members are expected to interact and share information for the comprehensive assessment and to develop the plan of care. This may be accomplished in an IDT conference or by another mechanism to ensure the development of an integrated plan. A substitute mechanism for a team conference should facilitate discussion, sharing, and collaboration among team members.
6) Is there a requirement for the whole IDT to meet and discuss every revision to the patient plan of care? Not necessarily. If the reassessment is a comprehensive one, such as those done monthly for unstable patients and annually for stable patients, it is expected that the required members of the IDT will discuss the information from the assessment and develop the plan of care as a team. The team must review the patient outcomes every month; if any outcome drops below goal, the plan for that portion of the POC would need to be revised by one or more IDT members, including the patient, as applicable.
7) Is the transplant designee still to be identified in the plan of care? No. The new regulations do not require a long-term program, which was the document that required the participation of a transplant surgeon or designee. The IDT comprehensive assessment must demonstrate that

each patient is evaluated for suitability for transplantation referral, using selection criteria provided by the transplant center.

8) Define what is meant by “area” transplant center, mentioned at V554. Patients must be informed of all transplant programs in their geographical area and the selection criteria of each program.
9) Do all existing patients need to have a comprehensive assessment and plan of care in place on 10/14/08? No. Every facility is to make a plan for completing this new process for all its existing stable patients by 10/14/09. Unstable patients require monthly assessments, so the first of these would be due in November 2008.
10) Does an acute patient who dialyzes in an outpatient facility require the full assessment and care plan process (patient has been discharged from a hospital and is coming to the outpatient facility until kidney function is regained)? Every patient is expected to receive the same level of care. If the acute patient were treated in the outpatient facility longer than 13 treatments/30 days, the assessment/plan of care would be expected to be completed.
11) If a stable patient does not meet one quality indicator in the plan of care, does the entire IDT need to reassess or can only one member of the team update and revise the plan of care? If the patient does not meet the expected goal, IDT must reassess that specific area. Plan of care does not “require” a patient to meet every goal. Any member of the team, including the patient, may document why goals are not met. In some areas, such as rehabilitation, volume status, and nutritional status, the majority of the actions taken might be developed by one team member.
12) When an existing patient changes modalities, what is the assessment/plan of care requirement? Whenever an existing patient changes modalities, the patient is treated as a “new” patient and must have a comprehensive reassessment and plan of care within 30 days, or 13 HD treatments, whichever is later.
13) Describe the acceptable level of involvement of the patient in the interdisciplinary team (IDT): are they expected to attend meetings? How is patient involvement measured? How would this be documented? The “acceptable” level of involvement depends upon patient choice. On one hand, one could see evidence that the patient signed (or evidence of refusal to sign) the plan of care (POC). On the other hand, one could see routine attendance by the patient at regularly scheduled POC meetings. The involvement of most patients will fall in between these two extremes.
14) If the patient does not wish to participate in the IDT, what documentation is expected in their medical record? The patient has the right to refuse to participate in the IDT discussions about his/her care, and the IDT should document their attempts to include the patient in such discussions and the refusal. Because the patient’s situation and/or outlook may change, the IDT should continue to make and document good faith attempts to include the patient in the IDT discussions, or those with individual members, to assess the patient’s care needs.
15) Does the patient have to participate in care plan meetings? No, but they should be encouraged to participate. The patient or their designee is an integral part of the IDT, as defined at V501 and V541, and is expected to be included in discussions and decisions regarding their plan of care.
16) V560 requires that every dialysis patient be seen by a physician/APRN/PA monthly and periodically while the patient is receiving dialysis (if an in-center patient). For patients in remote areas, would seeing their primary care provider, who would then be in contact with the nephrology physician team, be sufficient to meet this requirement? The plan of care would need to address specific hardships patients might have in being able to see their physicians

monthly. The expectation is that a member of the medical team of the dialysis facility provides routine care, including monthly visits.

17) When a home dialysis patient lives a great distance from the facility, can they be seen monthly by the physician in the physician's office? Yes. The patient's medical record at the dialysis facility must have, at a minimum, a monthly progress note regarding the physician visit.
18) If there are no state regulations pertaining to the practice of APRNs and PAs, can they see patients and write orders? Be sure that you look at the medical practice boards for PA requirements and the Board of Nursing for the limits of practice for APRNs. If there are no state regulations governing the practice of these individuals, the policies of the facility would need to direct the practice in the facility.
19) How often are social workers and dietitians required to see patients and document progress notes? There is no requirement for frequency of SW and RD contacts with patients and progress notes. The documentation by the SW and RD should be as needed to show assessment, planning and implementing care to meet the patient's individualized needs.
20) How is the Measures Assessment Tool (MAT) to be used? The MAT is a reference guide for current professionally-accepted standards and values for listed clinical elements. The listed elements are community-accepted standards and target levels. Each patient should be treated individually. When a specified target is not met, either the plan of care should be adjusted to achieve the community-accepted standard or an explanation should be provided by the interdisciplinary team member or group. Initially, goals for some patients may need to be different from these targets and then incrementally changed to the standard value as the patient outcomes improve.
21) Are there new Kt/V guidelines for PD? Yes. According to KDOQI PD Adequacy 2006, the latest Kt/V measure for adequate peritoneal dialysis is a weekly Kt/V of 1.7.
22) The anemia target range listed on the measures assessment tool (MAT) per Medicare payment policy is 10-12; many Networks have a goal that at least 85% of patients achieving a target of at least 11-12%. How do you reconcile these different goals, if facilities are required to meet Network goals? The MAT reflects nationally accepted clinical standards, including the updated anemia target mentioned. Since this goal is the CMS expected target, the Networks may consider adjusting their goal.
23) When a patient has HIV or sickle cell anemia and is resistant to ESAs, with a low H/H, should assessment and plan of care address this, and should there be an alternative treatment for anemia? Yes, the IDT must address the patient's anemia and the factors that limit achievement of anemia management goals in their assessment and plan of care. If the multiple factors this patient has (that impact anemia management) prevent achieving and sustaining the community-accepted standards, the assessment should acknowledge the impact of these issues on anemia management.
24) How is volume status measured? Volume status is measured in terms of the dialysis patient's "target" or "dry" weight. The "dry" weight is the weight at which the patient attains normotension for most of the interdialytic period while avoiding orthostatic hypotension or postural symptoms either during or after dialysis. Excess fluid accumulation may have adverse effects, e.g. hypertension, left ventricular hypertrophy, cardiovascular complications, and hospitalizations. Removal of too much fluid in one dialysis treatment or going below the patient's target weight may cause hypotension, cramping, and clotting of the vascular access. Each patient should be weighed before and after each treatment, and a target weight identified for each patient.
25) What if the patient misses or shortens treatment time or gains excessive fluid between treatments, resulting in an inability to achieve an adequate dialysis? The interdisciplinary team is responsible for ensuring that each patient understands the consequences of his/her

behavior in terms of treatment results. In addition, the staff should work with the patient to address behaviors that result in poor treatment results, such as missing and shortening treatments. Ultimately, the patient can choose to continue behaviors that result in lessened treatment results. With documentation of education efforts, the patient's choice can be an explanation on a plan of care for not receiving standard treatment results.

26) What happens if the patient has wasting disease (cachexia) or chronic inflammation, which contributes to poor nutritional status? The plan of care should acknowledge those factors which limit the achievement of nutritional goals. Each patient may not meet all target standards developed for the elements in the plan of care. However, the medical records of patients with outcomes lower than expected should demonstrate continuing efforts which are tailored, implemented, assessed, and revised to address individual challenges.

27) How can dialysis facilities be responsible for vascular access results? What does the dialysis facility do if records are not available from the surgeon regarding the decision and placement for the current vascular access? The Dept. of Health and Human Services' Breakthrough Initiative on Fistula First describes actions that dialysis centers can take to both increase fistula use in dialysis patients and decrease the inappropriate use of catheters. If records from the surgeon are not available, the patient's physician, advanced practice registered nurse, or physician assistant can provide information for the medical record from communication with the surgeon.

28) The regulation states that the facility should use a standardized mental and physical assessment too "chosen by the social worker," but the National Quality Forum and the CMS Clinical Performance Measures (CPMs) have selected the KDQOL-36 as the assessment tool for adult patients. What tool should be used? Facilities can use any standardized survey of physical and mental functioning, including the KDQOL-36, to comply with the regulation. In the future, facilities will need to report electronically in CROWNWeb the percentage of patients who have taken the KDQOL-36 annually. Using this tool starting with the implementation of date of these regulations will allow tracking of comparable historical data.

29) What is the schedule for administering the standardized mental and physical assessment survey tool? The survey is to be administered by the time of the first reassessment, i.e., within four months of initiating treatment, and repeated at least annually.

30) What survey tool for mental and physical functioning should be used for pediatric patients? The 4/1/2008 CMS CPMs do not specify what survey to use with pediatric patients (< 18 years old). The social worker should choose and age-appropriate standardized mental and physical assessment survey for pediatric patients.

31) Are there any additional requirements for nocturnal in-center dialysis? The major differences with nocturnal dialysis are that the treatments are longer and the flood flow rate and dialysate flow rate are slower. The requirements generally are the same as for dialysis done during the day: safe water, sufficient staff to monitor the patients (including being able to see every patient during treatment), and a safe and effective treatment. The survey process should include making observations during the nocturnal shift, and including some of those patients in your sample. There are fewer dietary and fluid restrictions for patients on nocturnal treatment.

32) For a patient who comes to dialysis from a nursing home that is incontinent of urine and stool, whose responsibility is it to change the incontinent briefs? Is this an infection control issue? The dialysis unit staff should work with the nursing home to develop a plan of care for this patient to lessen the prevalence of this problem. It is not acceptable to allow a patient to remain wet or soiled. It could be an infection control issue if the incontinent stool is not handled correctly.

33) Is it a deficient practice for all patients in the facility to be on the same model dialyzer? Depends. Each patient must be assessed for individual care needs, care planned and delivered to meet those individual needs. Using the same model of dialyzer and dialysis prescription for all of the facility patients may not represent individualized assessment and care.
34) How specific should the physician order be for dialysate solutions for PD patients? The PD prescription minimally includes the number of exchanges or cycles to be done each day, the volume of fluid used with each exchange, whether fluid is always present in the peritoneal cavity, and the concentration of glucose or other osmotic agents to be used for fluid removal. Use of automated, manual or combination of these two methods, should also be included.

