

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-13-ESRD

DATE: March 18, 2011

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: End Stage Renal Disease (ESRD) Update of Frequently Asked Questions (FAQs)

Memorandum Summary

- **Refreshed FAQs Available:** A refreshed version (Version 1.3) of the End Stage Renal Disease (ESRD) FAQs related to the ESRD Conditions for Coverage (CfCs) is attached to this memorandum. All new questions are printed in red for easy reference. To assist in navigation among the FAQs, these questions are organized around the respective Conditions and V-tags.
- **Ongoing FAQs on CMS Web Site:** The current version of the ESRD FAQs is available on the Centers for Medicare & Medicaid Services (CMS) Survey & Certification (S&C) Web Site at http://www.cms.gov/GuidanceforLawsandRegulations/05_Dialysis.asp . These FAQs are refreshed periodically.
- **Email ESRD Mailbox for Further Questions:** Further questions or comments regarding the S&C ESRD Program can be sent to the ESRD mailbox at ESRDSurvey@cms.hhs.gov. This mailbox is established for surveyors, patients, providers, and CMS staff with a survey-related ESRD question or comment.

CMS wants to promote common understandings about the regulatory process and the specific rules that guide the CMS S&C process. In order to promote consistency of standards and expectations regarding the ESRD CfCs, we actively support our ESRD email mailbox for questions and comments and periodically refresh our compendium of FAQs on our CMS S&C Web site.

We will continue to distribute refreshed versions of our FAQs on the Web site. Any questions or comments about the FAQs may be addressed to the ESRD mailbox at ESRDSurvey@cms.hhs.gov. Questions regarding this memorandum may be addressed to Judith Kari at Judith.Kari@cms.hhs.gov.

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Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

ESRD Conditions for Coverage Frequently Asked Questions (FAQs)

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ESRD Conditions for Coverage Frequently Asked Questions (FAQs)

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	Condition: Compliance with Federal, State, and Local Laws and Regulations	
101	Compliance: When would the regulation requiring compliance with Federal, State, and Local law be cited?	Refer to the Principles of Documentation, Principle #6. If a finding of non-compliance with State or local law has been completely adjudicated, that is, the finding was upheld after appeal within the local or State jurisdiction, then this Condition could be cited. State surveyors should refer potential non-compliance with Federal laws (such as OSHA or FDA) to the appropriate Regional Office of CMS for determination of referral to the responsible Federal entity for enforcement.
	Condition: Infection Control	
113	Gloves: Must staff members wear gloves when setting up a “clean” dialysis machine, including “stringing” the bloodlines?	The 2001 MMWR says “gloves are required whenever caring for a patient or touching the patient’s equipment.” No exceptions are made for when the equipment is presumed to be clean. The staff member is likely to have contact with dialysate during the set-up process and other potentially contaminated items or surfaces. Staff should wear gloves to prevent contact with potentially contaminated items and also chemical germicides that may remain on machine surfaces following disinfection.
113	Gloves: Must staff members change gloves between “setting up” the machine and initiating the patient’s treatment?	Yes. Initiation of treatment is a point where there is high risk for contamination of the vascular system. New, clean gloves are required to be used to initiate patient treatment.
113	Gloves: Must staff always change gloves and do hand hygiene when moving between a specific patient and that specific patient’s machine?	The goal is to protect the patient and the vascular access from potential contamination. Times when the same gloves “touch” the patient after touching potentially contaminated surfaces should be minimized, while recognizing the need to protect the patient’s access and maintain patient safety.
113	Gloves: Must staff, such as dietitians, social workers, etc. wear gloves when in the patient treatment area, if they are not delivering care to the patients?	Gloves are not necessary for casual contact with the patient, e.g., shaking hands, taking his/her arm, touching a shoulder. Any staff member who touches any potentially contaminated surfaces is required to wear gloves when touching that surface.
113	Hand hygiene: If a computer data entry station required for documenting daily treatment data is located away from the hemodialysis machines, what are the infection control requirements related to hand hygiene?	When data entry stations are located away from the treatment stations, staff leaving the patient station should use hand hygiene before touching the computer data entry station.
113 464	Hand hygiene: What should the facility do if the patient refuses to wear a glove to hold their sites or to wash their hands?	Educate the patient again regarding the reasons for the request. If the patient still refuses, the facility should not allow the patient to hold his/her own sites.
114	Sinks: Are two sinks required in the isolation room?	No. There must be a sink immediately available for use either in or adjacent to the isolation room. Recognize that some State licensing rules may be more stringent.

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V Tag	Question	Answer
114	Sinks: Is the sink in the isolation room considered “clean” or “dirty?” If “dirty,” may the staff disinfect his/her hands using hand sanitizer and go to a clean sink in the treatment area to “wash” their hands?	There should be a sink available for hand washing in or near the isolation room. If the isolation room has only one sink, it should be designated for hand washing or a designated hand washing sink must be immediately available for use adjacent to the isolation room. Although hand sanitizer can be used prior to leaving the isolation room when hands are not visibly soiled, staff should have ready access to sinks when hand washing is appropriate.
114	Sinks: Do sinks have to be labeled “clean” or “dirty?”	No. Although labeling is not required, sinks do need to be designated as either “clean” or dirty.”
114	Sinks: Can sinks used to drain saline bags, disinfect clamps and prime buckets, etc. be used for hand washing?	No. These are considered “dirty” activities and should not be accomplished in a sink used for hand washing.
114	Sinks: 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. Federal regulations do not address this issue. Staff must avoid recontamination of their cleaned hands when they turn the water off. Some States have requirements in this area.
114	Sinks: If all sinks have motion sensors or foot pedals to start the water flow, 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.
115	Personal Protective Equipment (PPE): When is personal protective equipment (PPE) required to protect the caregiver’s face and eyes?	Caregivers must have protection of the mucus membranes, which requires that the mouth, nose and eyes be protected. Caregivers must either use face shields or eye wear (glasses with side shields) and a mask to protect their eyes, mouth, and nose when performing procedures during which spurting or splattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood).
115	Personal Protective Equipment (PPE): Are staff expected to use face shields, or is wearing glasses sufficient eye protection?	The staff member’s mucous membranes must be protected from possible contamination by spurts or splashes of blood or body fluids. Glasses alone would not protect the wearer’s nose or mouth, nor provide protection from splashes coming from the side. Glasses with or without side panels do not provide sufficient eye protection. Appropriately fitted safety goggles could be used with a mask covering the mouth and nose for protection. Face shields are the preferred method of protection from potential splashes.
115	PPE: How are masks expected to be worn?	When a mask is needed, the mask should cover the caregiver’s nose and mouth.
115	PPE: May staff members wear lab coats rather than gowns for infection control?	Lab coats that cover the arms and the body to the knees and are closed in front are as acceptable as a gown for PPE.
115	PPE: May a home patient’s partner use an apron rather than a gown as PPE when such coverage is required?	The patient’s partner should use the same protection as staff members during times when there is a risk for spurting or splattering of blood. A washable lab coat would be an option, with the caregiver instructed in appropriate use of bleach in the wash should the lab

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V Tag	Question	Answer
		coat be contaminated with blood. Education regarding infection control precautions for patients and their partners is required by V585.
115	PPE: Do gowns worn as personal protective equipment (PPE) need to be impermeable?	Yes.
115	PPE: Are surveyors expected to bring their own PPE to the facilities they survey?	It would not be appropriate for surveyors to carry PPE from place to place. Facilities are expected to provide PPE for visitors, including surveyors.
116	Dedicate equipment: If a non-reuse dialyzer and bloodlines are primed for a patient who does not come for treatment one day, can the facility use this equipment for a second patient?	Yes. If the dialyzer of the first patient is the same type and size as a dialyzer ordered for the second patient and if the second patient is treated at the machine that has been set up for the first patient who did not come for treatment, then the dialyzer and lines can be used for the second patient. Note that the electrolyte content of the dialysate must match what is ordered for the second patient before initiation of that patient's treatment.
116	Dedicate equipment: Must each patient have his/her own B/P cuffs?	The intent is to provide clean equipment to each patient for each treatment. Blood pressure cuffs that can be cleaned and disinfected between uses are acceptable. Patients may have their own cuffs, or disposable or washable covers may be used.
116	Dedicate equipment: May the same fistula clamp be used for multiple patients?	If the clamp can be adequately cleaned and disinfected (i.e. immersed in disinfectant solution for sufficient time), it may be used for multiple patients.
116	Dedicate equipment: Can 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 impervious and is cleaned and disinfected in between uses for patients.
116	Dedicate equipment: Do patient education tools, such as flip charts, which are used with or by multiple patients, need to be disinfected between patients?	Yes. If patient education tools are taken to the dialysis station for use by patients during treatment, those tools must be able to be disinfected between use by different patients.
116	Dedicate items: If a staff member carries an item, such as a syringe containing heparin, to the dialysis station, but does not put it down (no contamination), can it be returned to the common supply area?	No. Medications that are taken to a dialysis station cannot be returned to a common supply area.
116	Dedicate equipment: Can facilities place hand sanitizers on the side of dialysis machines?	Yes. It is acceptable if the dispenser for the hand sanitizer is included in the cleaning done between uses of the machines for different patients.
117	Med prep: Can medications be drawn up the night before for the first shift of patients the next day?	No. Medications should be prepared as close to time of use as possible to prevent loss of potency or sterility, or tampering.
118	Single-use: Can a single-dose ampule be used for more than one patient?	No. While V118 refers to "vials," the intent is to prevent the possible contamination of medication in single-use containers, which could be ampules as well as vials.
118	Single-use: Can intravenous medication vials labeled for single-use be used multiple times?	No. CMS is following the guidance of CDC, as published in the CDCs 2001 document on recommendations for dialysis facilities and the CDCs

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V Tag	Question	Answer
		August 15, 2008, MMWR which clarified a previous communication on the use of parenteral medication vials.
118	Single-use: 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.
122	Disinfect: How is a "hemodialysis station" defined?	A hemodialysis station is defined as the dialysis machine, a purified water connection, the dialysate concentrate container or connection, and the treatment chair.
122	Disinfect: The manufacturer's DFU for an EPA-registered bleach product required a 16% dilution. Should the facility follow the manufacturer's guidance for the dilution to disinfect surfaces or should the facility use a 1:100 solution?	If the product in use is EPA registered, the facility must follow the manufacturer's directions for use (DFU). The product labeling should specify how to prepare and use the product as well as the required contact time.
122	Disinfect: Can a disposable wipe be used to clean equipment or must a cloth soaked in bleach be used?	The requirement is that the equipment be cleaned and disinfected; the type of cloth or wipe to use is not specified. Adequate disinfectant must be applied to achieve the minimum contact time. The disposable wipe or cloth used should be sufficiently wet to allow proper application of the disinfectant,
122	Disinfect: Can hemostats be wiped clean or must they be soaked in bleach?	The expectation is that equipment that is reused will be adequately disinfected between uses. The method of cleaning is not specified.
122	Disinfect: What is the minimum contact time required for a 1:100 dilution of bleach to be effective? What is the source for this information)?	While some brands of bleach include directions regarding dilutions and contact time, many brands do not address dilutions or contact time in their labeling. Consult CDC guidance documents for the minimum contact times, recognizing these may be different for various concentrations of bleach. Web addresses for two such documents that discuss manufacturer's directions for contact time for bleach (current as of 12/10) were: CDC's MMWR (4/27/01): www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm CDC's Environmental Management of Staph and MSRA in Community Settings (not dialysis-specific): www.cdc.gov/mrsa/environment/index.html
124	HBV: Within what timeframe is the Hepatitis B testing to be done prior to a patient being admitted?	All new patients should be tested and their HBV serologic status (i.e., HBsAg, total anti-HBc, and anti-HBs results) known prior to admission. 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 treated as potentially HBV+ until the results are known. Expect results within 7 days of submission of the testing For patients transferring from other dialysis facilities, the

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V Tag	Question	Answer
		timeframes for previous tests depend on the patient status. If the patient has an antibody titer (anti-HBs) of ≥ 10 mIU/mL, a test for this antibody within the previous 12 months is expected. If the patient does not have an antibody titer, an HBV antigen (HBsAg) test within the previous 30 days is expected. Each patient is expected to be tested for total anti-HBc at least once, and the results of that test should be included in records transferred with the patient.
124	HBV: What tests for Hepatitis B must a dialysis facility request and have on file in the medical record in order to accept a patient for a transient dialysis?	Records obtained for transient patients should clearly identify the patient's hepatitis status. Results for Hepatitis B surface antigen, antibody to hepatitis B core antigen (anti-HBc) and antibody to hepatitis B surface antigen (anti-HBs) should be known. The timeframes for these tests depend on the patient status. If the patient has an antibody titer (anti-HBs) of ≥ 10 mIU/mL a test for this antibody within the previous 12 months is expected. If the patient does not have an antibody titer, an HBV antigen (HBsAg) test within the previous 30 days is expected. Each patient is expected to be tested for total anti-HBc at least once, and the results of that test should be included in records transferred with the patient.
124	HBV: What should a dialysis facility do related to HBV testing and isolation of transient patients requiring dialysis in a disaster or emergency?	Part of the emergency plans for every facility should include patient education regarding personal HBV status. The patient records provided for patients prior to any planned evacuation must include documentation of HBV status. Should a patient arrive for transient dialysis without information regarding his/her HBV status, that patient would need to be treated as potentially positive until his/her status is known.
124	HBV: What are the requirements when a patient is HBc positive and HBSAg negative?	<p>The patient's physician and possibly a consultant specialist in liver disease should be involved in this patient's evaluation. This situation is addressed on p. 28 of CDC's MMWR 4/27/01 at the following URL and quoted below: www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm</p> <p>Isolated Anti-HBc--Positive Patients. <i>Patients who test positive for isolated anti-HBc (i.e., those who are anti-HBc positive, HBsAg negative, and anti-HBs negative) should be retested on a separate serum sample for total anti-HBc, and if positive, for IgM anti-HBc. The following guidelines should be used for interpretation and follow-up:</i></p> <p>If total anti-HBc is negative, consider patient susceptible, and follow recommendations for vaccination.</p> <p><i>If total anti-HBc is positive and IgM anti-HBc is negative,</i></p> <ul style="list-style-type: none"> • <i>If anti-HBs is <10 mIU/mL even after revaccination, test for HBV DNA.</i>

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V Tag	Question	Answer
		<ul style="list-style-type: none"> • <i>If HBV DNA is negative, consider patient susceptible (i.e., the anti-HBc result is a false positive), and test monthly for HBsAg.</i> • <i>If HBV DNA is positive, consider patient as having past infection or "low-level" chronic infection (i.e., the anti-HBc result is a true positive); no further testing is necessary.</i> • <i>Isolation is not necessary because HBsAg is not detectable.</i> <p><i>If both total and IgM anti-HBc are positive, consider patient recently infected and test for anti-HBs in 4--6 months; no further routine testing is necessary.</i></p> <ul style="list-style-type: none"> • <i>Isolation is not necessary because HBsAg is not detectable.</i>
126 127	HBV: What are the expectations for HBV screening and vaccination for the facility dietitian, social worker, and medical staff (physicians, APRN, PA)?	Each facility is expected to offer HBV vaccine to all staff members who have direct patient contact. The only screening required for any staff member is to determine if the vaccine resulted in the development of antibodies. The same hepatitis vaccination and screening requirements apply to non-employee medical staff who have direct patient contact (physicians, APRN and PA).
127	HBV: How is it determined if patients or staff members respond to the hepatitis B vaccine?	The CDC defines an adequate response to vaccination as a laboratory result of ≥ 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.
127	HBV: Is there a CDC recommendation for HBV revaccination of staff who do not respond to a first series?	In the CDC 2001 MMWR recommendations, if staff do not respond to a first HBV vaccination series, another series of vaccination is recommended. If the staff member does not respond to the second series, no additional vaccination is recommended.
128	Isolation: When an ESRD facility is acquired by another provider, i.e., undergoes a change of ownership, does the facility need to have an isolation room?	A change of ownership (CHOW) would not routinely spur a reconsideration of the need for an isolation room. Each facility is expected to have the capacity to treat HBV positive patients. If the facility's "capacity to treat" was based on an agreement with a facility owned by the previous owner of the facility undergoing a CHOW, the need for a new agreement should be considered.
128	Isolation: Does the isolation room need to be designed for bloodborne isolation, air borne isolation, or both?	In dialysis facilities, an isolation room or area is required for isolation of patients who are Hepatitis B+, which is a bloodborne virus. It is not expected that outpatient dialysis facilities would have capacity to isolate for airborne organisms.
128	Isolation: If a facility dialyzes an HBV+ patient twice a week and the isolation room is terminally cleaned and the machine removed, can the	No. According to the CDC, the isolation room can only be used for HBV surface antigen positive patients. Hepatitis B virus can survive on surfaces in the environment for at least 7 days and transmission can

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V Tag	Question	Answer
	room be used for HBV- patients?	occur through direct or indirect contact with contaminated surfaces. These surfaces can be contaminated with high levels of hepatitis B virus without evidence of visible contamination (thus creating a challenge for effective decontamination). For these reasons, the isolation room cannot be used for HBV- patients in between uses for HBV + patient treatments. The regulation requires the isolation room/area be reserved for HBV+ patient use until there are no longer any HBV+ patients on census.
128	Isolation: Isolation station space requirements 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?	CMS has not incorporated the AIA guidelines as rules. The width of a current station can be determined by measuring the area the width of the treatment chair and the dialysis machine with components. A measurement of these items will determine the expected width of the space separating the HBV+ area from other patients.
128	Isolation: What are the space requirements for an isolation area for existing facilities? Must existing facilities request a waiver?	<p>An "existing" facility is defined in the Interpretative Guidance as one that was certified or had a building permit or completed plan reviews (whichever applies for that specific location) as of 10/14/08. Existing facilities are not required to request a waiver, but are expected to have "capacity to treat" a HBV+ patient. This "capacity" could be an isolation room or an area, or an agreement on file with a local facility that will accept their HBV+ patients.</p> <p>If an existing facility treats an HBV+ patient, it must either maintain an isolation room with a door or an area that provides separation of the isolation station from other stations by the width of a dialysis station (machine and chair).</p> <p>If an existing facility expands the treatment area (moves at least one wall) or relocates (changes physical location), it would need to add an isolation room or get a waiver from CMS.</p>
128	Isolation: How is a facility expected to treat a HBV+ patient if the facility does not have the space for an isolation room/area and if there is not another center locally that can take the Hepatitis B+ patient?	The intent of the regulations is to assure that all facilities have the capacity to treat HBV+ patients. The options are to accommodate an isolation room or an area, to negotiate a transfer agreement with a local facility that can accept HBV+ patients, or, if the patient chooses, provide home treatment for patients who are HBV+. If a patient chooses home treatment, the facility would still be required to provide (or arrange for provision of) in-center dialysis if necessary (in case of home equipment failure, for example).
129	Isolation: When is an isolation room required for hepatitis B + (HBV+) patients? 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 isolation area may continue to use that "isolation area."