Care at Home

Highlights

- All of the ESRD Conditions—patient's rights, patient assessment, patient plan of care, and QAPI, must be met, regardless of whether the setting is in-center or at home. (IG)
- A certified dialysis facility approved for outpatient maintenance dialysis services needs no additional certification or approval to provide in-center self-dialysis or to teach an in-center patient to perform all or part of their dialysis treatment (e.g., self-cannulate, monitor blood pressure). (IG)
- Home dialysis training must be provided, and the patient and/or helper verified as competent to perform home dialysis before they are allowed to function independently. (IG)
- Retraining must be provided whenever there is a change in home dialysis helper, treatment modality, or home dialysis equipment. Retraining may also be indicated if there are problems such as repeated episodes of peritonitis, vascular access infections, or a failure to achieve expected outcomes, including goals for dialysis adequacy and anemia management. (IG)
- The nurse responsible for home dialysis training must be a registered nurse who meets the practice requirements of the State in which he/she is employed; have at least 12 months experience in providing nursing care; and an additional 3 months experience working as a nurse in the specific modality for which the nurse will provide patient/helper training. (IG)
- The facility training program should include instruction aimed at enabling patients/helpers to detect, prioritize and report problems and to ensure that they are prepared to recognize and promptly act upon those situations which could present hazards to patient safety. Training home dialysis patient/helpers to "handle" medical emergencies that may be anticipated (syncope, significant blood loss, cardiac events) would include immediate responses/actions and methods for contacting emergency medical systems. (IG)
- The facility must provide home dialysis patients access to resources and assistance 24 hour/day, 7 days/week. (IG)
- Patients/helpers must understand how to properly dispose of needles, effluents, disposable items, blood tubing, and dialyzers to minimize risks of infection or injury to self and others and to prevent environmental contamination. The training staff must ensure that patients understand local waste management rules. (IG)
- The facility is responsible to assure that records of dialysis treatment in the home setting are retrieved and reviewed by the appropriate personnel at least every 2 months. (IG)
- Home dialysis patients' medical records must include dialysis treatment records and evidence of their timely review by home dialysis personnel. If the patient or helper has not provided the appropriate records at least every 2 months, reasonable efforts by the facility staff to obtain these records must be made and documented. The patient's plan of care should address any problem with adherence to this requirement. (IG)
- To assess a patient's home dialysis environment, a home visit should be conducted at the initiation of home therapy and whenever a problem is identified with either patient health or equipment that could be related to treatment at home. (IG)
- The home training and support facility must identify a specific member of the interdisciplinary team to be responsible for the coordination of each individual home patient's care. The coordinating staff member is the "contact person" on the interdisciplinary team, is responsible

for facilitating communication between the IDT and the patient/helper, and ensures oversight and monitoring of the patients' home dialysis in accordance with the plan of care. (IG)

- Medicare payment rules do not require a physician visit in order for the physician to receive payment of the monthly capitated payment (MCP) at the rate of two to three visits per month. The requirement at V560, which calls for at least monthly evaluation of all patients by a physician, an advanced practice registered nurse, or physician assistant, applies to home dialysis patients, as well as in-center patients. Patients may see their physicians in their offices instead of at the dialysis facility. (IG)
- Facility home training staff must conduct on-site evaluations of the home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis. Each home water treatment system must include either an RO or a DI treatment component or alternate technology that achieves AAMI standards, and a method to remove chlorine/chloramines. (IG)
- Not all home water systems are regulated by the EPA Safe Drinking Water Act and my not meet EPA standards. Because of variables with the regulation of the water supply to a home for safe drinking water standards, annual analysis of the quality of the product water may not be sufficient, since the quality of water from the well may change over time and since private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. (IG)
- The home patient's record must include review and acknowledgement of any problems with the source water and a monitoring schedule for the source water. (IG)
- Water treatment/testing
  - Bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed to ensure that the water and dialysate are within AAMI limits. (Reg)
  - The medical director must review the results of all water and dialysate cultures and endotoxin levels, and analysis of source and product water for chemical contaminants of each home hemodialysis patient. The facility must maintain documentation of the medical director's review. (IG)
  - At least one carbon adsorption bed or filter should be installed, even if the water supply is from a well and no chlorine is present. If chlorine is not present in the water, the carbon should be changed on a routine schedule. When water is obtained from a municipal water supply, two carbon adsorption devices connected in series and providing the equivalent of an empty bed contact time of 10 minutes, is recommended. (IG)
  - Deionization systems for home hemodialysis are not required to have a mechanism to prevent product water from reaching the point of use if the conductivity of the water is one microsiemen/cm or more; however, this feature is strongly recommended. (IG)
  - A log sheet should be provided by the dialysis facility and used to record all measures of water treatment system performance as required by the equipment manufacturer or the dialysis facility. (IG)
  - The chloramine concentration shall be checked prior to each treatment. (IG)
  - If the patient exhibits clinical symptoms associated with water and dialysate contamination that cannot be readily attributed to other causes, the facility must arrange for back-up dialysis until the problem is investigated and resolved. (IG)
  - Facility policies must address, and responsible staff member must be aware of, what responsive and corrective actions they should take if microbial and/or chemical test results were elevated, or should a patient exhibit such clinical symptoms. (IG)
- The dialysis facility is responsible for identifying a plan and arranging for timely emergency back-up dialysis whenever needed by the home dialysis patient. (Reg/IG)
- The facility should assist each home dialysis patient in developing a personal disaster plan that identifies actions to take in the event of a natural or other disaster affecting his/her home treatment. (IG)

- The regulations for durable medical equipment (DME) suppliers require the DME to report all data for each patient regarding services and items furnished to the home patient to the supporting ESRD facility every 45 days. (IG)

Care at home Q & A

1) Can an LPN/LVN be in charge of the home dialysis program? No. Home dialysis training must be conducted primarily by an RN who meets the qualifications (12 months as RN, plus 3 months in the specific home dialysis modality).
2) How frequently should data be reviewed for home patients? Time sensitive data and information such as radiology, pathology, and lab results, along with hospitalization reports, should be reviewed upon receipt by a physician or practitioner functioning in lieu of a physician. “Self monitoring” data from home patient must be retrieved and reviewed by the facility at least every two months.
3) When State regulations do not allow PCTs to access CVCs in dialysis centers, can a PCT who independently contracts with a home dialysis patient access the patient’s CVC at the patient’s home? If the PCT is not employed by or performing staff-assisted home dialysis for the ESRD facility, they are functioning as the patient’s private home hemodialysis caregiver, and as that caregiver, may access the patient’s CVC.
4) If a facility offers staff-assisted home hemodialysis, are the surveyors required to visit the patient’s home to observe the staff? If so, what if the patient(s) refuse to allow the surveyors in their home? No. A surveyor is not required to visit a home dialysis patient in his/her home to observe staff.
5) Does home therapy include patients who are dialyzed in nursing homes as their place of residence? If the ESRD facility is involved in the delivery of care to those patients, the ESRD facility is responsible for meeting these CfC for the patients dialyzed in nursing homes.
6) Can dialysis facilities that are certified to provide home care to patients residing in long-term care facilities continue to provide that service under these new regulations? Yes. CMS will issue an updated Survey and Certification letter with instructions regarding this service under the new regulations.
7) How is CMS going to reconcile the Conditions for Coverage (CfC) home patient visit requirement versus the home patient MCP guidance? The monthly capitation payment (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 CfC require equivalent care among facility-based and home patients. Therefore, a monthly visit is required for each home patient, either by a physician, an advanced practice registered nurse, or a physician assistant. This visit may be conducted in the dialysis facility, at the physician’s office, or in the patient’s home.
8) What are the “acceptable reasons” for a home patient not to be seen by a physician every month? If a home patient chooses not to be seen by a physician every month, that is an “acceptable reason” because patient choice is a hallmark of these ESRD regulations. However, if there is a pattern of a home-based patient consistently not seeing a physician, the patient’s interdisciplinary team should assure that he/she is not unstable according to the definition in these regulations, and address the lack of medical oversight with the patient through the “plan of care” process.
9) A facility’s current practice is to culture and collect endotoxin samples annually for each home patient. Does the requirement for quarterly sampling apply to conventional home hemodialysis patients in remote areas? The requirement for quarterly sampling does apply to conventional home hemodialysis patients.

Quality Assessment and Performance Improvement (QAPI)

Highlights

- This Condition looks at facility aggregate data and requires facility-based assessment and improvement of care, while the Plan of Care Condition expects patient-based improvement of care. (IG)
- The professional members of the facility's interdisciplinary team (IDT), which must participate in QAPI activities, consist of a physician, registered nurse, masters-prepared social worker, and registered dietitian. (IG)
- There must be an operationalized, written plan describing the QAPI program scope, objectives, organization, responsibilities of all participants, and procedures for overseeing the effectiveness of monitoring, assessing, and problem-solving activities. (IG)
- Within their individual QAPI program, facilities are expected to use the community-accepted standards and values associated with clinical outcomes as referenced on the MAT (measures assessment tool). (IG)
- If a facility has areas of QAPI program that do not meet target levels (per MAT) or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving those outcomes. (IG)
- QAPI program must be ongoing—continuously looking at indicators as they become available, trending outcomes and developing improvement plans as indicated. Generally, this would require at least monthly review of indicators. (IG)
- CMS-generated data reports, including the Dialysis Facility Reports (DFR) and other Consolidated Renal Operations in a Web-enabled Networks (CROWNWeb) reports will be provided to facilities to help them focus their QAPI programs. (IG)
- QAPI requires the use of aggregate patient data to evaluate the facility patient outcomes. Hemodialysis and peritoneal dialysis patients should be reviewed separately since factors affecting their clinical outcomes may be different; both groups of patients must be reviewed on an ongoing basis. (IG)
- Data related to patient outcomes, complaints, medical injuries, and medical errors (clinical variances, occurrences and adverse events) should be used to identify potential problems and to identify opportunities for improving care. (IG)
- The QAPI program must include; (Reg)
  - Adequacy of dialysis—Identify any commonalities among patients who do not reach the expected targets. Develop and implement a plan to address problem, monitor effectiveness of plan, and adjust portions of the plan that are not effective. (IG)
  - Nutritional status—Intent is to maximize the number of patients who achieve goal for this area, as low albumin levels are highly predictive of mortality risk. Albumin is affected by inflammation and other factors as well as by diet. The IDT may not be able to have a majority of patients achieve the desired goal for this, but should be actively intervening on actionable factors. (IG)
  - Mineral metabolism and renal bone disease—Since this is heavily influenced by patient diet, it is critical that patient education, encouragement, and support be included in improvement

plans for this indicator. The IDT should evaluate the efficacy of any standardized CKD mineral and bone disorder guideline/algorithm in use if facility QAPI goals in this area are not achieved over consecutive evaluation periods (if other factors have not been identified as cause of failure to meet goal). (IG)

- Anemia management—Facility should evaluate iron indices, ESA doses, evidence of blood loss, and anemia management protocols/algorithms if facility goals are not achieved over consecutive evaluation periods. (IG)
- Vascular access—Goal is to: (1) improve rate of use and preservation of AV fistulas; (2) decrease the inappropriate use of catheters; and (3) improve the care provided for all types of vascular access. (IG)
    - Fistula survival may be affected by cannulation technique problems, episodes of hypotension/hypovolemia, and differences in surgical outcomes. (IG)
    - The QAPI program should include efforts to reduce the use of catheters and the incidence of infection related to catheter use. (IG)
- Medical injuries and medical errors identification—The facility must compile and the QAPI team must review reports and complaints related to any patient or staff injuries, and treatment or medication errors. An example of medical injury is a patient fall. Occurrences such as treatment prescription errors, intradialytic morbidities, and staff needle sticks should be identified, reviewed and trended. “Intradialytic morbidities” is any adverse symptom that occurs during the dialysis treatment to include, but not be limited to, seizures, chest pain, hypotension, and cardiac arrest. Other events which should be tracked include hospitalizations, deaths, acute allergic-type reactions, blood loss > 100 ml, and patient transfers by ambulance from the dialysis facility to a hospital emergency room. There should be a mechanism to ensure all adverse events are recorded as soon as possible after they occur. (IG)
- Hemodialyzer reuse (if applicable)—Must comply with QA requirements specific to reuse (V360-368), which outline periodic reuse process and practice audits. QAPI meeting minutes should demonstrate oversight of the reuse program and include at least summaries of the required reuse audits. (IG)
- Patient satisfaction and grievances—Facilities must monitor and track patient grievance reports and outcomes. (IG)
- Infection control—Facility must record and follow up on all patient infections and serious adverse events. The occurrence of these events should be recorded using a centralized log book or other tracking mechanism and regularly reviewed, with documentation of actions taken. (IG)
    - Surveillance information available for review should include, but not be limited to, patient vaccination status, viral hepatitis serologies and seroconversions for HBV (and HCV, if known), bacteremia episodes, pyrogenic reactions, vascular access infections, and vascular access loss due to infection. (IG)
    - Medical director must periodically review recorded episodes of bacteremia, vascular access infections, soft tissue infections, and other communicable diseases to aid in tracking, trending and prompt identification of potential environmental/staff practice issues or infection outbreaks among patients. (IG)
    - Actions taken by the facility must be appropriate to the degree of risk to patients and staff. Actions could include in-service training in infection control, implementation of different protocols for cleaning equipment between uses, and audits of practice regarding infection control precautions for dialysis settings. (IG)
- Outcome data, achievement of treatment goals, adverse events, infections, fall, errors, etc. must be monitored as the data is available or as these events occur. Tracking and trending, analysis of

root causes, with development/implementation/evaluation and revision of improvement plans must occur as indicated. (IG)

- Once improvement is made, the facility must have a mechanism to ensure that improvement is sustained. (IG)
- The minutes of the governing body or the minutes of the QAPI committee should demonstrate communication between the governing body and the medical director. (IG)
- The facility must immediately correct any identified problems that threaten the health and safety of patients. (Reg) These problems include, but are not limited to: (IG)
  - Dangerous levels of contaminants in product water;
  - Unsafe levels of electrolytes in dialysate;
  - Failure to conduct an accurate pre-assessment;
  - Setting an inaccurate fluid removal rate;
  - Failure to provide adequate observation of patient, patient vascular access, patient equipment;
  - Defective clinical equipment;
  - Failure to adequately disinfect reprocessed dialyzers;
  - Failure to reduce residual germicides in reprocessed dialyzers to safe levels;
  - Lack of qualified staff to perform crucial tests or to meet critical patient needs;
  - Evidence that staff assigned to perform crucial tests or to meet critical patient needs are not competent;
  - Potential for cross-contamination between infected and non-infected patients; and
  - Failure to use machine-provided safety devices (muting machine alarms, bypassing the air detector, etc.)

QAPI Q & A

1) Since there is no time frame mentioned in the regulations, how often should we expect the QAPI meetings to take place? The scheduling of these meetings must be sufficient to address the facility's QAPI needs. Data must be reviewed as it becomes available; most data is available monthly. If immediate action is required, there must be a system to allow such action to be taken.
2) Can the IDT for the QAPI team be all "corporate people" as opposed to facility staff? Can the QAPI all be done at the corporate level? The facility's IDT must be responsible for the facility's QAPI. Corporate staff may participate in the program, but cannot replace the individual facility's staff. Multiple facilities can conduct QAPI IDT meetings jointly, but records of each facility's trends, analysis, plans, timetables, and accountability must be maintained.
3) Is there a requirement for documentation of the QAPI program activities? V626 requires the facility to "maintain and demonstrate evidence" of the QAPI program for review by CMS. This means there must be documentation of the QAPI activities demonstrating focus on, at a minimum, the indicators specified in V629-637, and performance improvement activity.
4) How is the Measures Assessment Tool (MAT) used for QAPI? The MAT is a reference for community-accepted standards and values for listed elements of QAPI. Within their individual QAPI program, facilities are expected to use the MAT for community-accepted standard/values associated with clinical outcomes. Facilities are expected to use CROWNWeb and Dialysis Facility Report to determine comparison or "average" values associated with clinical outcomes. If a facility has areas of QAPI that do not meet target levels (per MAT) or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving those outcomes. The important aspects of the QAPI program are appropriately monitoring data/information; prioritizing areas for improvement; determining

potential root causes; developing, implementing, evaluating, and revising plans that result in improvements in care.

5) Are facilities expected to use the CAHPS (a standardized experience of care assessment survey) to track patient satisfaction/grievances? V636 and V765 require facilities to monitor and track patient grievances. Effective 4/1/2008, CMS endorsed the measurement of in center hemodialysis patient satisfaction using the CAHPS survey as a CPM.
6) Is there some way to get a copy of the CAHPS survey? Yes. You can go to www.cahps.ahrq.gov and download a single survey or the entire CAHPS kit. This survey is validated for adult in-center hemodialysis patients.
7) What should be trended and tracked for medical injuries and errors? Facilities are expected to track patient/staff injuries, treatment errors, medication errors, hospitalizations, deaths, cardiac arrests in the facility, acute allergic-type reactions, and major blood loss, at a minimum.
8) Where would tracking for blood loss, machine malfunction, clotting, prolonged bleeding, and allergic reactions be reviewed under the requirements for QAPI? Some seem like infection control issues and some seem like medical errors. The facility may decide in what portion of the QAPI program to discuss these issues; the important point is that each of the problems listed must be included in the QAPI program, and those that may be related to infection control would need to be tracked and trended as part of the infection control auditing.
9) What is the definition of a “cluster of adverse events,” as referred to in the interpretive guidance at V637? The CDC defines a cluster as “an unusual aggregation, real or perceived, of health events that are grouped together in time and space.” The relevant time span is dependent on the nature of the adverse event.
10) Is CMS considering required reporting of adverse events? Adverse event reporting requirements are generally a state mandate, rather than a federal requirement. CMS is not considering making such an addition at this time.
11) If the facility incident reports are sent to the corporate risk management department, rather than being kept onsite, is it acceptable to only review the aggregate data kept by the facility? Are we authorized to request the actual incident reports? By virtue of the facility signing a Medicare agreement, a surveyor has the right to review any and all records of the facility, including adverse occurrences or incident reports. The facility must provide the actual incident report (or a copy) on the surveyor’s request.
12) Is it okay to look at the incident/accident reports prior to picking the sampled patients? In general, incidents and adverse outcome reports would not be used to select a sample group of patients. You might choose some patients from this source if you see issues that need follow-up.

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Special Purpose Renal Dialysis Facilities

Highlights

- A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances. (Reg)
  - Certification may not exceed 8 months in any 12-month period of time. (IG)
  - Camps that provide only peritoneal dialysis on-site are not required to be certified, as the treatment provided would be considered a "home" treatment. (IG)
  - "Emergency circumstances" for SPDF applies to a natural or man-made disaster that prevents the use of established dialysis facilities, and apples to a patient or group of patients who cannot otherwise be served in an area. The most common use of certification as an emergency SPDF is when the usual treatment facility (ies) are incapacitated by weather-related emergencies causing disruption to electrical service, water supplies, or vehicular access. (IG)
  - A hospital, long-term care facility, or other provider could request SPDF certification to provide dialysis to one or more patients that are denied outpatient dialysis by all dialysis facilities within reasonable driving distance because of physical (morbidly obese, bed bound, respirator-dependent, tracheotomy requiring frequent suctioning, etc.) or mental illness with a medical history indicating prior disruptive or threatening behaviors. (IG)
  - In the event a new ESRD facility, which has not yet been certified, is granted an emergency SPDF status, that facility would need to undergo an initial survey for full certification within the 8 month SPDF certification period in order to continue service. (IG)
- SPDF established as a vacation camp must comply with the following Conditions for Coverage: infection control, water and dialysate quality, reuse (if applicable), patients' rights and posting of patients' rights, lab services, medical director responsibilities, medical records, and home monitoring of water quality (if portable units are used). (Reg)
- SPDF established due to emergency circumstances must comply with all Conditions that camps must comply with as well as: compliance with Fed/State/Local laws, physical environment, patient rights, personnel qualifications, medical director and governance. (Reg)
- Care in any SPDF should be documented at the time it is delivered and sent to the patient's permanent facility within 30 days of the last treatment. Additional time may be needed for the transfer of documented care in the event of a natural disaster. For example, if a patient's original facility was destroyed and not rebuilt, the documentation transfer may be delayed or even impossible. (IG)

Special Purpose Dialysis Facility Q & A

1. Summer camps: if they can be certified for 8 months, will they have to be surveyed and certified every year, or will they be surveyed every 3-4 years? Usually vacation camp SPDFs operate a short period of time each year and are certified each year. Usually states that have vacation camps work with the camp to determine the extent of the survey needed, and whether an on-site survey is required each year.
2. Do peritoneal dialysis camps need to be certified as SPDF? Camps that provide only peritoneal dialysis on-site are not required to be certified as the treatment provided is considered a "home" treatment, and the dialysis facility providing training and support is expected to continue in the support role.