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V Tag	Question	Answer
		Existing facilities that begin caring for HBV+ patients after February 9, 2009 may designate an isolation area, unless they are expanding the treatment area, 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.
129	Isolation: If an existing facility does not have an isolation room, do they have to build one?	No.
129	Isolation: If an existing facility currently uses an area for HBV+ patients, may they continue to use this area, or must they add a room?	An existing facility may continue to use an isolation area, with the requirement that the HBV+ treatment area be separated from other treatment stations by a space the width of a treatment station.
129	Isolation: If an existing facility that currently uses an area for HBV+ patients expands their treatment area and physical capacity, may they continue to use an isolation area?	No. If an existing facility that is currently using an isolation area for HBV+ patients expands their treatment area and physical capacity, they must add an isolation room.
129	Isolation: Does "physically expand" mean adding stations? If a facility adds stations, will they need to add an isolation room?	If an existing facility expands their treatment area after February 9, 2009, they would be expected to add an isolation room or obtain a waiver of this requirement from CMS. If a facility adds treatment stations but does not increase the size of their treatment area, (i.e., the facility adds stations within the existing treatment area space which was built to accommodate more stations than were previously certified) the facility would not need to add an isolation room or obtain a waiver.
129	Isolation: If an existing facility that currently does not accept HBV+ patients expands their physical capacity, do they have to include an isolation room?	A facility that expands their treatment area would need to either add an isolation room or obtain a waiver of this requirement from CMS.
129	Isolation: 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 or if there are no HBV+ patients on census in the facility and the station has been terminally cleaned and disinfected.
129	Isolation: If a facility has an isolation room, may that facility 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 the capacity to treat HBV+ patients. This means the facility must have an isolation room, an isolation area (for existing facilities), or an agreement with another facility to accept patients who become HBV+. Any facility may choose to not offer isolation services, but only if the facility has an agreement with a facility that will accept patients who become HBV+.
129	Isolation: 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 the HBV+ patient.
129	Isolation: Does every new facility have to have an isolation room?	New facilities (facilities that have not obtained building permits or completed required plan reviews prior to

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V Tag	Question	Answer
		October 14, 2008) must either include an isolation room or obtain a waiver of this requirement from CMS.
129	Isolation: If the initial survey is done, and there is no isolation room and no waiver, would the facility be recommended for certification?	No.
129	Isolation: If a new facility was built before February 2009, but not surveyed until after February 2009, must it have an isolation room?	If the facility had a building permit or completed plan reviews prior to the effective date of these regulations (October 14, 2008), the facility would not have to have an isolation room or apply for a waiver and would be classified as an "existing" facility for this requirement. If that facility is going to accept HBV+ patients, there would need to be either a designated room or an area, separated from other stations by an area the width of a dialysis station, for isolation.
129	Isolation: After February 9, 2009, if a new facility does not believe it needs an isolation room, would applying for a waiver of that requirement delay the initial survey?	A new facility must have an isolation room or obtain a waiver of the requirement from CMS. If an initial survey is done, and the facility is found to have neither an isolation room nor a waiver, the State will not be able to recommend certification until this deficient practice is addressed, delaying the date of certification. A prospective facility may apply for a waiver of the isolation room requirement during the development of the facility, prior to being "ready" for their initial survey. Taking this action would not delay the survey.
129	Isolation: Are new facilities that provide only home therapies, including those that provide only peritoneal dialysis required to have an isolation room or a waiver?	Yes. All new facilities, including facilities that provide only home therapies, must either provide an isolation room or have been granted a waiver of the requirement from CMS.
129	Isolation: What process will be used for determining whether or not a facility can be granted a waiver for an isolation room?	A new facility may submit a request for a waiver of the isolation room requirement by providing evidence of an agreement with another facility that will accept HBV+ patients to the respective State Agency, which forwards all waiver requests to the applicable CMS Regional Office (RO). If that facility is less than 10 miles from the new facility, the waiver will be granted. If the facility is greater than 60 miles from the new facility, the waiver will not be granted. If the facility is between 10 and 60 miles from the new facility, the CMS RO will consult with the State Agency and the applicable ESRD Network to determine the approximate drive time between the two facilities to weigh the burden to potential HBV+ patients who would have to travel this distance for treatment.
129	Isolation: For the isolation room waiver, what does the "same geographical area" mean?	The "same geographical area" is defined in the waiver process as less than 60 miles between the facilities with an agreement related to treatment of HBV+ patients.
130	Isolation equipment: 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 several HBV+ patients can be dialyzed at the same time.

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131	Isolation staff: Can a patient who requires a booster dose of Hepatitis B vaccine be assigned to the same staff member who is assigned to care for Hepatitis B+ patients after the patient receives the booster dose?	No. According to the CDC, patients who require a booster dose may not be protected from the HBV virus and should not be cohorted with HBV+ patients. The CDC recommendation is that once a patient requires a booster they are no longer eligible to be cared for by the same staff member who is treating HBV+ patients, as there is no way to know exactly when the patient who required the booster dose might lose their antibody titer.
131	Isolation staff: How can a small facility that has only one nurse on duty per shift meet the requirement to not have a staff member care for HBsAg positive patients and HBV susceptible patients at the same time?	CMS recognizes that the single RN on duty in a small facility may be required to have direct contact with every patient during his/her shift including providing catheter care, administering medications, and performing other nursing responsibilities that may not be delegated. Some of these contacts are high risk in terms of bloodborne pathogen transmission. Potential ways to limit the risk for cross-transmission in a small facility that has only one RN on duty per shift include: <ul style="list-style-type: none"> • Ensuring that all other patients scheduled for treatment on the same shift as an HBsAg positive patient have been vaccinated for Hepatitis B and are immune; • Scheduling the HBsAg positive patient at the end of the day and ensuring that there is a break between the shift immediately before the treatment of the HBV+ patient so that no staff member is simultaneously caring for an HBV susceptible and an HBsAg positive patient; and • Scheduling susceptible patients who refuse vaccination to different shifts from the HBV+ patient. In every case, careful attention to infection control precautions to prevent cross contamination is critical.
132	Training: Do all dialysis staff members need the training listed at V132 for infection control or just “hands on” staff?	All dialysis staff members 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.
142	TB testing: What are the options for a facility if a patient with questionable results on a TB skin test refuses to have a chest x-ray?	If the patient's potential risk of having active TB cannot be determined, the patient may need to be referred to a hospital unit which has the capacity for respiratory isolation. The patient's treating physician should discuss the situation with the patient and educate the patient on the need to clarify the risk for the involved patient, other patients, and staff who could be exposed to TB.
143	US Pharmacopeia: Can we expect facilities to comply with US Pharmacopeia Chapter 797 which requires (among other things) that multidose vials be discarded 28 days after opening; and that injectable medications not prepared in a sterile environment be used within 1 hour of preparation?	CMS has not adopted the US Pharmacopeia Chapter 797 as regulation. Some States may have adopted some of these requirements. Facilities may choose to use this resource in developing policies.
147	Catheter care: If an ESRD facility is located inside a hospital and the hospital has a policy regarding	An ESRD facility is responsible for developing its own policies and procedures. If appropriate, the ESRD facility may adopt the hospital policies.

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	central catheters, must the ESRD facility follow the hospital policy? The hospital policy requires the catheter insertion site to be covered by an opaque “Bio-patch” that does not allow the site to be visualized. The policy requires this dressing to be removed weekly, and the site cleaned and redressed. Would this practice be acceptable?	The ESRD staff should routinely monitor the site of the catheter each treatment for swelling or redness; depending on the size of the dressing described, this monitoring may still be possible. If an ESRD facility adopts a hospital policy, then the ESRD facility should evaluate the outcomes of the policy when implemented in their chronic setting. If their catheter patients are doing well related to their infection rates and catheter exit sites with this protocol, the facility may want to continue the protocol. If there was an increase in infections, the ESRD facility may want to work with the hospital to adapt or change the policy to address the special needs for the dialysis population. This evaluation should be documented in the QAPI records.
147	Catheter care: What resource document refers to the catheter hubcaps or bloodline connectors being soaked for 3-5 minutes in povidone iodine and then allowed to dry prior to separation?	The NFK KDOQI Clinical Practice Guidelines for Vascular Access: Update 2000, Guideline 15, Table III-10. <i>Considerations for Accessing the Bloodstream Using Catheters</i> provides this recommendation. Recognize the manufacturers of some catheters warn against the use of povidone iodine.
147	Catheter care: Is it an acceptable practice for a dialysis facility to routinely use antibiotic lock solutions for all patients with catheters if the facility shows that this practice decreases infections.	No. CDC continues to recommend against this practice. While the use of antibiotic lock solutions may decrease the number of infections, data presented at the American Society of Nephrology in 2009 demonstrated that routine use leads to the development of resistant organisms. Efforts should focus on decreasing the use of central venous catheters as dialysis access.
N/A	Staff footwear: Can you give some direction for appropriate footwear in the treatment area: are sandals or “Crocs” okay?	Facility policy should address this practice. Generally, closed-toe shoes are required to protect the staff member’s feet from potential exposure to blood. Surveyors should wear closed toe shoes when surveying ESRD facilities.
N/A	Artificial nails: Can clinical staff wear artificial nails?	Facility policy should guide this practice. It is noted that research is emerging which indicates the use of artificial nails as a source of microorganisms that are easily transferred to patients. The CDC Hand Hygiene Guidelines state: “Do not wear artificial fingernails or extenders when having direct contact with patients at high risk...” Staff members who perform dialysis access care should not wear artificial nails.
N/A	TB testing: Do staff members need to be tested for TB? Why is this item included on the personnel file review tool?	There is no ESRD Federal requirement for TB testing. The personnel file review tool was constructed to support surveys in many States that do require TB testing for staff. CDC has recommendations for TB screening of healthcare workers based on risk classifications. All healthcare workers are recommended to undergo at least baseline screening.
N/A	TB: If new facilities are not designed for air borne isolation, where are patients with active TB expected to get treatment?	It is expected that patients with active TB would be dialyzed in hospitals where appropriate isolation is available until airborne isolation is no longer required.

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		Active TB would require respiratory isolation, and a room with positive pressure air handling, which is beyond the capacity of an outpatient dialysis facility.
N/A	Isolation: Does a facility need two isolation rooms if they have HBV+ patients and patients with Hepatitis C or TB?	<p>Only one isolation room is required. Isolation is only required for patients who are HBV+. The CDC does not recommend, and CMS does not require, isolation of patients with Hepatitis C+ virus infection.</p> <p>Active TB would require airborne infection isolation precautions. Outpatient dialysis facilities are not required to have the capacity to provide this level of isolation.</p>
	Condition: Water & Dialysate Quality	
181	Ultrapure dialysate: Does the use of an extra filter in the water distribution path or dialysate flow pathway on-line at the point of use constitute ultrapure dialysate?	<p>No. Ultrapure dialysate is defined as having a bacterial content of less than 0.1 CFU/mL and an endotoxin count of less than 0.03 EU/mL using sensitive assays. Placing an extra filter in the water or dialysate pathways may or may not result in the production of ultrapure dialysate.</p> <p>CMS only monitors for the requirements of conventional dialysate. Use of extra filters or other attempts to provide purer dialysate is seen as a “best practice” and is not required.</p>
“No tag” before 184	Compliance: 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 510(k) approval. However, all water treatment systems in use for Medicare certified dialysis programs are required to be in compliance with CMS regulations.
184	Restricted environment: Does an interior door connecting the treatment area to the water room have to remain locked throughout the treatment day?	The intent of this rule is to protect the water treatment and dialysate preparation systems from casual access and potential tampering. An interior door in an area constantly attended by staff, connecting the water room with the treatment area, does not have to be locked during the treatment day.
186	Alarms: For Reverse Osmosis (RO) equipment: Is it acceptable to have an alarm that is in a separate location and not visible, but is audible in the patient treatment area?	Yes. RD 62 (incorporated into RD 52 and the ESRD CfC at V186) requires that the RO include an audible alarm that 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.
186 200 203	Alarms: Where should water system alarms be located?	The quality alarms for critical water systems must be detectable in the treatment area. For RO systems, the alarm must be audible in the treatment area. For DI systems, the alarm must be both audible and visible in the treatment area. Generally, these requirements can only be met by locating a remote alarm in the treatment

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		area.
191 196	Color-blindness test: Are members of the staff who are responsible for performing water testing expected to be tested for color blindness, even if the facility has no policy for this?	If the facility uses tests for water safety that require determination of color differences, the persons assigned to do those tests (and make those determinations) must be able to discern color differences. The IG at V191 and at V196 addresses this issue 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.
192	Chlorine/chloramines test: 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 or banks of tanks with a sample port between them for the daily and each shift testing for chlorine/chloramine. A sample port after the second carbon tank of bank of tanks is also required for testing if the first test exceeds limits.
194	PPE: If the facility rebeds the carbon tanks on-site, what precautions must be taken?	If the carbon tanks are rebedded at the facility, the replacement carbon must meet the requirements specified at V194. The exhausted carbon must be disposed of in accordance with the local waste management requirements. The carbon manufacturer's guidance should be followed for PPE that might be required.
196	Chlorine/chloramines test: What is the maximum allowable level for total chlorine and chloramine?	The maximum allowable level for total chlorine (the free and bound chlorine combined) is ≤ 0.5 mg/L (ppm), and the maximum allowable level for chloramine is ≤ 0.1 mg/L (ppm). If a facility is doing only one test, and that is for total chlorine, then the ≤ 0.1 mg/L (ppm) limit must be used for the maximum allowable level, to ensure patient protection from chloramine exposure.
196	Chlorine/chloramines test: If a facility has a storage tank, where the stored water is used at the start of the day, is it required that the water system 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 processed at the time, even if the water in the storage tank is currently being used, ensures water safety as the newly processed water fills the storage tank.
196	Chlorine/chloramines test: Some States require facilities to test dialysis treatment water for both chloramine and total chlorine. Does CMS require this as well?	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 mg/L (ppm) and if the facility sets their allowable limit for chlorine equal to or less than 0.1 mg/L (ppm). If there are State requirements, the more stringent requirement would need to be met.
196	Chlorine/chloramine test: If a test for chlorine/chloramines is done at the start of the treatment day, is another test required to be done before the first shift of patients start treatment?	If the chlorine/chloramines test at start-up is done within 4 hours of the start of patient treatment, that first test of the day is sufficient for the first patient shift. Chlorine/chloramine testing would need to be repeated prior to initiating later shifts of patients or at least every 4 hours during the treatment day.
196	Chlorine/chloramines test: 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 equal to or less than 0.5 mg/L (ppm); the allowable level for chloramine is equal to or less than 0.1 mg/L (ppm). Free chlorine is different from total chlorine: total chlorine includes both free and combined chlorine.

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		<p>Tests for total chlorine include free chlorine. If the facility uses two tests, the tests would be for total chlorine and free chlorine; the test result for free chlorine is subtracted from the test result for total chlorine to determine the level of chloramine in the water.</p> <p>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 mg/L (ppm). If only one test is performed, the facility must set the target value for that single test at equal to or less than 0.1 mg/L (ppm).</p>
196	Chlorine/chloramines test: 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 FDA for testing of water for chlorine/chloramine and the test method used is sensitive to the levels required. The DPD methods using tablets/powders would meet this requirement.
196	Chlorine/chloramines test: Should a facility use the qualitative method when using test strips to test chlorine levels in the water to be used for treatment? V196 under "additional guidance" regarding test strips, states "In choosing whether to use "quantitative" or "qualitative" test methodology, it is important to recognize that the determination of low levels of chlorine (i.e., ≤ 0.1 mg/L [ppm]) requires the use of the quantitative method."	The facility should use the quantitative method. Directions for some test strips offer two testing methods. One, a qualitative method, only provides a + or – result; the other, a quantitative method, provides a numerical value for the result. The quantitative test must be used to determine low levels of chlorine (i.e., less than 0.1 mg/L [ppm]), and should be used for testing water for use in dialysis treatment.
196	Chlorine/chloramines test: If a facility is using test strips to test for chlorine and chloramines in treatment water, do the strips need to be validated? If so, how often should the validation be done: daily, weekly or just when first opening the container? If the facility is dating the bottle when opened and has an insert from the company that says the lot # of strips has been validated, would that be sufficient?	The facility is expected to have a method in place to validate the strips; this could be using the field validation provided by one of the manufacturer's for their strips, or by developing and implementing a policy to guide this safety assurance step. The frequency would be at least once for each lot number of testing strips, with the expectation that each bottle of strips would be used in accordance with the manufacturer's DFU (e.g., keeping the bottle closed when not in use; dating the bottle when opened [if required]; and discard within any stated timeline).
196	Chlorine/chloramine test: Who is responsible for the water system testing?	Facility policy must define which staff members are responsible for conducting the maintenance, monitoring, and testing of the water treatment system. The staff member(s) assigned these responsibilities must be trained and have demonstrated competence in the tasks assigned to them (see V260 and V696 for personnel requirements). Ultimately, the medical director is responsible for the safe operation of the water treatment and dialysate preparation systems.
197	Chlorine/chloramines test: If one of the two carbon tanks has been exhausted, can the facility operate with one carbon tank until the	V197 allows dialysis to continue with one exhausted carbon tank for up to 72 hours as long as test results after the remaining functional tank remain below the accepted limit of ≤ 0.1 mg/L (ppm) of chloramine.

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	exhausted carbon tank is replaced?	
197	Chlorine/chloramines test: If the primary carbon tank is exhausted, and the total chlorine reading after the secondary tank is at 0.1 mg/L (ppm), can patients still be dialyzed?	As long as the total chlorine is ≤ 0.1 mg/L (ppm), dialysis may continue. More frequent testing after the secondary carbon tank would be expected and the exact times the tests were done recorded.
198	Chemical injection system: What are the components of a chemical injection system?	Chemical injection systems include a reservoir to hold the chemical for injection, a pump to allow injection of the chemical, a meter to control the injection, and an alarm system.
200 203	Alarms: 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.
204	Deionization (DI): Can tap water go directly into the DI tank or is a softener required?	DI systems must be preceded by carbon tanks to prevent the formation of carcinogenic nitrosamines. There is no requirement for a softener to precede the DI tank; the DI can remove calcium and magnesium. Generally facilities use a softener to remove these minerals, as a softener is less expensive to maintain and can do some of the work that the DI (or a RO) would have to do if there was no softener in the pre-treatment cascade.
210	Recording: 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 if there is a provision for an aggregate report allowing multiple monthly reports to be easily compared for trends.
211	Continuous flow: Is it intended that a Reverse Osmosis system would run 24/7 to maintain flow in the distribution system?	The AAMI Renal Disease & Detoxification Committee has discussed this topic and confirmed that constant flow in the water distribution system was not the intent of this requirement. AAMI will be posting a "FAQ" document on their Web site to clarify this section of RD 52. CMS expects providers and surveyors to follow the AAMI interpretation.
212	Water distribution systems: Must facilities follow AAMI's Table 2 (Table on compatibility of disinfectants and piping materials) in making choices of materials to use in water and dialysate distribution systems?	CMS expects Table 2 to be used as a guide. If the facility has research data or information from the manufacturer to support the use of a different material from those listed in Table 2 in their distribution system(s), and that information takes into consideration the compatibility of the disinfectant that is in use, the surveyor would consider that information in determining compliance.
213 252 253	Testing: For initial surveys of water/dialysate systems, what is required for microbial monitoring for verification of the systems? V213 says that it is "recommended" that weekly testing be conducted for 1 month on new water distribution systems.	Recognize when "recommended" appears in the regulation column, the item is considered as required. 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 DFU. Dialysate/machine cultures should be taken weekly until a pattern of acceptable levels is

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		established (V253). It is acceptable for a new (or relocated) facility to open and admit patients prior to the completion of the month of testing, as long as some tests of the water and dialysate systems have been completed and the results are within the accepted limits, and the rest of the tests completed after the facility admits patients.
219	Disinfect: How often must a water system without a holding tank be disinfected? Where is this requirement?	V219 requires that all water distribution systems must be disinfected at least monthly, or more often if the manufacturer's DFU dictate.
219 403	Disinfect with chloramine: Can chloramine be used to disinfect the systems in the dialysis facility?	Chloramine is made by combining chlorine with ammonia. The ammonia extends the effectiveness "life" of the chlorine. City water treatment systems use chloramines to extend the "life" of the chlorine, allowing sufficient chlorine to remain 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. While it is theoretically possible, using chloramine for disinfection in the facility would result in a requirement to safely dispose of the ammonia released when the chloramine disassociates.
228	Labeling dialysate: Is it necessary to label each individual jug used to deliver concentrates (acid and bicarbonate) to the point of use? How extensive does the labeling need to be, especially for bicarb jugs?	<p>Each jug must be labeled sufficiently to positively identify its contents and any required date/time of discard. Both bicarbonate and acid jugs must be labeled. Labeling for bicarbonate jugs would need to include "Bicarb" and, if the facility does not discard all bicarb at the end of each day, the label would need to include the date and time the bicarbonate was mixed to allow discard within the manufacturer's guidelines.</p> <p>For acid jugs, the label should include sufficient information to allow determination of any differences in the acid concentrates available in the facility. At a minimum, the levels of potassium and calcium in the acid concentrate should be indicated on the label of the jug. The more acid "choices" available in the facility, the more extensive the labeling required. If the choices in a facility are more limited the labeling may be less extensive. If a facility uses many different acid concentrates, the labeling must be more detailed, clear and specific. Using only a product number is not sufficient. If more than one mixing ratio is available for use in a facility (hopefully a rare practice), the mixing ratio symbol (triangle, square, circle) must also be included in the labeling.</p>
229	Recording: When mixing bicarbonate in individual jugs, what are the requirements for testing and recording the mixing (e.g. lot numbers, date, time, etc.)?	The requirements for recording this information refer to mixing of batches. Mixing an individual jug does not require that this information be recorded in a log. The individual container must be clearly labeled with the contents.
229 236	Recording: Must a permanent record be kept of each batch of	Yes. A permanent record of all batches of concentrates mixed in the facility must be kept. The information to be

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	concentrate mixed in the facility?	recorded is detailed in the regulation at V229. A permanent record must also be maintained if concentrates are mixed by individual jugs or if additives are used to alter the concentration of the electrolytes in the acid concentrate. If the mixed concentrate is a single jug used for one patient, the required information could be recorded in the patient record.
233	Combining: 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 is not an acceptable nursing practice.
234	Mixing: Why is overmixing bicarbonate a problem? Where is the time limit for mixing specified?	Manufacturers of bicarbonate powder for use in making the bicarbonate concentrate for dialysis specify 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.
236	Labeling: If individual 1 gallon acid concentrate jugs, supplied by the manufacturer, are used, must these be labeled with the patient's name?	If the concentrate is prepared for use by multiple patients, the jug would not have to be labeled with a specific patient's name. If a jug of concentrate is specifically prepared for one patient, the labeling must include the name of the patient.
236	Labeling: If an additive is used to raise the potassium or calcium concentration of a single jug of acid concentrate, what labeling is required, if full information is recorded in the patient's record?	The individual jug would need to be labeled with the date and time of the mixing, the final concentration of the added electrolyte(s), the initials of the person who added the "spike" of calcium or potassium and, if the jug is intended for use only for a single patient, the name of that patient.
239	Storage: Must the bicarbonate concentrate in elevated tanks be emptied daily, even if it risks air locks in the distribution system?	The manufacturer's DFU for the elevated tanks must be followed. Recognize that bicarbonate is an excellent media for bacterial growth and that the manufacturer's guideline for storage time of mixed bicarbonate must be followed. Water used for rinsing the system of bicarbonate may prevent the formation of air locks.
248 249	Alarms: Why would the conductivity alarm go off if the dialysis machine is using the centrally delivered dialysate concentrates, rather than individual jugs of bicarbonate and acid?	Possible reasons would include: <ul style="list-style-type: none"> • Individual components of the dialysate were not mixed correctly when the centrally delivered concentrates were prepared; • The acid or bicarbonate is intended for a different mixing ratio than the setting of the machines in use; • It could be a kink in the line if happening at only one station; or • The facility may change the machine settings for the sodium level of the dialysate to be delivered and end up with conductivity alarms (and patient problems). <p>Note that conductivity alarms are always important to troubleshoot immediately and effectively.</p>
249	Conductivity/pH: If the bicarbonate level in the dialysate is changed from one patient to another, does this affect the	Changes in the bicarbonate level could affect the conductivity readings. Staff members are expected to verify the conductivity and pH of the machine prior to each treatment with a hand-held method, comparing the

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	conductivity reading on the machine? Should staff be expected to know the “safe range” for variability of the conductivity with different bicarbonate levels?	hand-held readings with machine readings in order to verify the machine is operating safely. Staff should know the allowable variability between the hand-held readings and the machine readings.
249	Mixing: What are some safeguards for the risky business of changing from one dialysate proportioning ratio to another?	<p>The best practice is to restrict use of all machines in a facility to one proportioning ratio. The medical director and the responsible staff person must be knowledgeable about the mixing ratio that the machines are set up to use. If a facility changes from one mixing ratio to another, all direct care staff must be educated to understand the concept of mixing ratio; all machines reset to the new ratio, and all supplies (acid, bicarbonate, and additives) rechecked to remove all supplies of the previous mixing ratio from the facility or segregate these with clear labeling for return to the supplier. If machines are labeled with the required mixing ratio, these labels must match the ratio in use.</p> <p>If different ratios are in use in the same facility, supplies for the different ratios must be segregated and labeled clearly to avoid a mismatch; all staff must understand there is more than one ratio available in the facility; staff must be carefully instructed on the risks of mismatch; and audits must be frequently done to assure these safeguards are effective.</p>
250	Conductivity/pH: 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 if switching to a different composition of acid concentrate in the same treatment.
250	Conductivity/pH: If the pH and conductivity of the dialysate is checked with an independent meter at each dialysis machine prior to each patient treatment, must the conductivity of each jug of bicarbonate be verified with an independent meter?	The facility should follow the bicarb manufacturer’s directions for use for testing bicarbonate concentrate after mixing. Generally any testing required is done of the entire “batch” rather than of an individual jug. Any testing of the bicarbonate concentrate would be separate and in addition to the dialysate testing required before each patient treatment.
250	Conductivity/pH: Is testing of each machine with a handheld meter required for each patient shift even if the same concentrates are being used?	Yes. Some machine manufacturers do not require conductivity testing for each treatment, but all require pH testing with an independent method.
252	Water cultures: Must new facilities have at least four weeks of negative water system cultures prior to treatment of their first patient?	No. As long as there is at least one set of negative cultures, it is permissible to admit and treat patients while continuing the weekly monitoring of the water and dialysate delivery systems until negative results for four consecutive weeks are achieved.

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252 253 314	Testing: How many water, reuse and dialysate cultures are required for a new facility?	No specific number of cultures is required; when culture results are within the AAMI standards, the new facility may open, with continued weekly cultures for at least a month. Validation of the water and dialysate systems should continue with weekly cultures until a pattern has been established (V252, 253). For reuse systems, 3 months of weekly testing with results below the action level is required (V314). As with the water and dialysate cultures, a reuse program can begin as soon as cultures are within limits, with continued weekly cultures for three months.
253	Testing: How many dialysate cultures must be done from dialysis machines each month?	Dialysate cultures must be collected from at least 2 dialysis machines per month, and each machine must be cultured annually, at a minimum. Recognize that some State ESRD licensing rules may be more stringent.
253	Testing: Should dialysate cultures be collected at the end of dialysis?	It is not necessary to collect effluent dialysate samples at the end of dialysis. Samples should be collected before, and as close as practicable to, the next machine disinfection
254	Testing: When should water and dialysate cultures be taken in relation to disinfection?	The purpose of culturing the water and dialysate systems is to ensure that the frequency of the disinfection schedule is sufficient to protect those systems from contamination. The samples should be obtained when the risk of contamination risk is highest (so called “worst case scenario”). Samples for culture and endotoxin levels of the water and dialysate should be taken before disinfection of the water system/dialysis machines, as close to the time of disinfection as possible, while recognizing that time must be allowed to ensure the sample to reach the laboratory during its hours of operation.
254	Testing: Is it acceptable to do water and dialysate bacterial cultures on the same day, but prior to disinfecting the water system (e.g., do the cultures in the a.m. and the disinfection in the p.m.)?	Yes. The requirement is that the cultures be done before disinfection, in the “worst case” scenario when contamination risk is highest, that is, as distant in time from the last disinfection as possible. Limitations on when the sample is collected include the logistics of getting samples to the lab so that the sample arrives when the lab is open.
255	Testing: When culture results above the action level of >50 cfu require the sample to be redrawn, what is the expected or reasonable number of days between the results being returned and the cultures being repeated?	Facility policy should define the expected response time to a positive culture result, and include a system to insure prompt review of culture results and a requirement to notify the medical director immediately of results above the action levels. Generally redrawing samples should occur 3 to 5 days from the date the results are known, depending on the day of the week the results are reported. V255 lists specific requirements for repeat cultures, and requires that the cultures be repeated weekly if growth exceeds the permissible standards.
256	Testing: The Millipore manufacturer’s directions for use (DFU) require incubation at 25-37 degrees C for 48-72 hours, but the	The regulatory requirements are within the manufacturer’s DFU. The expectation is that the facility would meet the AAMI requirement which is incorporated into CMS regulatory language.

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	AAMI language at V256 regarding these samplers requires incubation at 35 degrees C for 48 hours. Why the difference and which is expected?	
260	Contract staff: May a facility use a contract service (such as the water treatment vendor that installed the system) to monitor the facility for alarms, timers, etc?	A facility may contract with a vendor for the service of water treatment. It is unlikely that outside staff would be available during all treatment times to routinely monitor the function of the system, but the contract staff could ensure there were functional 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.
260 681 696	Training: Is annual training and competency verification required for biomedical technicians (i.e., personnel responsible for the water and dialysate systems or maintaining the equipment)?	For persons responsible for operating or monitoring the water and dialysate systems, V260 requires training that is specific to the tasks they perform, and periodic (at least annual) audits of the operators' compliance with procedures. V696 requires water system technicians to complete a training program approved by the medical director and governing body. V681 requires that all staff demonstrate competency in their duties. This requirement would apply to the staff responsible for maintaining the equipment.
274	Compliance: Does the language at V274 mean that AAMI updates can be automatically adopted as regulation, without having to go through the whole "process"?	No. AAMI updates must go through the rule-making process to be adopted as regulation.
274 253 254	Water test results: What action would be expected if water cultures exceed the AAMI action levels in a facility that is using individual filters to each dialysis machine in the water supply line?	The facility is expected to take action to investigate and resolve the issue whenever the water cultures exceed AAMI action levels. Although individual filters on each dialysis machine water supply line may offer additional protection of patients from water microbial content, their presence does not supersede the requirement for maintaining the water treatment system in a manner to produce acceptable water for dialysis. The medical director is required to take an active role in evaluating the entire water treatment system whenever culture results exceed the action levels. The facility should follow the manufacturer's directions for use (DFU) for the individual filters in the machine water supply lines, as well as their own policies, in evaluating the potential role of those filters in the culture results.
275	Adverse events: How long following dialysis can patients have reactions potentially related to the water or dialysate used for treatment? Are facilities expected to take water and dialysate cultures if the reactions occur 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 one or more patients report symptoms after leaving the dialysis facility, the

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		treatment record for that patient should be closely reviewed for any potential connection to the patient's symptoms. If multiple patients from the same treatment shift experience similar symptoms after leaving the facility, the medical director and facility staff should evaluate all systems for any possible relationship. This evaluation and review could include culture collection.
N/A	Testing: Can test strips sensitive to less than 0.5 mg/L (ppm) be used to test for residual bleach after rinsing bleach from equipment?	Yes.
	Condition: Reuse	
304	Centralized reprocessing: Does a Centralized Reprocessing Center need to be surveyed if the Center is owned by a company that is not related to the user dialysis facility?	Centralized reprocessing sites are not certified separately, as the sites merely perform a function for a certified ESRD facility, which remains responsible for compliance with the CfC for reprocessing. Since the ESRD facility's reprocessing is done by the centralized site, the survey of the ESRD facility using the site must include review of the reprocessing steps done at that centralized site and may include an actual site visit to the centralized reprocessing site.
N/A	Centralized reprocessing: When multiple dialysis facilities use a centralized reprocessing center, must the recertification surveys of each user facility include a review of the reprocessing procedures at the centralized center?	The survey agency(ies) that are responsible for the oversight of the user facilities should review the operation of the reprocessing center at selected intervals. Repeat visits to the reprocessing center should be guided by the compliance history and may not be indicated each time a user facility is surveyed. Communication between State survey agencies who oversee user facilities in different States which use the same centralized reprocessing center is vital and expected.
311	In lieu of physician: Can an advanced practice registered nurse (APRN) or physician assistant (PA) sign treatment orders which allow a patient to participate (or not) in the reuse program? Can the APRN or PA evaluate patient symptoms that could potentially be related to incorrect dialyzer reprocessing?	Yes. These are appropriate roles for the advanced practice registered nurse or physician assistant, functioning in lieu of a physician.
318	Air testing: Is air quality testing required when peracetic acid is used as the germicide?	Paracetic acid consists of acetic acid and hydrogen peroxide. While there is no identified permissible exposure limit (PEL) for peracetic acid, a facility using peracetic acid would be expected to test air levels of acetic acid and hydrogen peroxide.
318	Reuse room: Does the reuse room have to have a door?	No. The reprocessing room or area must be protected from access by unauthorized persons and designed to maintain acceptable air levels of germicide vapors. The AAMI guidelines allow reprocessing to be done within the patient treatment room.
320	PPE: Is it a deficient practice if the reuse tech wears the gown worn in	These regulations do not prohibit a reuse technician from using the same gown in the reuse room to go into