Laboratory Services

Highlights

- The dialysis facility must provide or make available, lab services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. (Reg)
- Under Clinical Laboratory Improvement Amendments of 1988 (CLIA), lab services can only be provided by an appropriately certified laboratory. Arrangements with these providers must be in writing and signed and should specify the types of laboratory tests to be performed, methods for collection and handling the specimens, and delivering results—including a timeline for reporting of “alert” or “panic” values to a responsible person. (IG)
- There should be a provision for service from a local laboratory for time-sensitive testing. (IG)
- The dialysis facility may provide some testing directly—generally this is limited to CLIA-waivered tests, such as blood glucose tests performed with home monitoring devices, and stool testing for occult blood. (IG)

Lab Services Q & A

- No questions posed by renal community regarding lab services.

Personnel Qualifications

Highlights

- All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. Staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. Staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions. (Reg)
- Each facility is expected to determine how each staff member will "demonstrate" competency. Specific competencies expected to be able to be demonstrated by staff assigned to these tasks include, but are not limited to, skills at testing for chlorine/chloramines levels; operating reuse equipment; following infection control practices designated for dialysis facilities by CDC; identifying and treating intradialytic morbidities; and, monitoring patients and equipment alarms during treatment. (IG)
- Medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12 months experience in providing care to patients receiving dialysis. (Reg)
- Nurse manager must be a full-time employee of the facility, be a registered nurse, and have at least 12 months of experience in clinical nursing and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis. (Reg)
- Self-care and home dialysis training nurse must be a registered nurse and have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training. (Reg)
- Charge nurse (responsible for each shift) can be RN, LPN, or LVN who meets the practice requirements in the State in which he or she is employed, and have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis. (Reg)
    - Recognize that a LPN/LVN cannot be in charge of a dialysis facility without specific authority from the applicable State board of nursing. CMS did not intend for, and State boards of nursing may prohibit a LPN/LVN supervising a registered nurse. An LPN/LVN cannot be the only licensed person in a dialysis facility while patients are on dialysis. (IG)
- Staff nurse must either be a RN or a practical nurse that meets the practice requirements in the State in which he/she is employed. (Reg)
- The facility must have a dietitian who must be a registered dietitian with the Commission on Dietetic Registration and have a minimum of one-year professional work experience in clinical nutrition as a registered dietitian. (Reg)
    - Experience in clinical nutrition as an intern (prior to registration) would not count toward this requirement, nor would foodservice experience after registration as a dietitian meet this requirement. (IG)
- The facility must have a social worker who (1) holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education *or* (2) has served at least 2 years as a social worker, one year or which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies (i.e. holds a master's

degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education). (Reg)

- Staff without master's degrees in social work, including bachelor's prepared social workers, may function as assistants under the supervision of the qualified social worker and provide services such as assisting with transportation arrangements; providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care; and locating resources to assist in payment for adequate nutrition, housing and medications. Only masters-prepared social workers may do assessments, develop psychosocial plans or care, provide counseling to patients and families, and participate as the social worker in the facility's QAPI program. (IG)
- The grandfather clause at (2) applies to very few social workers, as it only applies to those social workers who have worked in dialysis or transplant facilities since September 1, 1975 and who had at least two years of social work experience on September 1, 1976 when the original ESRD Conditions for Coverage became effective. (IG)

- Patient care (dialysis) technicians (PCTs) must (1) meet all applicable State requirements; (2) have a high school diploma or equivalency; (3) have completed a training program that is approved by the medical director and governing body, under the direction of an RN; (4) be certified under a State certification program or a national commercially available certification program—for newly employed PCTs, within 18 months of hire, and for PCTs employed on 10/14/08, within 18 months after such date. (Reg)
  - A "patient care (dialysis) technician" (PCT) means any person who provides direct care to patients and who is not classified as another professional, e.g., nurse, dietitian, or social worker. A biomedical technician or dialysis assistant would be classified as a PCT if he/she has responsibility for direct patient care or to set up machines for patient use. A technician who maintains or "takes down" machines after use without direct patient contact is not considered a PCT. (IG)
  - PCTs with greater than 4 years work experience as of 10/14/08 that are lacking evidence of a high school diploma may use that work experience in lieu of the requirement for high school diploma. (IG)
  - PCTs must meet any State requirements related to practice standards, certification, or licensure. (IG)
  - All PCTs who are not yet certified must have completed the approved training program before independently providing patient care. For "experienced" PCTs (meaning those who have been employed as a PCT for more than two years as of 10/14/08) who do not have documentation of having competed a training program covering the listed content, competency may be demonstrated by successful completion of written exam(s) over the required content and a skills checklist completed by observation of the PCT's skills by a registered nurse. Successful completion of these exam(s) would not negate the need for these PCTs to achieve certification within the specified time period. (IG)
  - Facility policies and procedures should define the curriculum of PCT training program, length of the course and the method of determining successful completion of the course. (IG)
  - PCT certification can occur under the aegis of either a national commercially available program or a State program. There are currently three such national certification programs—(1) the Certified Clinical Hemodialysis Technician (CCHT) exam, offered by the Nephrology Nursing Certification Commission; (2) the Board of Nephrology Examiners for Nursing and Technology (BONENT) exam; and, (3) the National Nephrology Certification Organization (NNCO) exam. (IG)

    - State certification programs, which have a formal certification and competency program that is specific to PCTs (including standardized tests, which reflect the content listed in the regulation, administered in a proctored environment by an independent examiner), can satisfy the certification requirement. If the state requires certification by a national commercially available certification program, this regulation expects continued certification under the requirements of the national program. (IG)
    - If a patient care technician who is not certified changes jobs from one dialysis facility to another, the time he/she was employed in the first facility will count toward the 18 month deadline for certification unless he/she had a gap in employment as a PCT of more than 18 months. (IG)
    - A reuse technician who does not provide direct patient care does not require certification as a PCT. (IG)
    - If a reuse technician or water treatment technician changes positions to become a PCT, he/she must be certified in 18 months from the date he/she started in the new PCT position. (IG)
- Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body. (Reg)
    - *Any* staff member who operates the water treatment system must complete a training program approved by the medical director and the governing body prior to independently performing water treatment system tasks. (IG)

Personnel Qualifications Q & A

1) Must personnel files be maintained at the facility, or may these files be maintained at the corporate offices? The files of personnel who work at the facility must be available for review; this could result in faxing of copies from a corporate office or an agency to the facility for review.
2) Clarify when a physician is required in the care of patients versus an APRN or PA. A physician is expected to participate in the IDT. An APRN or PA may provide treatment orders, assess patients, respond to emergencies, etc. Look at outcomes: if the outcomes indicate patients are receiving safe and effective care, there is no requirement for a specific level/number of visits/number of hours that the physician must be involved. Recognize that the Medicare reimbursement regulation bases payment on the physician seeing the patient at least monthly; additional monies are paid for more frequent visits, with the maximum paid for four times per month. APRN or PA may do three of those visits.
3) Does the physician have to be present at the IDT meeting or can they attend by conference call? To facilitate full IDT participation, any member, including the physician or the patient, may participate by phone.
4) Can a medical director also act as facility administrator? Yes, as long as he/she fulfills the duties and responsibilities outlined for both positions.
5) What happens when a physician has completed a board approved training program in nephrology, but the person is not board approved, and the person has been serving as medical director for an extensive period of time? In addition to completing a board-approved training program in nephrology, and having at least 12 months experience in nephrology, the medical director must be certified in internal medicine, pediatrics, or nephrology. If a person, as specified above, is not available, the Secretary of the Dept. of Health and Human Services may “approve” another physician to direct the facility. An alternative “Secretarial approval” process is expected to be rare and related to physician accessibility. A time-limited “approval” may be

issued in some cases to give an individual physician time to qualify as a medical director. **See appendix for waiver process.

6) Would it be acceptable if the nurse manager changed each day, i.e., the charge nurse of the day or the shift is considered the nurse manager that day? If all the nurses are qualified as nurse managers, there is no regulation to prohibit this. Look at outcomes: consider turnover of staff; whether new staff are oriented prior to being assigned responsibilities for care of patients or support roles; and QAPI regarding patient outcomes, medical errors/injuries, and patient satisfaction.
7) Must the facility have a nurse manager? The facility must employ a full-time nurse manager who is available at all hours the facility is open.
8) Is there a definition of the job duties of the Nurse Manager? Can he/she hire and terminate employees? V 684 addresses the qualifications for the Nurse Manager, not the job duties. The facility policies and job descriptions should guide this.
9) Does the nurse manager need to be on-site every day the facility is open, including Saturdays? No.
10) Do the regulations address the duties of the nurse manager? In a broad way: V684 states that the nurse manager is responsible for nursing services in the facility.
11) When a nurse manager position is vacant, and a nurse manager from a “sister” facility acts in the interim, what provisions need to be made at both facilities? This sort of temporary accommodation should be carefully monitored and time limited. Active recruitment efforts must be demonstrated, and the oversight (administrative and clinical) expected from the nurse manager must be evident at each facility.
12) Can one RN be the nurse manager and administrator of 4 or 5 ESRD facilities? No. The nurse manager position is a full-time position. An RN could function as the nurse manager in two facilities only if each facility was open only three days per week, and the days were not overlapping.
13) What nursing experience must a nurse manager have? The nurse manager must have 12 months of clinical nursing experience, with an additional 6 months providing care to patients on dialysis.
14) Can one RN be both the nurse manager and the charge nurse? Yes.
15) Does the nurse manager need to be available 24/7 for on-call coverage? The nurse manager can share on-call coverage with other qualified staff.
16) What qualifies as “experience” for the nurse manager, self-care training nurse, and charge nurse? The “experience” qualifications for the nurse manager and self-care training nurse must be as a “registered nurse”. The “experience” qualifications of the charge nurse are in “providing nursing care”. These experiences may be in either a chronic or acute setting.
17) Can an RN serve as the nurse manager if all of her related experience (the 1 year requirement) was obtained overseas? There is no reciprocity among countries for licensing of registered nurses. RN’s from other countries must apply for U.S. licensing as an RN under the aegis of a State practice board. The State practice board will require the applicant to demonstrate knowledge of the English language and “equivalency” to the U.S. in training curriculum and the functional role of the RN in his/her country. If the RN has registered as an RN in the U.S. and shown that an RN from his/her country is “equivalent” to an RN in the U.S., then experience in the other country will meet the regulatory requirement.
18) If the CEO is an RN, can he/she also be the Chief Nursing Officer? Yes.
19) What are the qualifications for the Facility Administrator? The regulation does not specify the qualifications for the administrator. These should be defined by facility policy. The administrator must possess sufficient educational and practical experience to fulfill the responsibilities listed in the CfC Governance, V752.

20) Can a facility administrator also be the social worker? Yes.
21) Can an administrator act in that role for 2 facilities? Yes.
22) Can there be a different charge nurse on MWF and TTS? A charge nurse must meet the qualifications in the regulation but can work different days and shifts.
23) Can an LPN/LVN be "on call" for home patients? This depends on your state nurse practice act and the policy of the facility. If your state nurse practice act does not allow an LPN/LVN to assess the patient, that individual could not take call, or would have to triage calls, referring calls requiring assessment to an RN, but handling calls not requiring assessment such as calls for assistance with equipment or supplies.
24) If a facility requires LPNs to function as patient care technicians, do the LPNs need to be certified as PCTs? No.
25) What happens if the dietitian does not have at least one year in a clinical setting? 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 do the patient assessments, plans of care, QAPI program review, or care at home components of the regulations. The facility may define other tasks for a dietitian with less than one year of experience in a clinical setting.
26) Could there be some "grandfathering" for registered dietitians who are currently working but did not have the year of experience as required in the new regulations? These requirements for personnel qualifications are applicable to persons being hired after 10/14/08 and to those RDs who do not yet have a year clinical experience as of 10/14/08. The regulation does not have a grandfather clause or any exception for this requirement. A dietitian who does not have one year of post-RD clinical experience may be able to obtain that experience working under an RD who does meet these qualifications.
27) What does "specialization in clinical practice" mean in the qualifications statement for the masters-prepared social workers? The phrase "specialization in clinical practice" is used generically in this regulation to reference the clinical background of the master's prepared social worker. The curriculum of masters-level programs in schools of social work accredited by the Council on Social Work Education (CSWE) is presumed for this regulation to include content sufficient for "clinical practice specialization." This phrase has been used generically in the ESRD Federal regulations since 1976. CMS recognizes that some States have specific qualifications for a "clinical social worker."
28) What is a proctored exam? Who can be a proctor? Could the exam be offered at a dialysis provider corporate office? A proctored exam means that an outside, independent person receives and protects the exams; provides oversight of the test administration (ensures candidates sit at an appropriate distance from one another, do not have potential to share answers, discuss the test, or take copies of the test away from the test site); and is responsible for returning the completed tests to the entity providing the exam. The tests are generally timed.
29) What does CMS mean by a "standardized test"? A "standardized test" means a test developed and tested to validly and reliably measure the knowledge required to demonstrate competency in an area.
30) Is there a national database for certification of hemodialysis PCTs? Not at this time.
31) Who is classified as a "patient care dialysis technician"? Technicians are described using a variety of terms, including "biomedical technician" and "machine technician." The CMS requirements for the "patient care dialysis technician" apply to any technician who has any responsibility for setting up the dialysis machine for patient use. A technician who maintains or "takes down" machines after use without direct patient contact is not considered a "patient care dialysis technician."

32) If a PCT does not have 4 years of experience in lieu of a high school diploma, what role can they have? V692 allows a PCT to substitute 4 years of PCT experience in lieu of documentation of high school diploma or equivalent. If a currently employed PCT does not have 4 years of PCT experience by 10/14/08, he/she may perform other functions in the dialysis facility, but would not qualify to function as a PCT after that date.
33) Some experienced PCTs do not have evidence of a high school diploma or GED. How will this be handled? CMS recognizes that some experienced PCTs working in dialysis facilities as of the effective date of these rules may not have evidence of a high school diploma or GED. PCTs with more than four years of work experience as of 10/14/08 who are lacking evidence of a high school diploma may use that work experience as an "equivalency" to a high school diploma.
34) With the new regulations, PCTs are expected to complete a training program focused on the operation of the kidney dialysis equipment and machines, providing direct patient care, and communication interpersonal skills. What is expected of experienced technicians? For "experienced" PCTs, meaning those PCTs who have been employed as a PCT for more than two years as of 10/14/08, who do not have documentation of a training program covering the listed content may demonstrate competency by successful completion of a written exam(s) over the required content and a skills checklist completed by observation of the PCT's skills by an RN. These PCTs would be expected to achieve certification within the specified time period.
35) If a hemodialysis PCT took a training course prior to the CMS requirement for certification, will they meet the certification criteria? If there is documentation that the course taken meets the curricula requirements, or if the PCT has been working for more than two years as a PCT and passes a test over the content of the curricula, the training course requirement would be met. Each PCT must successfully complete a certification exam from a qualified entity in order to meet the certification criteria.
36) Will CMS track technicians who do not have appropriate qualification/certifications, but move from one facility to another? CMS does not maintain a registry of technicians. However, CMS intends to "count" experience from one facility to another in determining the 18 months time limit for completing certification, unless the PCT has at least an 18-month break in employment as a PCT.

Responsibilities of the Medical Director

Highlights

- The medical director is accountable to the governing body for the quality of medical care provided to patients. (Reg)
- Each dialysis facility must have a single medical director who meets the qualifications under the Condition for Personnel at V682 identified as responsible for carrying out the duties of this position. The position of medical director may not be shared by several physicians. (IG)
- The medical director is expected to be actively involved in the oversight of the facility patient care delivery and outcomes (e.g., to attend and contribute during IDT meetings for his/her patients, to participate in performance improvement plans, and to be involved in the education of staff). (IG)
- The medical director is assigned operational responsibility for the QAPI program. Operational responsibility includes review of quality indicators related to improved patient health outcomes and monitoring this data on a continual basis in the Condition for QAPI; education of facility and medical staff in the QAPI objectives; reviewing the method of prioritizing the importance of improvement projects; inclusion/encouragement of all staff in participating towards achievement of QAPI goals; communication with the governing body regarding the needs identified by QAPI; and participating in the evaluation of the effectiveness of performance improvement plans/ activities. (IG)
- The medical director is responsible for ensuring that facility staff members receive the appropriate education and training to competently perform their job responsibilities. (IG)
- There must be evidence that the medical director reviewed and approved the patient care policies and procedures and any revisions as they are made. Policies are expected to be adequate, accurate, and up-to-date. (IG)
- Policies relative to patient admission must address the expectation for an initial assessment by a member of the medical staff (physician, APRN, or PA) before the initiation of the patient's first dialysis treatment in the facility, in order to develop the admission treatment orders and to provide for prompt recognition and action to address urgent patient medical needs (anemia with Hgb < 10, fluid overload, hyperkalemia) prior to completion of the comprehensive patient assessment. This evaluation could be accomplished by review of medical records and consultation with the referring physician, and is not intended to require the medical staff member to "see" the patient in the facility prior to this first treatment. Orders for treatment must be in place prior to the initial treatment, as well as a patient evaluation by a registered nurse for any immediate needs. (IG)
    - At the time of publishing these regulations, according to the American Nephrology Nurses' Association, the minimal nursing evaluation prior to initiating treatment for a patient new to the facility should include:
        - Neurologic: level of alertness/mental status, orientation, identification of sensory deficits
        - Subjective complaints
        - Rest and comfort: pain status
        - Activity: ambulation status, support needs, fall risk
        - Access: assessment
        - Respiratory: respirations description, lung sounds
        - Cardiovascular: heart rate and rhythm, presence and location of edema

    - Fluid gains, BP and temperature pre-treatment
    - Integumentary: skin color, temperature, and type/location of wounds if applicable
- The medical director must monitor and review each involuntary patient discharge to ensure that the facility interdisciplinary team follows the discharge and transfer policies and completes the required steps under the Condition for Governance at V766 and V767. (IG)

Medical Director Q & A

1) Many facilities have a group of physicians that collectively serve the facility as medical directors. What provisions are made for this practice? For these regulations, each facility must have a single medical director identified as responsible for carrying out the duties of this position. The governing body and medical director may designate additional physicians to direct different program components in that facility, e.g. home hemodialysis program/peritoneal dialysis program, as long as all components ultimately report to the facility medical director and are under the same QAPI program and governing body oversight.
2) In facilities that have co-medical directors now, can one be medical director and the other an associate medical director? CMS requires a single medical director who takes responsibility as outlined in the regulations.
3) Is there a limit to the number of facilities for which a physician can be Medical Director? There is no restriction on the number of facilities where an individual physician can function as Medical Director. The CfC of Medical Director outlines the responsibilities that the Medical Director must fulfill. If the Medical Director is over multiple facilities and there are survey findings in areas which may affect the safety of patients or quality of care, consider whether the Medical Director is meeting all of the responsibilities, or if his/her absence and lack of guidance may have contributed to the findings.
4) Clarify the “initial assessment” requirements that must be met prior to the patient’s first treatment & what would a surveyor expect to see to validate these requirements were met? At V715, there is a requirement that a physician, APRN, or PA conduct an initial assessment in order to provide a treatment order and to identify critical problems that must be addressed prior to the first treatment. This requirement could be met by reviewing various medical records (from primary care physicians, hospitalization, etc.) rather than actually seeing the patient in the dialysis facility prior to treatment. In addition, the RN on duty must make and document an initial assessment of the patient prior to that first treatment. In contrast, V516 refers to the Initial Interdisciplinary Comprehensive Assessment that must include the input of all members of the IDT.
5) How often must the Medical Director be physically present at the facility? The Medical Director should devote sufficient time, and be actively involved in the oversight of the facility: attending care plan meetings, QAPI committee meetings, guiding development of performance improvement/action plans, and educating staff. As a guide, each facility’s financial cost report, filed with CMS, considers the Medical Director role a 0.25 FTE.