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	reuse to go to the treatment area and then return to the reuse room, as would happen if the reuse tech wears the same gown in the reuse room and to help remove used bloodlines and dialyzers from machines and gather those dialyzers for transport?	the treatment area to retrieve dialyzers for reprocessing or to assist with machine teardown. Expect facility policy to address this practice. Recognize that any time a cover gown is visibly contaminated it must be discarded and a new gown used.
326	Recording: 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 reuse records with the other records of that patient's care.
330 340	Disinfect: If a barrier is used between the reuse equipment and the dialyzer, does the port have to be disinfected after the barrier is removed and prior to capping the port? Where is the use of barriers addressed in the regulations?	The port should be disinfected before the barrier is applied. The barrier protects the reuse equipment from contamination by the dialyzer. While the regulations do not address the use of barrier adapters, the regulations do address the prevention of cross-contamination. V340 refers to disinfecting the ports, and capping the ports with clean caps. If the ports are disinfected prior to placing the barrier adaptors, that disinfection would meet this requirement.
331	Refrigeration: What is the expected temperature for refrigerators used to store used dialyzers until reprocessing begins?	In the 2002/2003 RD47 update, AAMI did not specify a temperature range for dialyzer refrigeration. If a facility does not immediately begin reprocessing, dialyzers are expected to be refrigerated, and the facility should develop policies to address refrigerator temperatures, monitoring, and maximum refrigeration time. After being used, the dialyzer to be reprocessed contains residual blood and provides a media for bacterial growth. This potential must be considered in determining the storage temperatures with a goal to control the risk of microbial growth, while preventing freezing.
331	Transportation/handling: Are bags required to transport used dialyzers to the reprocessing area?	No. The CfCs require used/dirty dialyzers to be transported to the reprocessing area in a clean, sanitary manner. This means with all 4 ports capped, without leakage, and in a manner which prevents cross-contamination of other dialyzers.
334	Header cleaning: If a dialyzer has removable end caps, is end cap removal and header space cleaning required?	No. End cap removal is not required. If the facility opts to remove dialyzer end caps and perform header space cleaning, this practice must be done within the AAMI guidelines as outlined at V334.
334	Header cleaning: Can a reuse tech use their gloved finger to remove the o-ring while cleaning the header of a dialyzer?	Yes. The o-ring may be impossible to remove with just a stream of water. The intent of V334 is to not damage the fiber bundle by use of anything other than a stream of water to clean the header. It is acceptable to use a gloved finger to remove the o-ring from its location in the end cap to allow cleaning and disinfection of the o-ring.
334	Header cleaning: When cleaning headers, must the end caps and o-rings be kept together and with the original dialyzer?	Yes.

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336	Total cell volume (TCV): When a dialyzer must be replaced mid-treatment, can a preprocessed dialyzer be used?	Yes. A preprocessed dialyzer would have had its original volume measured, and this dialyzer can be used mid-treatment. The preprocessed dialyzer must be labeled with the name of the patient for whom it will be used and rinsed free of residual germicide prior to use.
340	Port caps: Can dialysate port caps be used for different dialyzers or must the port caps be kept with the same dialyzer?	Port caps may be used (and reused) for any reprocessed dialyzer, after the cap is disinfected from its previous use.
341 350	Germicide presence: What testing must be done to ensure there is sufficient concentration of peracetic acid in reprocessed dialyzers?	Testing is required at two points: 1. 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 a least one dialyzer for each reprocessing system once a month (V341). If the germicide is not diluted automatically, this test must be done for each batch of germicide. 2. Every peracetic acid reprocessed dialyzer must be tested for the presence of sufficient germicide concentration prior to rinsing the germicide in preparation for dialysis (V350).
345	Storage: When a patient is away from the facility for an extended period of time (4-5 months), can the facility periodically reprocess the dialyzer to refill with fresh germicide?	This practice is acceptable if the facility policy allows for it and the facility follows the germicide and dialyzer manufacturer's DFU for maximum storage time of reprocessed dialyzers.
350	Germicide presence: Does the test for presence of germicide have to be documented prior to the patient's treatment being started?	V350 requires testing for the presence of germicide prior to the rinsing of the germicide. It is expected that the documentation would be done at the time of the test, prior to the treatment being initiated.
362- 368	Audits: Who is considered qualified to conduct the reuse audits, such as observing the reuse process?	The "designated staff members" who are to do the various required audits (V362-368) are not specified. The expectation is that these individuals would be knowledgeable of the processes being observed. The auditors could include the chief tech, the administrator, the nurse manager, or a member of the facility's regional or corporate staff.
N/A	Single-use dialyzers: Do single use dialyzers need to be labeled for the patient?	No. Single use dialyzers do not need to be labeled for use by a particular patient.
	Condition: Physical Environment	
401	Safe environment: May fans be used in the treatment area to control or maintain a comfortable temperature?	No. Fans present an increased risk for infection due to the spread of dust and the potential spread of microorganisms. The fan cord may also pose a safety hazard for trips and falls.
402	Mold removal: What are the requirements for mold removal?	While there are no specific requirements that address mold removal in the CfCs, it is required that the building in which dialysis services are provided be maintained in

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		<p>a safe condition.</p> <p>The CDC recommends immediately discovering the source of water/moisture intrusion and correcting it by decontaminating and repairing or replacing surfaces. See <i>Guidelines for Environmental Infection Control, 2003</i>: www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf</p> <p>The EPA Web site has helpful information about mold remediation: www.epa.gov/mold/mold_remediation.html</p>
403	<p>“Dummy drip chambers”: Why does the use of “dummy drip chambers” present an Immediate Jeopardy situation?</p>	<p>A “dummy drip chamber” is used to bypass the air detector on the dialysis machine. While the intent may be to speed the set up of dialysis machines, unintentional failure to remove the “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 DFU and presents the opportunity for a patient injury or death. There have been patient deaths associated with the use of dummy drip chambers. The presence and use of dummy drip chambers is acceptable in the machine maintenance area only.</p>
403	<p>Refrigerators: What are the expectations for refrigerators for medication storage?</p>	<p>Equipment maintenance includes the maintenance of medication refrigerators, which must be clean and have evidence that the temperature required for the medications being stored is maintained.</p>
403 681	<p>Personnel competence: Are any requirements specified for persons or companies that complete the electrical safety tests and PM (Preventive Maintenance) for dialysis equipment including machines, EKG, etc?</p>	<p>The CfCs require that all personnel are appropriately certified, as applicable; trained; and have demonstrated competence in performing their work. It is expected that individuals or companies responsible for electrical leakage testing and preventive maintenance on dialysis and other equipment would have evidence of training to do the type of work for which they have been assigned responsibility.</p>
403	<p>Equipment preventive maintenance: When a dialysis machine manufacturer’s DFU for preventative maintenance (PM) requires PM every 6 months, is this counted to the date or the month?</p>	<p>Completing the PM any time in the 6th month is acceptable. For example, if the PM was done on 1/15/09, the next PM would be due by the end of July at the latest.</p>
403	<p>Equipment preventive maintenance: May a technician be asked to open up a machine that has recently had preventative maintenance to allow inspection for leaks, cleanliness, etc?</p>	<p>Yes. This sort of inspection is usually reserved for occasions when a problem is suspected.</p>
403	<p>Equipment preventive maintenance: Is there a maximum number of dialysis machines for which one biomedical technician</p>	<p>While there is no limit on the number of machines a single biomedical technician can service, the required PMs for all machines are expected to be current and complete. Outcomes such as the required PMs not</p>

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	can be responsible for maintenance and repair?	being done, not being done in a timely manner, or prolonged turnaround time for repair of equipment resulting in delayed treatments due to a lack of functional machines would indicate that the facility biomedical department does not have sufficient resources to maintain the equipment as required.
403	Equipment preventive maintenance: Does the facility have to possess a printed copy of equipment manufacturer's information, or is a CD acceptable?	A CD as the source for manufacturer's guidance is acceptable, if the user is knowledgeable about the content of the guidance and can access the CD contents.
403	Equipment preventive maintenance: May the preventive maintenance logs for dialysis machine be electronic?	Yes.
403	Equipment preventive maintenance: If a piece of equipment has a "lock out" feature to prevent use if routine maintenance is not verified, must the facility maintain documentation of the maintenance?	Yes. The lock out feature serves as a safety mechanism to ensure maintenance is done, but would not serve as a record of that maintenance. Documentation must be maintained to demonstrate the manufacturer's guidance for maintenance was followed.
403	Back-flow preventer: Is a back flow preventer needed on the drain for the dialysis machines?	No back flow preventer is needed on the dialysis machine drain as the machines incorporate a one-way valve to prevent backflow of the spent dialysate back into the machine system.
404	Patient station: Is it necessary for the dialysis machine to be placed on the same side as the patient's vascular access site?	While it is generally more comfortable for the patient, placement of the machine on the same side as the vascular access site is not required in the ESRD regulations.
404 454	Patient station: Is there a square footage requirement for dialysis stations and a minimum distance between dialysis stations?	The ESRD CfCs do not specify a square footage requirement or a minimum distance between stations. V404 includes a requirement to provide "sufficient" space for providing needed care and services to patients, prevent cross-contamination, and accommodate emergency medical equipment and staff. It is also expected that the space would be sufficient to allow needed privacy. State or local regulations may include square footage requirements.
407	Visibility of patients: Do call lights in the isolation room need to be within the patient's reach?	All patients have to be visible to the treatment staff at all times. If a call light is provided in the isolation room, it needs to be functional and accessible to the patient.
407	Visibility of patients: Can an existing facility continue to use video monitoring for their isolation room?	No. The regulations specifically state that patients must be in view of staff during hemodialysis and that video surveillance will not meet this requirement.
407	Visibility of patients: Does the "no video surveillance" apply to nocturnal dialysis?	Yes. For in-center nocturnal dialysis it is expected that all the patients are able to be seen by staff throughout the treatment and that sufficient light to allow this monitoring is provided. Video surveillance is not be an alternative to direct monitoring of the patient.
407	Visibility of patients: Can mirrors be used to visualize patients during dialysis?	While mirrors may be used as an adjunct, they may not replace frequent direct observation of the patient.

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407	Visibility of patients: If patients refuse to keep their vascular accesses 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 site.
410	CPR: Are physicians, advanced practice registered nurses (APRN), and physician assistants (PA) required to maintain current CPR certification?	No. CMS does not regulate whether physicians maintain current CPR certification. If APRN and PA are functioning solely as medical staff in lieu of physicians, CMS does not monitor whether they maintain current CPR certification.
410	CPR: Why is the requirement to have current CPR certification under the Condition for Physical environment rather than under the Condition for Personnel qualifications?	CPR is considered part of the staff emergency preparedness, which is included under the CfC for Physical environment. Compliance is determined by reviewing personnel files, a task that also involves the review of the facility's compliance with the requirements at the CfC for Personnel qualifications.
411	Training: If a facility has a defibrillator rather than an AED, are staff members expected to have had an EKG recognition course?	The use of a defibrillator, rather than an AED, requires that staff with the ability to recognize arrhythmias and knowledge of protocols to properly use the defibrillator be present whenever patients are on treatment. The protocols must be approved by the medical director.
413	Emergency equipment: If a hospital-based unit is located in the hospital and has access to the hospital CPR team, would the dialysis unit need an AED?	The facility would need to determine the average response time of the CPR team. If that response time is less than about 4 minutes, the dialysis facility would not need to have a separate AED. If the average time is longer, then the dialysis unit would need to have an AED or defibrillator.
413	Emergency equipment: Are dialysis facilities expected to have "portable" oxygen onsite in the event of a need to evacuate the building?	Oxygen must be "on the premises and immediately available." A dialysis facility would need to have portable oxygen tanks onsite at all times or an oxygen concentrator capable of operating without electrical power to assure the availability of oxygen as needed during building evacuation.
413	Emergency medications: What emergency medications are required?	At a minimum, there must be medications available to treat allergic reactions to any drugs that are administered in the facility, and to treat common problems such as hypoglycemia. The medical director is expected to define in a policy or protocol which emergency medications would be indicated for these purposes and any additional medications to be kept on-site.
	Condition: Patients' Rights	
451	Informed of rights: Does allowing facilities 6 treatments to inform the patient of their rights meet the regulatory requirement to inform patients "when they begin their treatment?"	Yes. The regulation does not define the time period for "when they begin their treatment." CMS has the authority to define this in Interpretive Guidance.
451	Informed of rights: Is it required	There must be documentation that each patient was

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	that the facility document informing patients of their rights, or is verbally discussing these rights with patients, without any documentation, sufficient?	informed of his/her rights within their first 6 treatments at the facility.
451	Informed of rights: Can the facility notify a patient of his/her rights and responsibilities when discharge of that patient is being considered rather than providing this information upon admission?	No. The requirement is that patients are informed of their specified rights at the time of admission to the facility. The IG at V451 states that the facility is allowed 6 treatments (from the date of admission) to inform the patient of his/her rights.
451 470	Informed/posting of rights: Must all the patients' rights be listed in one document or can other documents address some of the patient rights?	Patients' rights information must be posted. The posted information may be combined into one document or may include several documents. For example, a "Dialyzer Reuse Information Form" could be used to inform patients of the facility's reuse practices.
452 470	Respect/dignity: Is the patients' rights information given to a patient expected to address the right to "sensitivity to his/ her psychological needs and his/her ability to cope with ESRD?"	Yes. This patient right is explicitly stated in the regulation and must be included in the patients' rights information given to patients and in the posted patient rights document(s).
452	Respect/dignity: Whose responsibility is it to change the undergarments of an incontinent patient while they are at the dialysis facility if the patient is a resident of a nursing home? Is this an infection control issue?	The dialysis unit staff should work with the nursing home to develop a plan of care for any patient with this issue to both address the incontinence and to lessen the prevalence of this problem. Allowing a patient to remain in wet or soiled undergarments does not demonstrate treating the patient with respect and dignity and is not acceptable. Failure to handle the incontinent waste correctly could result in an infection control issue.
452	Physical restraints: How should the use of physical restraints in the dialysis unit be monitored?	V452 addresses the use of restraints. Restraints should be rarely used. If used, there must be a specific physician's order for them, and the plan of care must address the use of restraints if they are used for more than a single occasion.
453	Understanding information: What evidence is required to demonstrate that a patient understands the educational and other information shared with him/her?	The patient medical record should include documentation of the evaluation of the patient's understanding of information provided. Examples of such evaluation methods may include "teach back," asking the patient to reflect back to the staff member what they understood, or may include the demonstration of a skill.
453	Understanding information: Is validation of patient understanding expected to be documented with each educational session even if there are no communication, literacy, or language barriers?	Yes.
454 456	Privacy: Does the patient's right to privacy prohibit conducting chair-side care planning with the patient if other patients can hear what is being said? Is it acceptable to do chair-side review of the patient's	The IDT should ask the patient if he/she wishes to have the plan of care conference in a private place or in the treatment area. Chair-side review of the patient's plan of care is acceptable and would not violate HIPAA if the patient

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	plan of care?	agrees and sufficient privacy can be provided. Other alternatives include the patient participating in the care conference in person or by telephone. Patients also have the right to decline to participate in their plan of care.
454	Privacy: May facilities post patient pictures in the waiting room with the patient's permission? Would this violate patient privacy?	If the patient gives permission for the use and display of their photograph, such use is not an invasion of the patient's privacy.
455	Privacy & involuntary discharge: Under HIPAA rules, is a facility permitted to contact another dialysis facility without the patient's permission when attempting to place the patient as required in the protocol for involuntary discharge?	Although it would be preferable to have the patient's permission, 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. Examples of "emergency care" include contacting other dialysis facilities as a part of the protocol for involuntary discharge and asking police to help locate a patient so that he/she can receive dialysis.
455	Privacy & records: What rights do patients have in regard to their 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).
456 556	Participate in care plan: Must the patient participate in care plan meetings?	No. Patients should be encouraged to participate. The patient or his/her designee is included as an integral part of the IDT and is expected to be included in discussions and decisions regarding her/his plan of care. If the patient chooses not to sign his/her plan of care, this choice must be documented along with the reason for not signing.
457	Advance directives: Must all patients sign an advance directive form?	No. The CfCs only specify that patients must be informed of the <i>right</i> to execute advance directives, and of the facility's policy regarding advance directives. Patients have the right to choose whether or not to have an advance directive.
457	Advance directives: What are the requirements for "Do Not Resuscitate (DNR)" policies for ESRD facilities?	The CfCs address advance directives, rather than "Do Not Resuscitate" policies, and do not require a patient to have an advance directive. The CfC does require each dialysis facility to educate its patients about their right to execute an advance directive, which could include the patient's wish to not be resuscitated. If this is the patient's choice, there is an expectation for a physician's order for "DNR." The dialysis facility is required to educate the patient regarding whether the facility will honor the patient's advance directive.
459	Informed of policies: How does a facility maintain patient confidentiality for any HBV+ patient if the facility is required to educate patients on the policies for isolation of patients.	The regulations require that all patients be informed of facility policies regarding patient care, including those related to the isolation of patients. These policies would not direct staff to provide patient specific information, but would specify whether or not the facility has an isolation room or area or where patients who are HBV+ would be transferred for care. The facility would not be disclosing the status of any specific patient, but simply explaining what provisions are available for isolation of patients who are HBV+.