Medical Records

Highlights

- Each patient's medical record, whether hard copy, electronic, or a combination of both, should include complete and pertinent details about the patient, assessments by the IDT, updated plans of care, all interventions and treatments prescribed and delivered, and details of any events occurring with the patient during the course of treatment. No matter what format, the record of care must be readily accessible to every authorized member of the healthcare team so that care can be coordinated to best meet the needs of the patient. (IG)
- The medical records system must ensure that records are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. (IG)
- All locations where medical records are stored or maintained must ensure the integrity, security, controlled accessibility, and protection of the records. (IG)
- Facility personnel should have sufficient knowledge of electronic system functions to assure their ability to safeguard records on that system in the event of a problem, including backup of electronic medical records and restoring data. (IG)
- Staff members should be aware of the facility's plan to ensure uninterrupted maintenance of the patient's medical record in the event of a computer failure. (IG)
- The facility policy for stored medical records must ensure prompt retrieval. Facility policy should address how staff members access records that are stored off-site, and the expected time to retrieve them. (IG)
- In the event of loss of medical records due to natural or man-made disaster, there should be evidence in the QAPI documentation of the event, what records were lost/destroyed, and what steps were taken to prevent similar losses in the future. The facility must have a plan for protecting medical records in an emergency (transport, secure in place, redundant backup, continuous automatic off-site backup), and for minimizing loss. (IG)
- Medical records must contain written authorization for health information release prior to release of any medical records that require the patient's/designee's authorization to release. (IG)
- Facility policy must identify timeframes for the completion of medical records (signing of verbal orders, completion of discharged patients' records). The medical record system must have a method for identification of the author, date and time of each entry. The author's identification may be by written signature, initials, computer key, or other code. If initials or computer codes are used as signatures, there must be a means to identify the author of the entry. (IG)
- Rubber stamp signatures are not permitted. (IG)
- The facility should have a system to maintain and regularly review treatment records kept by all home patients (including those whose equipment and supplies are furnished by a durable medical equipment supplier) and to incorporate those records into the patient's medical record. (IG)
- All patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death. (Reg)
    - Some states have more stringent requirements for medical record retention. Retention requirements begin after the patient is no longer on census at the facility. (IG)

    - Retention requirements also apply to records of machine maintenance, dialyzer reuse, water treatment and dialysate preparation as each of these records is part of the medical record for the patients on service at the time those records were completed. Since many patients are treated on the equipment each day, determination of the retention period may be difficult. Facility policy should address retention of these records. (IG)
- When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer. (Reg)

Medical Records Q & A

1) How quickly must staff produce medical records requested by surveyors? Staff members should be able to provide a printed copy of requested portions of the medical record in less than one hour and printed copies of the complete current medical record in less than four hours.

Governance

Highlights

- This Condition requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. (IG)
- This Condition also holds the governing body accountable for establishing an internal grievance process and decreasing the potential for involuntary discharge of patients; for emergency coverage and backup; for electronic data submission; and the relationship of the facility to the ESRD Network. (IG)
- The individual(s) responsible for the conduct and oversight of the operations of the facility must be identified in writing. This may be demonstrated in governing body bylaws or minutes, or in ownership documents. (IG)
- Facilities that are part of a dialysis organization with multiple widespread facilities must have a local governing body designated to guide the day-today operation of the facility. (IG)
- A signed agreement between the facility and the applicable Network is required prior to the initial certification survey. The CEO or administrator is responsible to receive and act on correspondence from the ESRD Network and to promptly respond to any request from the applicable Network. (IG)
- The governing body or designated person responsible must ensure that an adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients. (Reg)
    - Sufficient numbers of staff must be present in the treatment area to be able to see every patient during treatment (including lunch breaks, shift change, etc.). (IG)
    - Staffing assignments and schedules should demonstrate a pattern of sufficient staff coverage to ensure safe patient care. (IG)
- The governing body is expected to make diligent efforts to promptly fill vacant positions. If the nurse manger, social worker, dietitian, or other required or necessary position is vacant for more than a month, the governing body must make some provision for temporary coverage. (IG)
- There must be a registered nurse on duty and available at all times when in-center dialysis patients are being treated. If only one RN is on duty, that RN is expected to spend the majority of his/her time on the treatment floor. Short personal breaks away from the treatment floor are acceptable. (IG)
- An RN must be on-duty whenever patients are present, including the beginning and end of the treatment day. (IG)
- In some cases, the RN who is on duty may not be qualified under these regulations as a “charge nurse” (at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis). In those instances, if allowed under the applicable State nurse practice act, a qualified LPN or LVN may function in the charge role. (IG)
- Continuing education programs should be offered to all staff to help them maintain and improve their knowledge, skills, and licensure, if applicable. “Continuing education” includes internal training programs, as well as external professional educational programs. (IG)

- The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial or services. (Reg)
  - The facility's process must include clearly defined timeframes for a grievance to be acknowledged, investigated, and addressed. (IG)
- The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures—The medical director ensures that no patient is discharged or transferred from the facility unless: (1) the patient or payer no longer reimburses the facility for the ordered services; (2) the facility ceases to operate; (3) the transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or (4) the facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery or care to the patient or the ability or the facility to operate effectively is seriously impaired. (Reg)
  - If staff believes a patient may have to be involuntarily discharged, the medical director must ensure that the IDT: (1) documents the reassessment, ongoing problem and efforts to resolve it; (2) provides the patient and the local ESRD Network with a 30-day notice of the planned discharge; (3) obtains a written physician's order that must be signed by both the medical director and the patient's attending physician, concurring with the patient's discharge or transfer; (4) contacts another facility, attempt to place the patient there, and documents that attempt; and (5) notifies the State survey agency of the involuntary transfer or discharge. (Reg)
- Involuntary discharge or transfer should be rare and preceded by demonstrated effort on the part of the interdisciplinary team to address the problem in a mutually beneficial way. (IG)
- The medical director must be informed of and approve any involuntary discharge or transfer of a patient. (IG)
- Patients should not be discharged for failure to comply with facility policy unless the violation adversely affects clinic operations (e.g., violating facility regarding eating during dialysis should not warrant involuntary discharge). (IG)
- Patients should not be discharged for shortened or missed treatments unless this behavior has a significant adverse affect on other patients' treatment schedules. (IG)
- A facility may alter the patient's treatment schedule or shorten treatment times for patients who persistently arrive late. Patients should not be discharged for failure to reach facility-set goals for clinical outcomes. (IG)
- Facilities are not penalized if a patient or patients do not reach the expected targets if the plan of care developed by the IDT is individualized, addresses barriers to meeting the targets, and has been implemented and revised as indicated. (IG)
- In the event facility staff members believe the patient may have to be involuntarily discharged, the IDT must reassess the patient with intent to identify any potential action or plan that could prevent the need to discharge or transfer the patient involuntarily. (IG)
- Evidence must be on file to substantiate that the patient received notification at least 30 days prior to involuntary discharge or transfer and that the ESRD Network was also notified at that time. While the early notice to the State agency is not required, facilities may choose to notify the patient, Network, and State agency at the same time. (IG)
- Because the goal of contacting another dialysis facility is for continuity of care, the HIPAA privacy rule does not require patient consent to contact that other dialysis facility. However, it does limit sharing of protected health information to medical records requested by the other provider and prohibits sharing information obtained through hearsay. (IG)
- In the case of immediate, severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure. (Reg)
  - An "immediate severe threat" is considered to be a threat of physical harm. For example, if a patient has a gun or 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. (IG)
    - Abbreviated procedures may include taking immediate protective actions, such as calling “911” and asking for police assistance. (IG)
    - A 30-day notice is not required in the case of imminent severe threat to safety of other patients or staff. (IG)
    - After the emergency is addressed and staff and other patients are safe, staff must notify the State agency and ESRD Network of the involuntary discharge, and document this contact and the exact nature of the “immediate severe threat” in the patient’s medical record. (IG)
- The facility must provide information to all patients, including home patients, regarding who to call and how to obtain emergency medical care when away from the dialysis facility. (IG)
- The dialysis facility must have available at the nursing /monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached. (Reg)
- The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis, and other hospital services, and emergency medical care which is available 24 hours per day, 7 days per week. (Reg)
- Beginning February 1, 2009, all dialysis facilities must electronically submit data to allow patient enrollment in and disenrollment from the ESRD benefit program, assessment of clinical outcomes, and claims processing. (IG)
- The dialysis facility must cooperate with the ESRD Network in fulfilling the terms of the Network’s current statement of work. Each facility must participate in ESRD Network activities and pursue Network goals. (Reg)
    - The ESRD facility must respond promptly within any specified deadlines to requests for information, data, or corrective action plans from its ESRD Network. The facility must participate in Network projects and activities aimed at addressing identified needs and improving quality of care in the individual facility or the Network-wide area. (IG)

Governance Q & A

1) Are all medical staff members required to attend QAPI meetings? The medical director is responsible for the facility’s QAPI program; at least one member of the medical staff needs to participate on the interdisciplinary team. The medical director may serve as the medical staff representative for the QAPI program.
2) What facility provisions for emergency medical care are expected? The patients should be able to contact a call service for a responsible staff member, physician, or on-call staff for dialysis-related emergencies 24 hours a day, 7 days a week. In cases of need for emergent medical care, e.g., severe chest pain, loss of consciousness, incontrollable bleeding, patients should call “911” for immediate medical care.
3) Give examples of when “services provided on the premises” applies. All services have to be provided at the physical location of the ESRD facility, with the exception of home therapies. If an in-center HD and home training department have the same CMS certification number (provider number) but are located in different parts of the town, each would require a separate provider number; if a hospital has an ESRD facility on the campus and another one 5 miles away, the distant one would be considered a “satellite” and each would need its own provider number.
4) If patients are not being treated, but in the facility (e.g., the waiting room), must a registered nurse be present? No. The regulation requires that an RN who is responsible for the nursing

care provided is present in the facility at all times that in-center dialysis patients are being treated.