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462	Informed of charges: May a facility only provide patients information about costs of services “if and when a service needed will cost the patient any money?”	No. Every patient must be provided information about charges that may not be covered by Medicare upon admission.
462	Informed of charges: 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 that are not covered by Medicare or for services that may not be considered “reasonable and necessary” in a particular situation (e.g., more than 3 HD treatments a week) the patient should be informed and asked to sign an Advance Beneficiary Notice (ABN). This form serves to document that the patient was informed of the charge and the patient’s agreement to accept the charge for that item or service.
470	Posting of rights: Can a large dialysis organization use the list of patient rights in the IG for all their facilities or does each facility need to tailor their list of patient rights to include any additional rights specified by their applicable Network?	Each facility must provide their patients with information on all applicable rights. If the Network or State licensing requirements include additional rights, the facility would need to post those as well as the patient rights listed in these regulations.
	Conditions: Patient Assessment & Plan of Care	
501	Interdisciplinary Team (IDT): 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 is not one of the physician’s treating the patient, he/she would not be an appropriate routine substitute on the IDT.
501 541 556	Interdisciplinary Team: May non-physician practitioners functioning in lieu of physicians conduct medical portions of the patient assessment and the patient plan of care?	An APRN or PA can act for the physician in all aspects of the ESRD patient assessment (V501) and plan of care. (V541). The only area where an APRN or PA may not act for the physician in the ESRD Conditions for Coverage is in fulfilling the responsibilities of the medical director (V710).
501	Interdisciplinary Team (IDT): Can the social worker and RD on the IDT be contract employees?	Yes. Any position in the facility may be filled by a contracted employee, except for the nurse manager.
501	Interdisciplinary Team (IDT): 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 (IDTs) work together toward common goals; pool their expertise; and use one another as a forum for problem solving.
501	Interdisciplinary Team (IDT): Must the assessments, e.g. nutritional, psychosocial, medical history, be in one document or can they be in separate forms?	The assessments may be either in one document or in separate documents. The key is that the assessments are congruent, and that the assessments together cover all required aspects of care and equal one assessment of the patient. The regulations do not specify the format for the assessments.
501 541	Documentation: Can the patient assessment and patient plan of	Yes. The CfCs do not specify a format for the patient assessment and patient plan of care. Facility policy

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	<p>care be merged into one document as long as all topics are covered and reviewed?</p>	<p>should direct how these are documented.</p> <p>The patient assessment is intended to inform the IDT about each patient's individual needs. All of the elements listed in the requirements for the patient assessment must be reviewed prior to the development of the POC. The patient plan of care must address all the issues identified. The patient assessment and patient plan of care should be congruent among and between the members of the IDT, indicating interdisciplinary collaboration.</p>
<p>501 541</p>	<p>Interdisciplinary Team (IDT): How often are social workers and dietitians required to see patients and document progress notes?</p>	<p>There is no specified frequency of patient contacts for the social worker or dietitian or for progress notes to be written. The frequency of contacts and notes would depend on the assessment of the patient's needs and the on-going implementation of the patient's plan of care. Each member of the IDT would be responsible for providing and documenting care needed for each patient according to that patient's plan of care. Note that some State ESRD licensing rules may be more stringent.</p>
<p>501 516</p>	<p>Interdisciplinary Team (IDT): What is the definition of "comprehensive initial interdisciplinary" assessments?</p>	<p>"Comprehensive initial interdisciplinary assessments" are described in detail at the Condition of Patient assessments. The IDT (including the patient/patient designee if the patient chooses) is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs, addressing at least the fourteen aspects of care listed under this CfC. This assessment is used to develop the patient's plan of care. Each patient must have a comprehensive initial assessment completed within the latter of 30 calendar days or 13 hemodialysis sessions, beginning with the first dialysis treatment.</p>
<p>502</p>	<p>Current health status: Can a history and physical (H&P) be transferred from a previous ESRD facility with the patient be used instead of the physician/APRN/PA conducting another one for that patient?</p>	<p>If the transferred H&P is complete and current, it may be used as part of the assessment for that patient. If the patient assessment and plan of care are received with the patient, the IDT at the new facility may use those documents for the first three months of care before conducting a reassessment and updating the plan of care. If the PA/POC is not received with the transferred patient, the new facility IDT would need to develop these within 30 days or 13 treatments of the patient's admission to their facility.</p>
<p>502</p>	<p>Current health status: Are facilities expected to have the capacity to monitor diabetic patients to include the capacity to test blood glucose in order to recognize and treat hypo- and hyperglycemia and prevent the need for emergency response teams to transfer such patients to hospital?</p>	<p>Provision must be in place to ensure safe care of diabetic patients who may experience hypoglycemic episodes during treatment. Patient assessments must include an evaluation of current health status and medical condition, including co-morbid conditions, such as diabetes. This would include the capacity to determine blood glucose levels. Although the emergency medications onsite should enable treatment of hypoglycemia, the capacity for routine treatment of hyperglycemia is not expected. If patients must be transferred to the hospital by ambulance because the</p>

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		facility does not have the capacity to determine blood glucose levels, it demonstrates a failure of the IDT to consider and plan for the patient's needs.
502	Current health status: Can facilities use a copy of a history and physical (H&P) from a hospital admission?	A hospital admission H&P can be used if the H&P was done in the same time period the patient assessment is being completed, and if the hospital H&P addresses all aspects of the patient's history, and co-morbid conditions, including the etiology of their kidney disease.
502	Current health status: Must the nephrologist do the H&P?	Any physician may do the H&P and an advanced practice RN or a PA may conduct medical portions of the H&P in accordance with State law and facility policy.
502 543 544 546 547 549 715 758	Current health status: Is there an expectation that the physician orders will be followed? If not, is this a deficient practice according to these regulations?	<p>Yes it is expected that physician orders will be followed, and failure to follow the physician's orders would be a deficient practice under these regulations as a failure to follow the plan of care. The deficient practice would be cited under the aspect of care where the order was not followed. For example, if the missed order was for blood pressure management, this would be cited at V543 (fluid management). If the missed order was for time of treatment, this would be cited at V544 (achieve adequate dialysis). If the missed order was for anemia management or bone management, this would be cited at V547 or V549 (anemia), or V546 (bone management).</p> <p>If the nurse failed to draw weekly PT/INR level or quarterly TSH level, or some other part of treatment that is not specifically mentioned in the CfC for PA or POC, this could be cited (as applicable) at V502 (assessment of co-morbidities); V715 (all staff adhere to all policies and procedures; include the facility policy requiring physician's orders to be followed in the findings); or V758, (sufficient staffing of RNs to meet the patient needs).</p>
502 542	Current health status: Does every co-morbid condition need to be assessed in Patient assessment and addressed in the POC?	Each patient's co-morbidities must be considered in the development of the POC. If a co-morbid condition is active, for example, diabetes, the IDT should take that condition into account when planning the care for that patient. While the IDT would not be expected to assume "total" care of all co-morbid conditions, the POC should be developed with consideration of the individual patient's needs. One way of addressing co-morbid conditions would be to refer the patient to their PCP or a specialist. The facility record for that patient should include the result of that referral.
503	Dialysis Prescription: Can an RN increase/decrease the patient's blood flow rate (BFR) without a physician order?	The BFR is part of the order for treatment; there could be a "sliding scale" guide or protocol for adjusting the BFR. If not, there would need to be an order for the change. If the staff are not able to achieve the ordered BFR, the record should address this issue, including the date and time that this problem was communicated to the physician.
503	Dialysis Prescription: Does changing the temperature of the	A slightly cooled dialysate may prevent hypotension during treatment. Cooled dialysate may result in patient

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	dialysate affect the blood pressure and comfort of the patient? Is there a limit to the allowable change?	discomfort. The temperature of the dialysate must be controlled within a narrow range (~35-40 degrees C): too warm can cause hemolysis; too cool can cause the patient to chill. Changing the temperature of the dialysate requires a physician's order.
503	Dialysis Prescription: If the dosage of heparin administered does not match the physician order but the manufacturer allows a difference of +/- 200 units would this be considered a deficient practice?	The physician ordered dose should be delivered without regard to any differences allowed "by the manufacturer." If the dose given is different from that ordered, there should be an explanation for the difference and evidence of discussion with the physician to adjust the dose if indicated. If such documentation is not present, the administration of a dosage different than that ordered could be cited as a deficient practice.
503	Dialysis Prescription: 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 or not dialysate is to be left in the peritoneal cavity between exchanges if a cyclor is used, and the concentration of glucose or other osmotic agent to be used for fluid removal. Use of an automated, manual or combination of these two systems for PD exchanges should also be included.
503	Dialysis Prescription: Could all patients in the facility be treated on the same model dialyzer?	Each patient must be assessed for their individual care needs, care planned and delivered to meet those individualized needs. While it is possible that one dialyzer model could be appropriate for all patients in a facility, using the same model of dialyzer for all of the facility patients may not represent individualized assessment and care.
503 543	Dialysis Prescription: What is the standard hemodialysis treatment time and why three treatments a week?	There is no standard treatment time, however, in the past, physicians tried to reduce treatment time to less than 3 hours, and found patient outcomes worsened. Many nephrology professionals believe more dialysis time is better, as it more closely approximates "normal" kidney function. When the Medicare ESRD program began in the 1970's, reimbursement was based on 3 treatments per week. Currently a 4 th treatment may be reimbursed if clinically appropriate and ordered by the physician.
503	Sample size for Blood Flow Rate (BFR): Doing the survey tour and observations, are surveyors expected to look at the BFR for all patients on treatment or just a sample?	Start with a sample; if problems are identified, extend the sample. Recognize the need to include a sample of patients on different shifts on each day of the survey. If an issue is identified, more of the current charts should be reviewed. If an issue is identified, records of patients being cared for by different staff members should be selected to determine if the issue is with one particular staff member or a widespread deficient practice.
505	Laboratory profile: What does "respond promptly" to laboratory results mean?	The IDT must evaluate laboratory results as they become available and take action, as indicated.
506	Medication history: What documentation is expected for medication review?	A list of the patient's current medications with evidence of review for possible adverse effects, interactions, duplications and indication for continued use.
506	TB testing of home patients: Are there alternatives for TB testing for	The regulations do not require the dialysis facility to perform the TB testing, but do require the dialysis facility

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	the home patient, other than having the patient make two trips to the dialysis facility, which could be a great distance from his/her home?	to assure the testing is done and to know the results. A home dialysis patient may obtain testing and test interpretation for TB at his/her local health department or physician's office, with documentation of the date of the test and the results provided to the dialysis facility.
506	TB testing: Is it acceptable for dialysis facilities to use a chest x-ray to diagnose all patients for TB prior to admission, if the radiologist indicates on the report whether TB is present?	Yes. However, chest x-rays are generally not chosen as the first method of diagnosis for TB.
506	Immunizations: Is pneumovax and TB screening required for all patients or only new patients?	CDC recommends that all dialysis patients be tested at least once for baseline TB. The expectation is that each patient (new and continuing) would be assessed to determine if they have received their immunizations and that indicated immunizations would be offered. Note that Medicare reimburses for influenza and pneumonia vaccines.
510	Masters social worker: Who is qualified to evaluate psychosocial needs?	A "qualified social worker" is the IDT member who is responsible for evaluating the psychosocial needs of the dialysis patients and must be qualified in accordance with the requirements at V691.
511 147	Dialysis access: When is the patient's catheter site to be assessed, before or after dialysis treatment?	Before dialysis, the patency of the catheter must be assessed. Inspection of the insertion site could require a dressing to be removed, and may be done pre, during or after treatment.
513	Transplantation referral: What is the expectation for dialysis facilities in educating patients about transplantation? Is it sufficient if the facility gives the patient the list of transplant centers with name/phone numbers/addresses and contact persons and encourages the patient to call or does a dialysis facility have to make appointments for patients?	Dialysis facilities are not required to schedule appointments for patients. They are required to educate patients about transplantation, including providing information about various transplant programs' selection/exclusion criteria. Dialysis facilities are expected to assist patients who chose to seek transplantation and to support patients in completing their work-ups and in achieving any requirements of the transplant program, such as meeting a weight loss goal.
513	Transplantation referral: Is the IDT responsible for determining if a patient is a transplant candidate or can the patient choose to self-refer to the transplant program and let that program determine candidacy?	Both may occur. The IDT is expected to know the selection/exclusion criteria used by the various transplant programs in the geographic area of the dialysis facility. The dialysis facility can use that information to assist each patient in determining whether he/she is a potential transplant candidate. Also, patients may self-refer to a transplant program for an evaluation.
513	Transplant referral: What criteria from a transplant center are to be used to screen patients as potential transplant candidates?	Transplant centers are required, under the transplant regulations to develop "selection criteria" and to share these criteria on request with potential candidates and dialysis facilities. Selection criteria list diagnoses or conditions that would exclude a patient from consideration for transplantation and should be used by dialysis facilities to screen patients as potential candidates for transplantation.
514	Family/support system: What	While the IDT may not discuss a patient's protected

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	rules apply to staff talking with family members or significant others about a patient?	health information (PHI) with family members or significant others without the patient's permission, it is not a violation of HIPAA for staff to ask family members or significant 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.
515	Vocational/physical activity: How do patients who receive dialysis continue to work while keeping their dialysis appointments?	Facilities are expected to work with patients to provide schedules that best coordinate with the patient's work schedule. Some facilities do offer shifts that start after 5 p.m. Nocturnal shifts provide dialysis at night, freeing the day-time hours for work.
516	Frequency: Do transfer and transient patients need an initial comprehensive interdisciplinary assessment in 30 days or 13 treatments?	These requirements depend on whether or not a PA/POC is received from the previous treating facility. If a current comprehensive patient assessment (PA) and plan of care (POC) is received by the new facility for a transferring or transient dialysis patient, the receiving facility's IDT may use the transferred PA/POC initially. The receiving facility's IDT would need to conduct a reassessment within three months of the patient's admission and implement their revised POC within 15 days of completion of that reassessment. If no PA/POC is received with the transferring or transient patient, the IDT of the receiving facility is required to complete their comprehensive interdisciplinary assessment within 30 days or 13 treatments (whichever is longer) of the patient's admission and immediately implement the plan of care.
516 558	Frequency: What is the requirement for doing a PA/POC for a transient patient from another country?	A transient patient from a foreign country would be treated the same as any patient who comes to the facility for transient treatments without a PA/POC. If the patient is treated at the facility for 30 days or 13 treatments (whichever is longer), a PA/POC would need to be completed. If the patient continues on census an extended time, the same timelines for reassessments and implementation of new POCs would apply.
516	Frequency: When an existing patient changes modalities, what is the assessment/plan of care requirement?	Whenever an existing patient permanently changes modalities, the patient is treated as a "new" patient and must have a comprehensive reassessment and plan of care completed within 30 days or 13 HD treatments of the change, whichever is longer. Peritoneal dialysis patients will use the 30 days timeframe. If a PA/POC was recently completed which included a plan to change modality, that POC may be updated as the plan for modality change is implemented, rather than a "new" PA/POC being required to be developed.
516	Modality change: What are the expectations for the patient assessment and plan of care when a new patient switches from in-center HD to PD training during the initial (30 day) period allowed for	The IDT's initial assessment would be expected to address the patient's status on in-center hemodialysis and the choice of the home modality. The initial patient POC would include the plan for beginning with in-center treatment, and for training and supporting the patient as he/she transitions to home therapy. The POC area related to treatment modality would need to be updated

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	completion of the PA/POC?	<p>when the patient completed home training and began home dialysis.</p> <p>A full reassessment is expected to be completed 3 months after the initial assessment.</p>
516 557	Frequency: Is an acute patient who dialyzes in an outpatient facility expected to have a patient assessment and plan of care?	Every dialysis patient is expected to receive the same level of care. If the “acute” patient is treated in the outpatient facility longer than 30 days or 13 treatments, the IDT must complete a PA/POC.
517	Frequency: Is the 90-day reassessment of new patients a review of the initial assessment or a completely new comprehensive assessment?	The IDT is expected to conduct a new comprehensive assessment of the patient within 90 days of completion of the initial assessment to reflect the patient’s adjustment or lack of adjustment to the treatment modality.
517	Frequency: Is the 3 months for the reassessment “counted” from the date of the initial assessment or from the date of admission?	The 3 month reassessment is expected to be completed within 3 months after completion of the patient’s initial assessment.
518	Adequate dialysis: What procedure is used to draw blood samples for calculating “adequate” dialysis or Kt/V for hemodialysis patients?	<p>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 the publication of these regulations, the stipulated method (from the K/DOQI guidelines for HD adequacy) for drawing blood samples to measure Kt/V included the following:</p> <ul style="list-style-type: none"> • Pre- and post-samples are drawn at the same treatment; • Pre-treatment sample is drawn just prior to the start of treatment; • Slow flow/stop pump technique is used for the post-treatment 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”, stopping the blood pump (“stop flow”) may be substituted; • After 15 seconds, staff should draw the post dialysis BUN sample from the arterial port closest to the patient. <p>All staff members should be using the same method, as described above. Home hemodialysis patients should be instructed to draw their samples in this same way.</p>
519	Assessment frequency: Should the “annual” reassessment be based on the patient’s anniversary date, regardless of unstable reassessments done in previous months or does the “annual” reassessment mean a reassessment completed 12 months from the last reassessment that was completed?	The annual comprehensive reassessment would be due 12 months after the most recent comprehensive reassessment, whether that reassessment was routine (for a stable patient) or due to an unstable condition.
519 520	Annual/monthly assessments: What is required for updating an	Complete updates of the patient assessment are required annually for stable patients and monthly for