5) Must the facility have a contract for water treatment or can they use the service prn? Do they need a pest control contract? There is no requirement for a facility to have a contract with any service that is provided by an outside entity.
6) Does the facility have to have a contract with a hospital for admission of patients in emergencies? V770 requires that each facility have an agreement with an inpatient hospital that provides inpatient dialysis.
7) Are long term care facilities that provide dialysis in the LTC facility to patients, whose care might be paid for by Medicaid, required to have a contract with an ESRD facility for these patients? CMS has a Survey & Certification letter dated 2004 regarding the dialysis of patients in nursing homes. An updated letter will be developed for this service.
8) What happens when a staff physician determines that he/she can no longer care for a particular patient? If there is no other physician on the staff who is available or willing to accept responsibility for the care of the patient, attention must be paid to State practice boards for physicians, which generally require that some notice be given to patients to avoid the charge of abandonment. The facility would need to follow the steps for involuntary discharge, including 30-day notice, reassessment of the patient, attempts for placement, etc., during the physician's period of notice to the patient.
9) What is an "abbreviated involuntary discharge procedure?" Who determines what is contained in an "abbreviated involuntary discharge procedure?" Are patients required to help patients find a new facility if this "abbreviated involuntary discharge procedure" is used? 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." Any 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 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 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.
10) If the abbreviated involuntary discharge process is utilized, is the facility responsible for any attempt to place patient after the danger has passed? The Interpretive Guidance addresses the abbreviated involuntary discharge process and allows a facility to call "911" and summon help to immediately remove the patient from the facility if the staff/patients feel physically threatened. If the abbreviated discharge process is used, this discharges the patient from the facility and no follow-up is required. The facility must limit the use of the abbreviated involuntary discharge process to situations that pose a real threat.
11) If a patient brings a knife to the clinic and is screaming and yelling, threatening staff, what can the staff do? Call "911" and ask the police for assistance to protect the other patients and the staff. This may result in an abbreviated discharge procedure.

Appendix 1

MEASURES ASSESSMENT TOOL (MAT)

Tag	Condition/Standard ➡	Measure ➡	Values ➡	Reference ➡	Source
494.40 Water and dialysate quality:					
V196	Water quality	Max. chloramine (must determine)	≤0.1 mg/L daily/shift	AAMI RD52	Records
V196		Max. total chlorine (may determine)	≤0.5 mg/L daily/shift		
V178		Action / Max. bacteria – product water / dialysate	50 CFU/mL / <200 CFU/mL		
V180		Action / Max. endotoxin – product water / dialysate	1 EU/mL / <2 EU/mL (endotoxin units)		
494.50 Reuse of hemodialyzers and blood lines (only applies to facilities that reuse dialyzers &/or bloodlines)					
V336	Dialyzer effectiveness	Total cell volume (hollow fiber dialyzers)	Measure original volume Discard if after reuse <80% of original	KDOQI HD Adequacy 2006; AAMI RD47	Records Interview
494.80 Patient assessment: The interdisciplinary team (IDT), patient/designee, RN, MSW, RD, physician must provide each patient with an individualized & comprehensive assessment of needs					
V502	- Health status/comorbidities	- Medical/nursing history, physical exam findings	Refer to Plan of care & QAPI sections (below) for values	Conditions for Coverage KDOQI Hypertension & Anti-Hypertensive Agents in CKD 2004 (BP) KDOQI HD Adequacy 2006 (volume)	Chart
V503	- Dialysis prescription	- Evaluate: HD every mo; PD first mo & q 4 mo			
V504	- BP & fluid management	- Interdialytic BP & wt gain, target wt, symptoms			
V505	- Lab profile	- Monitor labs monthly & as needed			
V506	- Immunization & meds history	- Pneumococcal, hepatitis, influenza; med allergies			
V507	- Anemia (Hgb, Hct, iron stores, ESA need)	- Volume, bleeding, infection, ESA hypo-response			
V508	- Renal bone disease	- Calcium, phosphorus, PTH & medications			
V509	- Nutritional status	- Multiple elements listed			
V510	- Psychosocial needs	- Multiple elements listed			
V511	- Dialysis access type & maintenance	- Access efficacy, fistula candidacy			
V512	- Abilities, interests, preferences, goals, desired level of participation in care, preferred modality & setting, outcomes expectations	- Reason why patient does not participate in care, reason why patient is not a home dialysis candidate			
V513	- Suitability for transplant referral	- Reason why patient is not a transplant candidate			
V514	- Family & other support systems	- Composition, history, availability, level of support			
V515	- Current physical activity level & referral to voc &physical rehab	- Abilities &barriers to independent living; achieving educational & work goals			
494.90 Plan of care The IDT must develop & implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs as identified by the comprehensive assessment & changes in the patient's condition, & must include measurable & expected outcomes & estimated timetables to achieve outcomes. Outcome goals must be consistent with current professionally accepted clinical practice standards.					
V543	(1) Dose of dialysis: volume	Management of volume status	Euvolemic & BP 130/80 (adult); lower of 90% of normal for age/ht/wt or 130/80 (pediatric)	KDOQI HD Adequacy 2006	Chart
V544	(1) Dose of dialysis (HD adequacy)	Adult HD <5 hours 3x/week Adult HD 2x/week, RKF <2 mL/min HD 4-6x/week	Kt/V ≥1.2; Min. 3 hours/tx if RKF <2ml/min Inadequate treatment frequency Min. Kt/V ≥2.0/week	KDOQI HD Adequacy 2006	DFR
V544	(1) Dose of dialysis (PD adequacy)	Adult PD patient <100 mL urine output/day Pediatric PD patients, low urine urea clearance	Min. delivered Kt/V_{urea} ≥1.7/week Min. delivered Kt/V_{urea} ≥1.8/week	KDOQI PD Adequacy 2006	Chart
V545	(2) Nutritional status Monitored monthly	Albumin Body weight Other parameters in Patient assessment V509	≥4.0 g/dL bromcresol green (BCG) method % usual weight, % standard weight, BMI, estimated % body fat	KDOQI Nutrition 2000 KDOQI CKD 2003	Chart
V546	(3) Mineral metabolism & renal bone disease	Calcium Phosphorus Intact PTH q 3 months	All: >8.4 mg/dL & <10.2 mg/dL All: 3.5-5.5 mg/dL Adult: 150-300 pg/mL (16.5-33.0 pmol/L) Pediatric 200-300 pg/mL	KDOQI Bone Metabolism & Disease 2003	Chart
V547	(4) Anemia	Adult & pediatric Hgb on ESAs Adult & pediatric Hgb on ESAs	Hgb: <12.0 g/dL[3] Hgb: 10-12.0 g/dL[4]	[3]=FDA "black box" warning [4]=Medicare reimbursement policy [5]=KDOQI Anemia 2007 [6]=KDOQI Anemia 2006	DFR
V548	Monitor Hgb/Hct monthly	Adult & pediatric Hgb off ESAs Adult & pediatric Hgb on ESAs	Hgb: >10 g/dL[4] Hgb: 10-12.0 g/dL, <13.0 g/dL[5]		
V549	Monitor iron stores routinely	Adult & pediatric: transferrin saturation Adult & pediatric: serum ferritin	>20% (HD, PD), or CHr >29 pg/cell[6] HD: >200 ng/mL; PD: >100 ng/mL[6] HD/PD: <500 ng/mL or evaluate if indicated[6]		

Tag	Condition/Standard ➡	Measure ➡	Values ➡	Reference ➡	Source
V550 V551	(5) Vascular access	Fistula Graft Central Venous Catheter	Preferred[1,2] Acceptable if fistula not possible[1,2] Avoid, unless bridge to fistula/graft or to PD, if transplant soon, or in small adult/peds pt[1]	[1]=KDOQI Vascular Access 2006 [2]=Fistula First	DFR Interview CW
V552	(6) Psychosocial status	Survey physical & mental functioning annually KDQOL-36 survey annually	Achieve & sustain appropriate status	Conditions for Coverage CMS CPM	Chart Interview
V553 V554	(7) Modality	Home dialysis referral Transplantation referral	Candidacy or reason for non-referral	Conditions for Coverage	Chart Interview
V555	(8) Rehabilitation status	Productive activity desired by patient Pediatric: formal education needs met Vocational & physical rehab referrals as indicated	Achieve & sustain appropriate level, unspecified	Conditions for Coverage	Chart Interview
V562	(d) Patient education & training	Dialysis experience, treatment options, self-care, QOL, infection prevention, rehabilitation	Documentation of education in record	Conditions for Coverage CMS CPM 4/1/2008	Records Interview
494.110 Quality assessment & performance improvement (QAPI): The dialysis facility must develop, implement, maintain, & evaluate an effective, data-driven QAPI program with participation by the professional members of the IDT. The program must reflect the complexity of the organization & services (including those under arrangement), & must focus on indicators related to improved health outcomes & the prevention & reduction of medical errors. The dialysis facility must maintain & demonstrate evidence of its QAPI program including continuous monitoring for CMS review.					
V629	(i) HD adequacy (monthly) (i) PD adequacy (rolling average each patient tested ≤4 months)	HD: Adult (patient with ESRD ≥3 mo) PD: Adult	% with spKt/V ≥1.2 or URR ≥65% (conventional 3 times/week dialysis) % with weekly Kt/V_{urea} ≥1.7 (dialysis+RKF)	Conditions for Coverage CMS CPM 4/1/2008 (all)	DFR Records
V630	(ii) Nutritional status	Unspecified in Conditions for Coverage & CPMs Refer to parameters in Patient assessment V509	↑ % within target range	Conditions for Coverage	Records
V631	(iii) Mineral metabolism/renal bone disease	Calcium, phosphorus, & PTH	↑ % in target range monthly	Conditions for Coverage CMS CPM 4/1/2008	Records
V632	(iv) Anemia management Patients taking ESAs &/or Patients not taking ESAs	Mean hemoglobin (patient with ESRD ≥3 mo) Mean hematocrit Serum ferritin & transferrin saturation or CHr	↑ % with mean 10-12 g/dL ↑ % with mean 30-36% Evaluate if indicated	Conditions for Coverage CMS CPM 4/1/2008 (all)	DFR Records
V633	(v) Vascular access (VA) Evaluation of VA problems, causes, solutions	Cuffed catheters > 90 days AV fistulas for dialysis using 2 needles Thrombosis episodes Infections per use-life of accesses VA patency	↓ to <10%[1] ↑ to ≥65%[1] or ≥66%[2] ↓ to <0.25/pt/yr (graft) or 0.50/pt/yr(fistula) ↓ to <1% (fistula); <10% (graft) ↑ % with fistula >3 yrs & graft >2 yrs	[1]=KDOQI 2006 [2]=Fistula First CMS CPM 4/1/2008	DFR Records CW 2/09
V634	(vi) Medical injuries & medical errors identification	Medical injuries & medical errors reporting	↓ frequency through prevention, early identification & root cause analysis	Conditions for Coverage	Records
V635	(vii) Reuse	Evaluation of reuse program including evaluation & reporting of adverse outcomes	↓ adverse outcomes	Conditions for Coverage	DFR Records
V636	(viii) Patient satisfaction & grievances	Report & analyze grievances for trends CAHPS In-Center Hemodialysis Survey available Other surveys for pediatric & home patients	Prompt resolution of patient grievances ↑ % of patients satisfied with care	Conditions for Coverage CMS CPM 4/1/2008	Records Interview
V637	(ix) Infection control	Analyze & document incidence for baselines & trends	Minimize infections & transmission of same Promote immunizations	Conditions for Coverage	DFR Records
V637	Vaccinations	Hepatitis B, influenza, & pneumococcal vaccines Influenza vaccination by facility or other provider	Documentation of education in record ↑ % of patients vaccinated on schedule ↑ % of patients receiving flu shots 10/1-3/31	Conditions for Coverage CMS CPM 4/1/2008	Records
V627	Health outcomes: Physical & mental functioning	Survey adult/pediatric patients KDQOL-36 survey annually	Achieve & sustain appropriate status ↑ % completing survey	Conditions for Coverage CMS CPM 4/1/2008	Records
V627	Health outcomes: Patient survival	Standardized mortality ratio (1.0 is average, >1.0 is worse than average, <1.0 is better than average)	↓ mortality	Conditions for Coverage CMS CPM 4/1/08	DFR