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	assessment?	unstable patients. If a patient is stable, but is not achieving the target goal for one or more aspect of care, the IDT must recognize that target is not met, and take action to address that aspect of care. The action could include a review of that aspect of care and/or an adjustment or change in the plan of care.
520	“Unstable” patient: What are the criteria for an “unstable” patient?	The regulation defines the minimum criteria for “unstable” patients as: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis. Each of these criteria is described in detail in the Interpretive Guidance.
520	“Unstable” patients: Would a visit to the hospital emergency department qualify as a hospitalization for the purposes of classifying the patient as unstable?	A “hospitalization” is defined as being admitted to the hospital, rather an ER visit without admission. The IDT should be knowledgeable of a patient’s trips to the ER, and one or multiple trips to the ER could cause the patient to be classified as unstable, depending on the cause of the trip to the ER.
520	“Unstable” patient: If a patient is hospitalized 3 times within a 30-day period but the dates are in two separate months, would this patient be considered unstable?	Yes.
520	“Unstable” patient: Would a social worker's assessment that a patient had a “significant change” in psychosocial needs trigger a full reassessment by all members of the IDT?	Yes. A “significant change” in psychosocial needs is one of the criteria defined in the regulation as an unstable condition and unstable patients must have monthly comprehensive reassessments.
520	“Unstable” patient: If a patient has weight loss, low albumin, poor labs, poor appetite, or unplanned weight loss, must he/she also have evidence of inadequate dialysis and unmanaged anemia to be considered “unstable?”	The weight loss, low albumin, poor labs, poor appetite or unplanned weight loss would not, in themselves require the patient to be considered unstable. However, many of these problems might contribute to one or more of the criteria that define “unstable” in the CfC.
520	“Unstable” patients: What is meant by "concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis" for classifying a patient as unstable?	“Concurrent” means the patient is considered unstable if he or she has all three of these conditions simultaneously: poor nutritional status, unmanaged anemia, and inadequate dialysis. A patient who has one or two of these conditions at the same time would not automatically be considered “unstable.”
520	“Unstable” patient: Does an unstable patient require a complete reassessment and revision of the POC or is a reassessment of those areas where there are problems and updates of plan of care to	“Reassessment” is defined in the regulations as a comprehensive reassessment by the IDT. A patient that is classified as “unstable” requires a monthly reassessment. The requirement in the regulation is for a reassessment by the IDT if the patient is unstable. That reassessment

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	address these areas sufficient?	would include all of the care areas. If the IDT is doing this reassessment several months in a row, the team would be quickly able to determine those areas where there was no need for a revision in the POC (and document that there is no need to revise that portion of the POC) and focus their time and efforts on the areas which need revision.
540 625	Measures Assessment Tool (MAT): How is the Measures Assessment Tool (MAT) to be used?	The MAT is a reference guide for current professionally-accepted standards, values, and targets for the listed clinical elements. The MAT is to be used as a reference for the expected standards for: facility operations in water quality and reuse; individual patient assessments & plans of care; and the QAPI program. For example, for patient plans of care, each patient should be treated individually to assure specified targets are met. If not, either the plan of care should be adjusted to achieve the community-accepted standard or an explanation should be provided by the IDT member or group. Initially, goals for some patients may need to be different from the targets on the MAT and then incrementally changed to the MAT value as the patient's outcomes improve.
541	Plan of care frequency: Is a reassessment required each time a POC is completed?	Yes. Because each POC is built upon the information learned about the patient from the current assessment or reassessment, it is critical that the assessment or reassessment be completed prior to the development of the POC.
541	Plan of care frequency: When revising and implementing an updated POC for annual assessments, 3 month reassessments, and unstable assessments, must a new plan of care document be created or can the existing plan of care document be updated?	Each reassessment requires a review and update of the plan of care. While some of the POC may remain the same or similar, it is expected that each reassessment would be a time for a fresh approach, rather than simply updating portions of the plan of care.
541 627	Measures Assessment Tool: What is the Measures Assessment Tool (MAT) and where can it be found?	<p>The Measures Assessment Tool (MAT) is a grid listing the current community-developed standards of ESRD care for reference by surveyors and providers. Expected goals for the POC and QAPI are based on the standards listed on the MAT.</p> <p>The MAT is published on CMS' Web site for all ESRD survey and certification related tools and information at www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp. In addition, the MAT can be found on many kidney-community based Web sites.</p>

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541	Measures Assessment Tool (MAT): May a facility use different values for their targets for outcomes than those on the MAT?	The targets on the MAT are the minimum values for the outcomes and were drawn from recognized community-accepted standards. The facility may use higher (or more stringent) targets, but must not use targets for the facility outcomes that are lower than these minimums. For some areas, if the facility overall performance is lower than the goals on the MAT, it would be reasonable to have an intermediate goal (lower than the goal on the MAT) to allow for incremental improvement toward the MAT goal. An example would be the nutritional goal for albumin, where many facilities have had a lower interim goal than the MAT goal of 4.0.
542	Interdisciplinary Team (IDT): Are facilities required to have care plan meetings with all disciplines and patients at the same time rather than passing the plan of care from one discipline to another to have each person sign off on it?	The patient assessment and plan of care are required to be developed by the IDT, which includes the patient. While the PAs are generally accomplished independently by the individual IDT members, the POC must demonstrate input of all IDT members and a congruent plan. 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 develop the POC during chairside rounds; or have each discipline work with the patient and collaborate with their findings. Full team participation could also be accomplished through telecommunication. The POC must demonstrate the team's collaboration and congruence, which is unlikely if the plan of care is developed by each discipline working in isolation.
542	Interdisciplinary Team (IDT): Does the physician have to be present at the IDT meeting, or can he/she attend by conference call?	To facilitate full Interdisciplinary team participation, any member, including the physician or the patient, may participate by phone.
542	Interdisciplinary Team (IDT): Should the POC be one shared document or can each discipline have its own POC?	While the CfC do not dictate the form of the PA/POC, these documents must demonstrate that at least the 14 required aspects of care are assessed under PA and addressed in the POC. Allowing each discipline have "their own" POC would allow a fragmented POC, with disparate, rather than congruent, actions of the team members. Surveyors will be reviewing POCs to ensure the documentation reflects an integrated plan, with all members of the IDT working collaboratively toward the same goals.
543	Volume status: How is volume status measured?	The components of measuring fluid status include body weight, edema, and blood pressure. The orders for dialysis are expected to include a "target" weight, i.e. a weight at which the patient is considered to be "euvoletic;" 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. Each patient should be weighed before and after each treatment, and a target weight identified. Each patient should also be assessed pre and post treatment for the presence and extent of edema. Blood pressure monitoring is expected pre, during and post treatment and hypotension or

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		hypertension should be recognized and addressed during the treatment and in the POC.
543	Volume status: What is the standard for the time period to establish a dry weight for a new patient? Does the MD need to be contacted every treatment if the dry weight is not yet set? Can an RN determine the amount of fluid to be removed if the dry weight has not been set?	There is no set standard for the time period to establish a dry weight for a new patient, but these regulations expect the patient assessment to be complete and the plan of care implemented within 30 days or 13 treatments, which would include at least an estimated dry weight. The facility may have policies or protocols to allow the RN to “challenge” the dry weight, which would allow the RN to have the staff member caring for that patient to attempt to remove sufficient excess fluid to take the patient below their current estimated dry weight. The patient would need to be observed for any symptoms, such as hypotension or cramping which could indicate that the patient was free of excess fluid., and progress with determining the target weight should be communicated to the physician as well as to the IDT.
544	Adequate dialysis: What is expected if the patient misses or shortens treatment time or gains excessive fluid between treatments, resulting in an inability to achieve an “adequate” dialysis?	The IDT 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 educational efforts, the patient’s choice can be an explanation on a plan of care for not achieving standard treatment results.
544	Adequate dialysis: Why are the Kt/V values different for in-center HD, home therapies, and in PD patients?	These therapies have different treatment plans and lengths of treatment time. A Kt/V of 1.2 is the expected target for traditional, 3-4 hour treatments, three times a week. For PD, a more continuous therapy, the expected target is 1.7 for a weekly Kt/V. Home therapies are frequently done for longer treatment times (e.g., daily or nocturnal dialysis) and may have a different goal for Kt/V. More frequent, shorter treatments result in a lower Kt/V per treatment, but an equivalent clearance per week. Daily Kt/Vs are not additive; you must use a formula to calculate weekly Kt/V. Facility policies, QAPI goals, and the patient plan of care should address the expected Kt/V for each modality of dialysis provided by a facility.
544	Adequate dialysis: Please define eKt/V and spKt/V, and stdKt/V? Which one are we expecting to meet the MAT goal?	These are terms used to describe different methods of measuring the clearance of toxins during a single dialysis treatment: eKt/V = equilibrated Kt/V; spKt/V= single pool Kt/V; stdKt/V = standard Kt/V The Kt/V specified on the MAT (version 1.4) with a goal of 1.2 for traditional (3-4 hours, 3 X week) HD would be the single pool Kt/V or spKt/V.
545	Nutritional status: Does the nutrition plan of care require the documentation of the percentage of body fat every month? This parameter is listed on the MAT.	While a stable patient's percentage of body fat would not be expected to be assessed monthly and documented, if the patient was “unstable” and the reason for instability related to nutritional status, the patient's percentage of body fat should be measured as

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		part of the assessment along with other nutritional elements as listed in the regulation, Interpretive Guidance, and the MAT.
545	Nutritional status: The albumin standard on the MAT of ≥ 4.0 with the reference of the KDOQI Nutrition Guideline dated 2000 seems excessively high for many patients, who may be discouraged by such a high goal. Is it expected that every patient would be able to reach that goal?	<p>CMS recognizes that meeting the albumin goal may be a challenge for some patients, However several studies have shown significantly elevated risks of death and hospitalization when albumin is < 4.0 g/dL. The Nutrition Guideline lists other factors besides nutrition that could lead to hypoalbuminemia, including inflammation or acute or chronic stress.</p> <p>The expectation is that the facility will work toward this goal with every patient. A lower interim goal for albumin for some patients could also be considered, with that goal being incrementally raised as the patients' situations improve until the goal of > 4.0 can be attained.</p>
545	Nutritional status: Would a facility be faulted for not meeting the nutritional goal if the patient has a wasting disease (cachexia) or chronic inflammation contributing to poor nutritional status?	The plan of care should acknowledge factors that limit the achievement of nutritional status goals. The medical record of a patient whose outcomes do not meet the targets developed for the elements in the plan of care should demonstrate continuing efforts which are tailored, implemented, assessed, and revised to address individual challenges. In some cases, a target lower than the MAT would be appropriate for a specific patient with the issues listed in this question, with a plan for incremental adjustment of the target toward the MAT goal as the patient condition improves.
546	Mineral metabolism: Are the orders for dialysate expected to include the calcium level?	Yes. If a facility uses only one calcium level, this could be addressed in policy rather than in patient orders.
547	Anemia: When a patient has HIV, sickle cell anemia and is resistant to ESA, with a low Hct/Hgb, should the PA/POC address these issues? Should the POC include alternative treatments for anemia?	Yes. The IDT must address the patient's anemia and the factors that could limit achievement of anemia management goals in their assessment and POC. For a patient with the challenges listed in the question, the POC may need to address alternative treatments, such as blood transfusion.
547	Anemia: The hemoglobin (Hgb) target range listed on the MAT for anemia management per Medicare reimbursement policy is 10-12 g/dL, but many Networks have a goal that at least 85% of patients in a facility achieve a Hgb target of at least 11-12 g/dL. How do we reconcile these differences when facilities are required to meet Network goals?	Several targets for Hemoglobin (Hgb) are listed on the MAT with referenced sources including the CMS reimbursement policy and the FDA "black box" warning. Individual facilities may choose goals that are higher than the minimum goal of Hgb > 10 g/dL, but not > 12 g/dL due to the potential for adverse events for patients with Hgb > 13 g/dL. Cooperating with a Network goal of 85% of patients achieving a Hb target of 11-12 g/dL would be within the goals outlined on the MAT.
550	Vascular access: How can dialysis facilities be responsible for vascular access results?	<p>The Department of Health and Human Services' Fistula First Breakthrough Initiative Web site describes actions that dialysis centers can take to both increase fistula use in dialysis patients and decrease the inappropriate use of catheters. These actions include:</p> <ul style="list-style-type: none"> • Considering the outcomes of various surgeons used for vascular access and preferentially referring patients to surgeons with good outcomes

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		<p>in fistula placement;</p> <ul style="list-style-type: none"> • Implementing an access monitoring program to proactively address problems with access to prevent the need for the use of catheters; and • Removing catheters as soon as possible to prevent the high morbidity and mortality associated with their use.
550	Vascular access: What can the dialysis facility do if records are not available from the surgeon regarding the decision and placement for the current vascular access?	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.
551	Vascular access: Is vascular access "surveillance" as well as "monitoring" required for vascular access care under these CfCs?	<p>The ESRD facility must have an ongoing program for vascular access "monitoring" and must have a system in place for timely referral of patients who require vascular access "surveillance" strategies.</p> <p>"Monitoring" strategies include physical examination of the vascular access, including observations of changes in adequacy, assessment of pressures measured during dialysis, difficulties in cannulation, and issues in achieving homeostasis. "Surveillance" strategies include device-based methods of diagnosis, such as access flow measurements, direct or derived static venous pressure ratios, and duplex ultrasound.</p> <p>ESRD facilities are expected to provide "monitoring" strategies for vascular accesses on site. "Surveillance" strategies, as needed, may either be provided on site or may require a referral.</p>
552	KDQOL-36: The regulation states that the facility should use a standardized mental and physical assessment tool "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?	The regulations require the social worker to choose and use the results of a validated survey of physical and mental functioning in recommending care for patients. The Conditions for Coverage were in the final publication process when CMS chose the KDQOL-36 as the validated survey of physical and mental functioning in adults for the clinical performance measures project. To comply with the goals on the MAT (the tool that describes current community standards), the KDQOL-36 must be used with eligible patients. In the future, when CROWNWeb collects CPM data, it will require facilities to provide, at minimum, the percentage of eligible patients who have taken the KDQOL-36 annually.
552	KDQOL-36: Where can the psychosocial assessment survey tool "KDQOL-36" be found?	The Web address for the free KDQOL-36 survey is www.gim.med.ucla.edu/kdqol/ . You must register (at no cost) to access the download page.
552	KDQOL-36: 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.
552	KDQOL-36: When should the social worker administer the initial KDQOL-36?	The KDQOL-36 survey developers recommend not doing the survey for the first 3 months after a patient begins dialysis. Facilities should administer the KDQOL-

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		36 as part of the 3-month reassessment before the POC meeting. This would allow results to be discussed at that meeting.
553	Document home option: The CfCs require the facility to document why patients are not candidates for home dialysis. How extensive is this documentation expected to be?	The patient's record should document an assessment of the patient for the capacity to do home therapy and the education provided to the patient to allow an informed choice. If a facility does not provide the option of home dialysis, there should be evidence patients are given unbiased information about other facilities that offer this option.
554	Transplant status: Do facilities need to have a signed transplant agreement?	No. This is not required in the new regulations.
554	Transplant status: Define what is meant by the "area" transplant centers?	"Area transplant centers" refers to all transplant programs in the geographical area of the dialysis facility.
554	Transplant status: Is the transplant designee still to be identified in the POC related to transplant?	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.
556	Interdisciplinary team (IDT): When the IDT develops the POC, 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 POC. This may be accomplished in an IDT conference or use of 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.
556 456	Interdisciplinary team (IDT): What is an acceptable level of patient involvement with the IDT in planning his/her care? How should patient involvement in the IDT be measured and documented?	The patient chooses his/her level of involvement in the IDT work. At a minimum, there should be evidence that the patient is invited to attend patient care conferences and that the POC is shared with the patient. The patient's signature (or evidence of refusal to sign) must be included on the POC. Optimal involvement would be evidence that the patient routinely attends and participates in the care conferences. Patient involvement could be anywhere along this spectrum and could vary dependent on patient need and interest.
556 501	Interdisciplinary team: Are facilities expected to invite patients to POC meetings? If so, would having patients sign a letter regarding their intention to participate or not participate comply with the requirements of this regulation?	Facilities are expected to encourage patients to participate in the PA/POC. Letters may be used as one way of encouraging patient participation, but simply having a signed letter in the chart, with no other evidence the patient was involved in the PA/POC, would not demonstrate compliance with the intent of the regulation. Patients should be offered multiple ways to participate, including attending meetings in-person, by phone, or, with the patient's permission, by holding plan of care meetings at chair-side. If the care meeting is held at chair-side, then team members should speak in low

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		<p>tones to provide as much privacy as possible. Actions which have increased patient participation include:</p> <ul style="list-style-type: none"> • Scheduling meetings in advance • Scheduling all meetings for a doctor on the same day of the month • Posting a calendar of when meetings will be held • Alerting patients who want to participate by phone that the staff will call within a certain time frame
556	<p>Interdisciplinary team (IDT): If the patient does not wish to participate in the IDT, what documentation is expected in their medical record?</p>	<p>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. If the patient chooses not to sign their plan of care, this choice must be documented along with the reason for not signing.</p>
558 559	<p>Interdisciplinary team (IDT): Does the IDT have to meet monthly to discuss patient status?</p>	<p>While the IDT is expected to meet at least monthly for QAPI, they would only be expected to meet monthly to discuss the status of any unstable patients. The IDT is expected to work collaboratively to assess patients and to plan each patient's care.</p>
559	<p>Revise plan of care (POC): If a patient is stable but does not meet the goals of one or two aspects of care, can one member of the IDT make the update to the POC, or do all members of the IDT have to sign the update? Can the facility use other forms of evidence (like care plan meeting minutes) to confirm that the changes were directed by the IDT?</p>	<p>If the patient does not meet the goal for one or more aspect of care, a member of the IDT may make the change. For example, if a patient has a drop in hemoglobin, the anemia manager may use a protocol to adjust the anemia management. If the patient's hemoglobin does not respond or drops further the following month, then the IDT should be involved in adjusting the POC. The implementation of the POC is not about all the members of the IDT signing the plan of care; it is about the work of the IDT to help the patient meet the expected goals. This work could be documented in many formats: minutes of meetings, progress notes, changes in orders, or adjustments in the treatment records.</p>
559	<p>Revise plan of care (POC): Is there a requirement for the whole IDT to meet and discuss every revision to the patient plan of care?</p>	<p>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 (defined at V501) will discuss the information from the assessment and develop the plan of care as a team.</p> <p>Each patient should be continuously monitored by the team. 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.</p>
559	<p>Revise plan of care (POC): Should the POC be updated only when a reassessment is done or should sections be updated when a patient does not meet the goal for that aspect of care?</p>	<p>All of the care and outcomes of each patient must be continuously monitored and the POC updated/revised whenever a patient does not meet the goal for a particular aspect of care. If the patient is "stable," only those areas where the outcome goals are not met must be addressed with POC revisions between annual comprehensive reassessments.</p>

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559 520	Revise plan of care (POC): Are dialysis facilities required to do a POC for each patient every month?	<p>There is <i>no</i> requirement for a monthly POC on stable patients.</p> <p>Every patient is expected to be continuously monitored, For those aspects of care where the patient is not meeting the recognized goal/standard, the plan of care should be revised to address the area where goal/standard is not met.</p> <p>“Unstable” patients are expected to be reassessed monthly and their POCs revised within 15 days of completion of the reassessment.</p>
560	Monthly physician visits: V560 requires that every dialysis patient be seen by a physician/APRN/PA monthly. This rule also states that if the patient is on in-center HD, the patient is seen periodically in the center while receiving dialysis. For home dialysis patients located 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?	<p>The POC would need to address specific hardships that home patients located in remote areas might have in being able to see their physicians on a monthly basis. The expectation is that a member of the medical team of the dialysis facility provides routine care including monthly visits. However, in some limited instances, a remotely located home patient may be seen by a primary care physician.</p>
560	Monthly physician visits: How is CMS going to reconcile the CfC home patient visit requirement vs. the home patient MCP guidance?	<p>The monthly capitation payment (MCP) sets a specific monthly rate to reimburse physicians who manage ESRD home patients, without regard for actual face-to-face physician or practitioner visits. The CfC require equivalent care among facility-based and home patients. Equivalent care means that home patients are expected to be provided physician/APRN/PA contact monthly, as is expected for in-center patients. This contact could occur in the dialysis facility, at the physician’s office, or in the patient’s home.</p>
560	Monthly physician visits: What are the “acceptable reasons” for a home patient not to be seen by a physician every month?	<p>If a home patient chooses not to be seen by a physician every month, this is an “acceptable reason” because patient choice is a hallmark of these ESRD regulations. If there is a pattern where a home-based patient is consistently not seeing a physician monthly, the patient’s IDT would be expected to determine that the patient is not unstable according to the definition in these regulations and is meeting the MAT targets. The IDT would be expected to address the lack of medical oversight with the patient in the plan of care.</p>
560	Monthly physician visits: Clarify when a physician is required to direct or provide care for patients, vs. an APRN or PA.	<p>While the CMS regulations expect that a physician would participate as a member of the IDT and would provide protocols and orders to guide the treatment of patients, the regulations allow an APRN/PA to function in lieu of a physician in all aspects of the PA/POC, if State law permits this level of practice. Surveyors will look at patient outcomes. If the outcomes indicate patients are receiving safe and effective care, there is no requirement for a specific level/number of</p>

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		<p>visits/number of hours that the physician must be involved.</p> <p>Recognize that the Medicare reimbursement regulations for in-center dialysis patients base payment on the physician seeing the patient at least monthly; additional monies are paid for more frequent visits, with the maximum payment being for 4 visits a month. Three of those visits may be done by an APRN/PA.</p>
560 592	Monthly physician visits: Can patients be seen in the physician's office rather than in the facility?	Yes. The regulation requires that in-center patients be seen periodically while the patient is receiving treatment. The IG defines "periodically" as at least quarterly. Other visits for in-center patients and all visits for home patients could be conducted in the physician's office, with documentation of the outcomes of those visits being provided to the dialysis facility.
N/A	Nocturnal dialysis: Are there any additional requirements for nocturnal in-center hemodialysis?	The major differences with nocturnal dialysis are that the treatments are longer and the BFR and DFR 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 for nocturnal programs includes making observations during the nocturnal shift. The level of light in the facility during these treatments should be sufficient to allow clear visualization of patient's vascular access and line connections. Records of nocturnal patients would also be included in the sample reviewed. The POCs for these patients would need to recognize the particular dietary and fluid restrictions for nocturnal patients, which may be less than those for patients on a traditional dialysis plan.
	Condition: Care at Home	
582 589	Staffing: Can a home health (HH) nurse with or without dialysis experience be contracted by a dialysis facility to provide home visits to home patients?	The home training and support dialysis facility would have to provide orientation and training for the HH nurses (whether or not those nurses had dialysis experience), and provide a detailed guide of what to look for and what questions to go over with the patient. The dialysis facility would also have to reimburse the HH agency for this service, as it would not be a billable service for the HH agency. We would expect this to be rare, but an option to accomplish home visits for patients who live great distances from the home training and support facility.
584 685	Self care/home training nurse: 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 at V685 (i.e. 12 months as RN, plus 3 months in the specific home dialysis modality). These requirements are emphasized at V584.
587	Record review: How frequently should data be reviewed for home patients?	Time-sensitive data and information, such as radiology, pathology, and laboratory results, along with hospitalization reports, should be reviewed upon receipt by a physician or a practitioner functioning in lieu of a

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		<p>physician.</p> <p>“Self monitoring” data (dialysis treatment sheets) from home patients must be retrieved and reviewed by the facility at least every two months.</p>
588	<p>ESRD satellite: Does an ESRD satellite facility need to have both support personnel and training personnel?</p>	<p>"Satellite" has a specific meaning for ESRD certification purposes. "Satellite" refers to a hospital owned ESRD facility which is located outside of the hospital's main campus. An ESRD "satellite" facility must be separately certified for the specific services which it provides. If the hospital-owned "satellite" intends to provide home training and support for PD or home HD, the satellite would need to have qualified personnel for those roles. CMS requires facilities that provide home services to be able to provide both training and support. Therefore, the ESRD "satellite" facility would need to independently meet the requirements to be certified for home training <u>and support (e.g., it must have capacity to do both).</u></p>
589	<p>Home visits: For home hemodialysis, does an RN have to make the home visits or can an LVN/LPN do these?</p>	<p>The RN who is qualified as the home training nurse is primarily responsible for training, oversight, and support of the home patients. Other staff members can support the home program, and that would include occasionally making home visits.</p>
589	<p>Home visits: Must home visits be done annually or are they to be conducted as needed depending on the findings in the assessment and plan of care?</p>	<p>The Conditions for Coverage require an initial home visit when a patient starts home dialysis and when problems are identified as part of monitoring the patient's home adaptation. Home training staff are expected to conduct an onsite evaluation of the home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis. According to the Interpretive Guidance at V589: "...the number, timing, and frequency of home visits should be based on individual patient need as indicated in the patient's plan of care. Distance from the facility or concerns about staff safety should not preclude home visits. If a patient refuses a home visit, the interdisciplinary team must evaluate his/her refusal and the potential impact it may have on achieving the goals identified in the patient's plan of care as well as discuss alternative ways to assure the patient's health and safety at home."</p> <p>State regulations or facility policy may require home visits at specific frequencies. If so, the expectation is that the facility would comply with the most stringent regulation or policy.</p>
591	<p>Annual IDT assessment: 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 documentation is sent to the dialysis facility?</p>	<p>While this practice is anticipated to be a rare occurrence, if the required members of the IDT meet in person at the physician's office and the IDT fulfills the requirements for the comprehensive interdisciplinary reassessment and plan of care for the patient, this plan would be acceptable. Documentation of the IDT meeting should be sent to the dialysis facility to be included in the patient's medical record.</p>
592	<p>Home patient consultation with</p>	<p>The CfCs require all patients, both in-center and home</p>

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560	physician: With regard to the physician and <i>face to face</i> evaluation of home patients, if the physician evaluates patient labs, meds and other areas (e.g., adequacy, anemia, mineral and bone disease) and writes a note in the patient chart on monthly basis, and if the patient is stable, does the physician need to see the patient every month, every 60 days or every 90 days? If the patient is unstable, does the physician need to evaluate the patient <i>face to face</i> monthly until the patient becomes stable?	patients, to be seen by their physician, APRN or PA at least monthly, whether the patient is stable or unstable. This requirement can be met when the patient sees the medical practitioner in the physician's office and that record of care is incorporated into the dialysis facility medical record.
592	Home patient consultation with dietitian and social worker: After the initial assessment of stable patients, can the dietitian and social worker provide periodic evaluations by mail or phone monthly and <i>face to face</i> evaluations at least quarterly? What about unstable patients?	The frequency of contact for the social worker and dietitian will depend on the individual patient need, as assessed by the interdisciplinary team and included in the plan of care. For some patients, contact with these support staff may need to be very frequent, while for other patients, the contact could be infrequent. These "contacts" would need to be interactive—that is, more than just sending an email or letter, or leaving a message: there should be some evidence the patient received and understood the information or guidance provided.
595	Water/dialysate at home: Does the requirement to collect and culture endotoxin samples for each home patient on a quarterly basis apply to conventional home hemodialysis patients in remote areas?	Yes. The requirement for quarterly sampling applies to every home hemodialysis patient.
N/A	Traveling home patient: Can a single patient be shared between two facilities that are certified for home training and support if different information is included in each facility's records and on-going care is provided by both facilities?	It is expected that each patient would be included in the census of only one facility at a time. The current record of each patient should be complete in the facility that is responsible for that patient. Two facilities may not concurrently "care" for and submit charges at the same time for the same patient. This should not prevent a dialysis patient from traveling and two facilities billing for services on different days of the same month.
N/A	Staffing: Can a PCT who independently contracts with a home dialysis patient access the patient's central venous catheter (CVC) at the patient's home if the State regulations do not allow PCTs to access CVCs in dialysis centers?	If the PCT is not employed by or performing staff-assisted home dialysis for the ESRD facility, and if he/she is functioning as the patient's private home hemodialysis caregiver then as the private caregiver he/she may access the patient's CVC.
N/A	Respite for home patients: If a dialysis facility offers respite care for home hemodialysis patients, must the patient bring his/her equipment, e.g. NxStage machine,	Although CMS reimbursement rules require that each home hemodialysis patient have his/her own dialysis machine in the home setting, when a home dialysis patient requires in-center dialysis treatment, he/she can be dialyzed on a hemodialysis machine that is used by

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	to the facility or can the home patient use a machine that is shared with other patients in the facility?	other patients.
N/A	Staff assisted home dialysis: Is it acceptable for a dialysis facility that has a staff assisted home hemodialysis program to have two patients (husband and wife) on the program each with his/her own machine receiving dialysis at the same time with the same nurse for both?	The CfC do not address “staff assisted” home hemodialysis. Some State ESRD licensing regulations may apply. As part of being fully informed (Condition for Patients’ rights), both patients would need to be informed of and acknowledge the risks associated with having only one caregiver for two patients in case both experienced an emergency at the same time.
N/A	Surveyor home visits: 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 refuses to allow the surveyors in their home.	No. A surveyor is not expected to routinely make home visits to observe staff in home staff-assisted programs. In the rare case that a home visit is indicated, surveyors would be expected to obtain the patient’s permission prior to conducting the visit, and the patient has the right to refuse the visit. Surveyors are expected to visit nursing homes if staff-assisted dialysis in long-term care (LTC) facilities is offered. On arrival at the LTC, surveyors make contact with the administrator or director of nursing at the LTC facility to explain the purpose of their visit, but surveyors do not need permission to visit the LTC facility. Each patient or patient representative should be asked for permission for the interview, and they may refuse.
	Long-term care (LTC) facilities	
N/A	Long-term care (LTC) facilities: Are long term care facilities that provide dialysis to patients in the LTC facility, whose care might be paid for by Medicaid, required to have a contract with an ESRD facility for these patients?	Generally dialysis in the LTC facility is provided as a staff-assisted home hemodialysis service by a facility certified to provide this service. The ESRD facility is expected to have a contract with the LTC facility to clearly delineate the responsibilities of each entity for the care of these patients. The LTC facility may also be independently certified as an ESRD facility, with a separate CCN.
N/A	Long-term care (LTC) facilities: May a dialysis patient who dialyzes in a nursing home use his/her own chair during dialysis?	The chair used for dialysis should be able to be cleaned of any spills of blood or fluids and should be able to be placed in a reclined position (with the head lower than the chest) if needed for the care of the patient. If the patient’s own chair meets these requirements, that chair could be used.
N/A	Long-term care (LTC) facilities: Can dialysis facilities that are certified to provide home care to patients residing in long-term care (LTC) facilities continue to provide that service under these new regulations? Are there guidelines for dialysis in long term care facilities?	Yes: facilities that are certified to provide home dialysis services in LTC settings may continue to provide those services. Until new CfCs are published related to dialysis provided in LTC settings, CMS guidance for this service will be issued through Survey and Certification Letters.

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	Condition: QAPI	
626-638	Measures Assessment Tool (MAT): How is the Measures Assessment Tool (MAT) used for QAPI?	<p>The MAT is a reference for community-accepted standards and values for the listed elements of QAPI. Within their individual QAPI program, facilities are expected to use the MAT to evaluate the facility's aggregate performance as compared to community-accepted standards/values associated with clinical outcomes.</p> <p>In addition, facilities are expected to use data from CROWNWeb, Dialysis Facility Reports, and Network reports to determine comparison or "average" values associated with clinical outcomes.</p> <p>If a facility has areas of performance 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.</p> <p>The important aspects of the QAPI program are:</p> <ul style="list-style-type: none"> • Appropriately monitoring data/information; • Prioritizing areas for improvement; • Determining potential root causes; and • Developing, implementing, evaluating and revising plans that result in improvements in care.
626	Interdisciplinary team (IDT) documentation: 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 documentation of the QAPI activities demonstrating focus on, at a minimum, monitoring the indicators specified in V629-637 by the interdisciplinary team (IDT), and conducting improvement activities.
626 501 556	Interdisciplinary team (IDT) documentation: What documentation of the IDT work is expected?	For individual patients, the IDT work should be demonstrated in the patient assessments, the plans of care, progress notes, physician orders, treatment records, and for home patients, clinic visit reports. For the facility-level review, the IDT must participate in QAPI. Documentation should reflect team involvement in the continuous evaluation, planning and implementation of QAPI activities.
626	Interdisciplinary team (IDT): Since there is no time frame mentioned in the regulations, how often should 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. Since most data is available monthly, monthly QAPI meetings are standard. If immediate action is required, there must be a system to ensure a more rapid response occurs.
626 756 763	Interdisciplinary team (IDT): Can the IDT for the QAPI team be composed entirely of "corporate people" as opposed to facility staff? Can all the QAPI work for a facility be done at the corporate level?	No. The facility's IDT must be responsible for the facility's QAPI. Corporate staff (e.g., Regional VP, Area Bio Med), may participate in the program, but cannot replace the individual facility's staff. Multiple facilities can conduct QAPI IDT meetings jointly, but separate records of each facility's trends, analysis, plans,