SECTION 1: WAIVERS

V Tag	Section 1: Waivers	Guidance	Procedure
V129	**Waiver: Isolation Room** **New facilities & existing facilities which are expanding their capacity may apply for a waiver for an isolation room for hepatitis B+ patients.** As of February 9, 2009, all new or expanding facilities must have an isolation room or be granted a waiver for this requirement, showing that there is sufficient capacity in their geographic area for isolation rooms. Waivers may be granted to varying extent based upon the availability of alternative isolation rooms in the proximate geographic area.	A "new" facility is a facility that has not obtained approval for all required building permits (or has not completed the required plan reviews in geographic jurisdictions that do not require building permits) prior to the effective date of these regulations, i.e. October 14, 2008 An isolation "room" is a separate room with walls and a door to contain any spurting blood, body fluids, or other contaminants. The walls do not need to reach the ceiling, but should be at least 6 feet in height and must fully contact the floor in order to contain blood spills. The walls need to allow for continuous visual monitoring of the patients in the room. "Sufficient capacity" takes into account the availability of facilities with isolation rooms in a "proximate" geographic area. The "proximate" area should take into account the physical distance between a facility with at least one available isolation room/isolation station and the facility seeking a waiver. ▪ If the distance between these facilities is >60 miles, the facility cannot be granted a waiver of an isolation room/isolation station. ▪ If the distance is 10-60 miles, a facility may request consideration of a waiver. ▪ If the distance is <10 miles, then a facility will be granted a waiver automatically upon request in most cases. In addition to the physical distance between	A new or expanding dialysis facility may be eligible for a waiver of this requirement if: 1. Facility-based isolation rooms for HBV+ patients are available locally and such rooms; 2. Sufficiently serve the needs of the patients in the geographic area, Isolation room waivers may be granted at the discretion of, and subject to, additional conditions that are deemed necessary by the Secretary. Written requests for a waiver should be made to the applicable State Survey Agency. A model letter is included with this grid. The written request must include information on the geographical proximity of facilities with isolation rooms and the accessibility of the isolation room(s) as validated in a written agreement between the facility requesting the waiver and the facility(ies) having the isolation capacity. The State Survey Agency may consult with the applicable End Stage Renal Disease (ESRD) Network to clarify questions regarding availability of isolation rooms/isolation stations. The State Survey Agency will communicate information regarding the waiver to the applicable CMS Regional Office. The CMS Regional Office will inform the facility about the decision regarding the waiver.

V Tag	Section 1: Waivers	Guidance	Procedure
		facilities, "sufficient capacity" also requires a written agreement between facilities regarding their willingness and ability to take referred HBV+ patients. "Expanding" means that a facility increases the square footage of treatment space. Construction to comply with other Conditions for Coverage, e.g., to replace a flat-bottom water storage tank with one having a conical bottom or to add a carbon tank, is not considered expanding the treatment space. Each expansion requires a new consideration regarding isolation rooms, using the same criteria.	Documentation of the decision should be entered in the "Remarks" section of the form CMS-3427 in order to maintain this information in the automated systems.
V420	**Waiver: <u>Life-Safety Code</u>** **A facility may apply for a waiver for one or more specific provision(s) of the Life Safety Code, for appropriate periods, if application of the provision(s) of the Life Safety Code (LSC) would result in an "unreasonable hardship" for the dialysis facility.** A new or existing facility may request a waiver for a specific provision of the LSC. The facility must provide evidence that the waiver would not adversely affect the health and safety of the dialysis facility's patients.	"Unreasonable hardship" may be an economic, logistical, or construction hardship. A "new" facility is a facility that has not obtained approval for all required building permits (or has not completed the required plan reviews in geographic jurisdictions that do not require building permits) by October 14, 2008. An "existing" facility is a facility that has a CMS Certification Number (CCN). <u>Note:</u> The new life-safety code portion of the survey process will be phased in during 2009. CMS will issue a separate S&C Memorandum in December 2008 that will describe this process.	A new or existing facility may request a waiver for a specific provision of the Life Safety Code (LSC). A <u>new facility applies to the applicable State Survey Agency</u> for a waiver. A model letter for this application is attached. An <u>existing facility</u> requests a waiver for a specific provision of the LSC following a survey when a provision of the LSC is not met and is cited as a deficiency on the left side of the form CMS-2567. At that point, the facility may request a waiver through the State Survey Agency. The facility must request a waiver and cite "unreasonable hardship" and "no adverse effect" on the right side of the form CMS-2567, in lieu of a plan of correction. The facility should include justification statements explaining the "unreasonable hardship" and how the waiver will have "no adverse effect on the patient's health and safety" In their comments on the right side of the form CMS-2567.

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

SECTION 2: PHASE-IN TIME EXTENSIONS

V Tag	Section 2: Phase-In Time Extensions	Guidance	Procedure
V118	**Phase-in Time Extension: Single-Use Vials** **Facilities should apply single use to single-use vials.** Facilities should have a plan for the conversion of single-use vials for single use.	Manufacturers of single-use vials for erythropoiesis stimulating agents estimate that full supplies of single-use vials should be available for all dialysis units by Spring 2009. This time extension that is intended to recognize the current shortage of single-use vials in the commercial marketplace. All facilities should have plans for fully complying with this regulation by June 30, 2009.	Facilities that currently use single-use vials multiple times must continue to follow the CDC guidance letter of 2002 in the use of those vials. Facilities need to have a plan to convert to the single use of single-use vials as soon as supplies are available. No special letter-request needs to be submitted. During a State survey prior to June 30, 2009, facilities that are using single-use vials multiple times must provide the surveyor with the facility's plan for conversion to single-use vials. If a facility is surveyed prior to June 30, 2009, then the facility must present their plan for conversion to single-use vials. If a facility is surveyed after June 30, 2009, then the facility must have converted to single-use vials. If a facility does not comply with either of these scenarios, then the facility will be cited for noncompliance with this rule, and a plan of correction will be expected.
V209	**Phase-in Time Extension: Water Storage Tanks** **Water storage tanks should have a conical or bowl-shaped base and should drain from the lowest point in the base.** If existing facilities with older flat-bottom water storage tanks can demonstrate a history of water and dialysate cultures being below AAMI action levels, replacement of the existing tanks is not required.	The AAMI "action levels" for water and dialysate cultures are <50 cfu for bacteria and <1 EU for endotoxins. An "existing" facility is a facility that was in operation on October 14, 2008.	A facility that does not have a water storage tank with a conical or bowl-shaped base should be prepared to demonstrate a documented history of water and dialysate cultures being below AAMI action levels whenever a State survey is conducted. No special letter-request needs to be submitted for this time extension. If a facility continues to use a water storage tank without a conical or bowl-shaped base and the facility does not have a documented history of water and dialysate cultures being below AAMI action levels, then during a State survey, the facility will be cited for noncompliance with this rule, and a plan of correction will be expected.

V Tag	Section 2: Phase-In Time Extensions	Guidance	Procedure
V519 V558	**Phase-in Time Extension:** **<u>Interdisciplinary Assessment</u>** **Comprehensive, interdisciplinary assessment, at least annually, for all stable patients, and implementation of the plan of care based on those assessments.** Each facility needs to have a facility-wide plan to accomplish initial comprehensive, interdisciplinary assessments and plans of care for all existing patients by October 14, 2009.	A "facility-wide plan" for comprehensive, interdisciplinary assessments of all current stable patients as of October 14, 2008, is expected to include a schedule to allow completion of these assessments and implementation of the plans of care based on those assessments for all current patients by October 14, 2009. The facility-wide plan should reflect prioritization of those patients who fall farthest outside target ranges for the mandated areas of assessment and planning. Patients "new" to ESRD treatment or to their treatment modality, transient patients, transferred in patients, and unstable patients are not included in the phase-in time extension, but must follow the timelines, as specified in the Interpretative Guidance.	The facility-wide plan for completing the comprehensive assessments and plans of care should be available for review during any State survey. <u>No special request needs to be submitted</u> for this time extension. Facilities should follow the regulations and the Interpretive Guidance in ensuring that assessments and plans for all stable patients are completed by October 14, 2009. If a facility is surveyed prior to October 14, 2009, then the facility must provide an operational plan for patient assessments, and the complementary plans of care, for all patients who were on the census of that facility as of October 14, 2008. As the year between October 14, 2008, and October 14, 2009, progresses, more and more of the facility's patients should have completed assessments and implemented plans of care. If a facility is surveyed after October 14, 2009, then all patients who were on the census of that facility as of October 14, 2008, must have a patient assessment and a complementary plan of care. If a facility does not comply with either of the scenarios described above, then the facility will be cited for noncompliance with this rule, and a plan of correction will be expected.
V771	**<u>Data Submission</u>** **Effective February 1, 2009, dialysis facilities must submit data and information electronically in the format specified by the Secretary and at intervals specified by the Secretary**	Facilities are expected to submit data electronically on existing and future clinical performance measures The "electronic format" is the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system. The "clinical performance measures" and the data elements required for electronic submission will be communicated to dialysis facilities through CROWNWeb communications.	The CMS Office of Clinical Standards and Quality (OCSQ) designs and maintains the CROWNWeb system. OCSQ continues to update its communications regarding the CROWNWeb system as issues are addressed. The Survey & Certification Group remains in close contact with OCSQ and will update our communications based on OCSQ's continued resolution of issues (as discussed, for example in the 11/19/2008 Open Door Forum). In particular, we will update this Memorandum as we come closer to February 1, 2009.

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