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		timetables, and accountability must be maintained and available in the individual facility for review.
628	Tracking: Where would the IDT address the requirements for tracking blood loss, machine malfunction, clotting, prolonged bleeding and allergic reactions? Some of these events seem like infection control issues, and some seem like medical errors.	It is important to identify medical errors and infection control issues. 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. Problems such as those mentioned should have a QAPI plan and appropriate follow up. It is not sufficient to maintain a log with no evidence of QAPI action.
629 503 507 544 547 632 635	Tracking decreased heparin: If patient doses of heparin are decreased because of increased costs, and an increase in the incidence of clotted dialyzers results, would this be a deficient practice?	The incidence of clotted dialyzers should be monitored under the facility QAPI program related to treatment adequacy and anemia management. If the facility reuses hemodialyzers, clotted dialyzers would also need to be tracked as part of the reuse audits. If an increase in the incidence of clotted dialyzers is not recognized or not addressed with a root cause analysis (which might result in the identification of the decreased doses of heparin), this would be a deficient practice under QAPI. If a single patient has repeated clotted dialyzers, the IDT would be expected to identify this as a need to adjust the plan of care, possibly increasing the dose of heparin. If these actions were not taken, this would be a deficient practice under the plan of care aspect most affected: anemia management or dialysis adequacy.
634	Medical injuries/errors: What should be trended and tracked for medical injuries and errors?	Facilities are expected to track patient/staff injuries, treatment errors (e.g., wrong dialysate, wrong dialyzer, shortened time, failure to remove targeted fluid), equipment errors, medication errors, hospitalizations, deaths, cardiac arrests in the facility, acute allergic-type reactions, and major blood loss, at a minimum. Additional information about medical injuries and errors in dialysis can be found at the Web site for Patient Safety sponsored by the Renal Physicians Association and Forum of ESRD Networks: www.kidneypatientsafety.org
636	Patient satisfaction surveys: Can you clarify if the CAHPS patient satisfaction survey is required or if facilities can continue to use patient satisfaction surveys they have in place?	For survey and certification purposes, each facility must administer a patient satisfaction survey. The CAHPS survey is one alternative, but it is not currently required.
636	CAHPS: Where can one obtain a copy of the CAHPS survey?	The survey or a CAHPS kit is available for download at www.cahps.ahrq.gov/cahpskit/ICH/ICHchooseQX.asp . This survey is only validated for adult in-center hemodialysis patients. CMS is not currently requiring facilities to use the CAHPS survey for in-center patients. Facilities are expected to survey patient satisfaction (using a self-selected instrument) and address areas where satisfaction is low.
636	Patient satisfaction surveys: How often is a patient satisfaction survey expected to be completed?	The frequency of these surveys is not specified in the regulations, Interpretive Guidance, or Phase III Clinical Performance Measures documents. Each provider should establish a policy for administration of patient

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		satisfaction surveys to include the frequency of the survey. A reasonable expectation would be that these surveys would be conducted annually and when indicated by changes or problems within the facility.
637	“Cluster” of adverse events: 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 dependant on the nature and severity of the adverse event.
N/A	Reports of medical injuries/errors: If the facility incident reports are sent to the corporate risk management department rather than being kept on-site, is it acceptable to provide the surveyor only the aggregate data kept by the facility? Are surveyors 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) upon the surveyor's request.
N/A	Reports of adverse events: Is CMS considering required reporting of adverse events?	CMS is not considering adding such a requirement at this time. Some State ESRD licensing programs require reporting of adverse events, and the FDA requires reporting of potential problems related to medical devices.
	Condition: Special Purpose Renal Dialysis Facilities	
661	Vacation camp: If a camp is offering hemodialysis, but the camp is not billing Medicare for reimbursement, does the camp need to be certified as a SPDF?	Camps that do not bill Medicare for reimbursement do not have to be certified by Medicare.
662	Certification: If a summer camp is only certified for 8 months, does the camp have to be surveyed and certified every year, versus being surveyed every 3-4 years?	Usually vacation camp SPDFs operate a short period of time each year and are certified each year. States that have vacation camps may work with the camp to determine the extent of the survey needed, and whether an on-site survey is required each year.
	Condition: Personnel	
681	Records: Must personnel files be maintained at the facility or may these files be maintained at the corporate offices?	The location of the stored files is not specified. The files of personnel who work at the facility must be available for review; this could be met by having copies of requested files faxed from a corporate office or an agency to the facility for review.
681	APRNs & PAs: If there are no State regulations pertaining to the practice of APRNs and PAs, can they see patients and write orders?	The Medical Practice Board sets requirements for Physician assistants and the Board of Nursing governs the practice of advanced practice RNs. The policies of the facility must address the practice of these categories of personnel, and should be congruent with the allowable practices defined by these Boards.
682 683	Medical director waivers: Can a long time medical director who completed a board approved	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

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	training program in nephrology, but is not Board certified, continue as the medical director?	certified in internal medicine, pediatrics, or nephrology. If a person, as specified above, is not available, the Secretary of the Department of Health and Human Services (DHHS) may “approve” another physician to direct the facility. This process is considered a “waiver” of this requirement and is outlined in S&C letter 09-13. The waivers are time-limited approvals and potentially renewable after reapplication.
684	Nurse manager: Does the nurse manager need to be available 24/7 for on-call coverage?	The nurse manager is required to be a full time employee but may share on-call coverage with other qualified staff.
684	Nurse manager: Must the facility have a nurse manager?	Yes. The facility must employ a full-time nurse manager who is available at all hours the facility is open.
684 685 686	Nursing experience: 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. The nurse manager is required to have 18 months experience in nursing, to include at least 6 months in maintenance dialysis. The self-care training nurse is required to have at least 15 months experience in nursing, to include at least 3 months experience in the applicable home modality. The charge nurse is required to have 12 months experience in nursing, to include at least 3 months experience in maintenance dialysis.
684	Nursing experience: 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.
684	Nurse manager: Is there a definition of the job duties of the Nurse Manager? Can he/she hire and terminate employees?	V684 addresses the qualifications of the nurse manager, not the job duties. The facility policies and job descriptions should define the job duties.
684	Nurse manager: 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?	While it is unlikely the case, if all the nurses placed in that position are qualified as nurse managers, there is no regulation to prohibit this. The surveyor would look at outcomes, such as turnover of staff; whether new staff members are oriented prior to being assigned responsibilities for care of patients or support roles; and QAPI related to patient outcomes, medical errors/injuries, and patient satisfaction. If problems are identified, those findings could be attributed to not having a consistent nurse manager and/or to the failure of the facility's governing body to provide adequate resources and to assure there is sufficient staff available to meet the needs of the patients.

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684	Nurse manager: Does the nurse manager need to be on-site every day the facility is open, including Saturdays?	No.
684	Nurse manager: 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 a week, and the days were not overlapping.
684 686	Nurse manager: Can one RN be both the nurse manager and the charge nurse?	Yes. If an individual meets the minimum qualifications for both roles and can perform the functions of both, then that individual can serve in both roles.
684	Nurse manager: 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 documented, and the oversight (administrative and clinical) expected from the nurse manager must be evident at each facility.
685	Self-care/home training nurse: Would a nurse who worked in a hemodialysis program but only took call for a home hemo program qualify as "experienced" to supervise a home hemo program? Or would the nurse have to actually provide direct care for home hemo patients for at least 3 months to qualify as experienced?	V685 defines the requirements for the home training nurse as 12 months nursing experience and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training. There is no requirement for experience in "home" hemodialysis; the requirement is for experience in hemodialysis. If the nurse has 3 months experience in hemodialysis, that nurse would qualify to provide home hemo training and support.
685	Self-care/home training nurse: For the home training nurse, does the time in training count as part of that nurse's experience?	The requirement is to have 12 months experience as an RN, plus three months experience in the modality. The training period would count as part of that nurse's experience.
685	Self-care/home training nurse: If a home training unit has a qualified RN responsible for training, can an LPN/LVN do the actual patient training?	An RN must be primarily responsible for the home training programs. While other staff may be involved in home training programs, the qualified RN must be primarily responsible for the actual training and follow-up of home patients. An LPN/LVN could reinforce portions of the training and occasionally "cover" for the RN in facility, but cannot be responsible for the majority of the actual training of patients.
685	Self-care/home training nurse: Can an LPN/LVN be "on call" for home patients?	CMS does not address who may be "on call" for home patients. Whether an LPN/LVN could be "on call" is dependent on State nurse practice acts and the policy of the facility. If the 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 a RN, but could handle calls not requiring assessment such as calls for assistance with equipment or supplies.
686	Charge nurse: Can the three month orientation period for a nurse with no prior dialysis experience be used as the "three months providing	While three months of experience after the orientation period is completed is preferable, the use of the orientation period for this purpose is not prohibited. The nurse would be expected to have a minimum of 12

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	nursing care to patients on maintenance dialysis" to qualify as the charge nurse?	months experience as a nurse, to include the three months of dialysis experience.
686	Charge nurse: Can there be a different charge nurse on MWF and TTS?	Yes. Each charge nurse must meet the qualifications in the regulations; most facilities have more than one charge nurse, and some facilities choose to have each charge nurses assigned to a particular shift of patients. This could result in different charge nurses on MWF and TTS.
689 690	RD: Would a dietitian who moved to the U.S.A. from another country where she was the equivalent of a registered dietitian and has now taken the RD exam in the U.S.A., but has not worked in the U.S.A. for a year after receiving RD status in the U.S.A. meet the requirements to be a "qualified dietitian?"	Foreign educated dietitians may be able to have their education verified as equivalent by a US regionally accredited institution after which they can apply to take the CDR exam. Any dietitian certified this way would still require 1 year of experience after achieving registration to meet the "qualified dietitian" requirement. See www.eatright.org/CADE/content.aspx?id=10152
689 545 546	Dietitian: Can a dietitian use protocols or algorithms to direct dosage changes of medications? Can the registered dietitian write orders to adjust medications for anemia and CKD mineral bone disorder management?	The individual practice acts for dietitians, nurses and physicians would determine whether this practice was allowable in a particular State. The Federal ESRD regulations do not address the individual practice of professionals.
690	Dietitian: What portion of care may be done by a dietitian who does not have at least one year of experience in a clinical setting after achieving registration? Is there a "grandfather" clause for this requirement?	The regulation does not have a "grandfather" clause or other exception for this requirement. Dietitians without the required one year clinical experience would not be qualified to complete patient assessments, develop plans of care, or take responsibility for QAPI program review. A dietitian without the one year of clinical experience could work with a qualified dietitian in order to gain the required experience, but would not be eligible to independently provide the aspects of care (mentioned above) that are required to be performed by the qualified dietitian until the new RD had completed a year of clinical experience.
691	Masters-prepared social worker: What does "specialization in clinical practice" mean in the qualifications' statement for 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. Recognize that some States may have specific more stringent requirements that must be met for a "clinical social worker."
692 695	Patient-care dialysis technicians (PCTs): Under the ESRD Conditions for Coverage what constitutes a "patient care dialysis technician?"	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

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		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 under these regulations.
692 695	Patient-care dialysis technician (PCT) certification: What is meant by “provide direct patient care?”	“Direct patient care” is defined as any aspect of healthcare for a patient provided personally by a staff member, including but not limited to collecting data (e.g., vital signs, weights, symptoms since last treatment), setting up the dialysis machine, initiating/terminating treatment, care of the dialysis access, delivering any aspect of the hemodialysis or peritoneal dialysis process, responding to machine alarms, and administering medications as allowed by State practice acts.
692 695	Patient care dialysis technicians (PCTs): Define “setting up the dialysis machine for patient use.”	“Setting up the dialysis machine for patient use” means preparing the machine for use to include spiking the normal saline, checking and connecting the dialyzer, and all subsequent steps.
692 695	Patient-care dialysis technician (PCT) certification: Must a dialysis assistant who sets up machines for dialysis be certified as a PCT?	The Conditions for Coverage regarding certification for PCTs relates to the specific work that the PCT does, not to the title. A "dialysis assistant" may or may not be a PCT, depending upon the job description. CMS requirements for the “patient care dialysis technician” apply to the technician who has any responsibility for direct patient care, including setting up the dialysis machine for patient use. A technician who maintains or “takes down” machines (removes used supplies from the machine) after use without direct patient contact is not considered a “patient care dialysis technician” and does not require PCT certification.
692	Patient-care dialysis technicians (PCTs): Some experienced patient care dialysis technicians (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.
692	Patient-care dialysis technicians (PCTs): If a PCT does not have 4 years of experience in lieu of a high school diploma, what role can they have?	If a currently employed PCT does not have 4 years of PCT experience by October 14, 2008, he/she may perform other functions in the dialysis facility, but would not qualify to function as a PCT after that date. Individuals hired to be trained as PCTs after October 14, 2008 are required to have a high school diploma.
692	Patient-care dialysis technician (PCT) certification: If a technician has been certified by a CMS-approved national certification organization, i.e., BONENT, NNCO or NNCC, can the technician maintain recertification through a State program?	Yes. CMS will allow technicians who pass one of the 3 national certification exams to maintain ongoing certification through one of the CMS-approved State technician certification programs.
692	Patient-care dialysis technician (PCT): What can we do for staff	If the technician has a graduate degree from a legitimate graduate program, his/her education would

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	members who have worked as patient care technicians for less than 4 years who were foreign educated, have a graduate degree certificate, but can't provide a copy of a high school diploma?	<p>exceed the minimum requirement of a high school diploma or GED.</p> <p>Be sure that the diploma or GED certificate is legitimate. Information from the Federal Trade Commission about illegitimate "diploma mills" can be found at: www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt149.shtm.</p> <p>The American Association of Collegiate Registrars and Admissions Officers Web site has a database called EDGE (Electronic Database for Global Education) that provides registered members information on education provided in 162 countries for an annual fee: http://aacraoedge.aacrao.org</p>
692	Patient-care dialysis technician (PCT): We have a technician who has worked in dialysis <4 years. He graduated from high school in another country but does not have proof of that diploma. He obtained a GED from a high school online, but NNCC is not accepting it. How can this situation be resolved?	<p>Although several online schools advertise GEDs, there are no legitimate online providers of the GED, which must be taken through on-site testing. The GED Testing Service Web site includes locations for on-site testing: www.acenet.edu/AM/Template.cfm?Section=GED_TS</p> <p>This PCT must either obtain proof of his/her official high school diploma from his/her high school in another country or the PCT must take the GED at a testing site to document that s/he meets Federal regulations.</p>
692	Patient-care dialysis technician (PCT): How can a dialysis facility verify that a patient care technician's high school diploma is legitimate?	<p>As a first step, the Department of Education has a database that a facility can check if a high school exists: http://nces.ed.gov/globallocator/</p> <p>If the high school exists, it should be able to verify that the employee graduated.</p>
692	Patient-care dialysis technician (PCT): Will CMS accept the technician that has been grandfathered in? Example: In VA they put in a grandfather clause stating that techs who were working prior to April 2006 and have proof of training did not have to take a national exam. So will CMS accept them or must they now take the exam?	<p>CMS will not grandfather any technicians. Thus, all patient care dialysis technicians will need to take one of the 3 national certifying exams or a state exam that complies with CMS' requirements. CMS will allow technicians who pass one of the 3 national certification exams to maintain ongoing certification through approved State programs.</p>
693	Patient-care dialysis technicians (PCTs): 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 and interpersonal skills. What is expected of experienced technicians?	<p>For the purpose of this rule, "experienced" PCTs, "who have been employed as a PCT for more than two years as of the effective date of these regulations" and do not have documentation of a training program covering the listed content, may demonstrate competency by successful completion of a written exam over the required content and a skills checklist completed by observation of the PCT's skills by a registered nurse. These "experienced" PCTs would be expected to achieve certification within the specified time period.</p>
693	Patient-care dialysis technician (PCT): Where is the written exam and skills checklist derived--from	<p>The "test" and "checklist" referred to in the Interpretive Guidance are the responsibility of the facility to develop or obtain from another source. These would serve to</p>

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	the individual hemodialysis outpatient centers/acute hemodialysis units? Does this need to be completed in order to place on the application to take the certification examination?	validate that training includes those areas required by the regulation and that the staff member was successful in completing the training as a PCT. These documents become a part of the individual's personnel file, and help meet the requirements for the ESRD Conditions for Coverage.
693	Patient care dialysis technician (PCT) training: According to CMS rules V-693 where an approved training program is administered under the direction of a registered nurse, what is the guideline for possibly using champion PCTs to assist in the training?	The regulation requires that the training program for patient care dialysis technicians be under the direction of a registered nurse. It does not prohibit others from participating in the training, including the physician, advanced practice registered nurse (APRN), physician assistant (PA), dietitian, social worker, experienced patient care technicians, or other clinical staff. As examples, the Registered Dietitian(RN) could do the lessons on nutrition; the MSW could do the sessions on patient sensitivity; the biomed staff could do sessions on testing water for chlorine/chloramines; and experienced patient care technicians could do sessions on setting up and tearing down the dialysis machines pre and post treatment.
693 694	Patient-care dialysis technicians (PCTs): How is the content of PCT training verified when the personnel file only includes a certificate from the corporation and the training is done at a corporate off-site location?	Each facility must make available the content of the training program for the surveyor to validate that the program covers the specific topics required.
693 694	Patient-care dialysis technicians (PCTs): If a hemodialysis patient care technician took a training course prior to the CMS requirement for certification, will he/she 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. Every PCT must successfully complete a certification exam from a qualified entity in order to meet the certification criteria.
695	Patient care dialysis technician (PCT) certified: Will reuse techs be able to set up machines without being certified?	No. Any unlicensed person responsible for setting up or operating machines or providing direct patient care must be certified as a PCT. Persons who tear down machines do not have to be certified, so a reuse tech could do that task.
695	Patient-care dialysis technician (PCT) certification: Is a technician who does not set up or monitor machines, but who functions as a nursing assistant for acute dialysis treatments provided to hospital inpatients required to be certified?	The PCT certification requirement applies to all ESRD facilities that provide chronic outpatient dialysis for ESRD patients. The certification requirement does not apply to acute dialysis provided by hospitals.
695	Patient-care dialysis technicians (PCTs): Will CMS track technicians who do not have appropriate qualifications/certifications, who move from one facility to another?	CMS will not maintain a registry of technicians. However, CMS has instructed State surveyors 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.
695	Patient care dialysis technician (PCT) certified: If a PCT takes a	The length of an approved leave of absence from work (medical/military/family medical leave act (FMLA), jury,

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	leave of absence (medical/military/other) during the 18 month window for certification, is the leave counted in the timeline?	<p>other) is not counted in the 18-month timeline. The 18-month clock starts on the day of employment (or on October 14, 2008 for “legacy” PCTs) and stops on the last day the PCT works before the leave starts; the 18-month clock resumes when he/she returns to work.</p> <p>The PCT’s personnel file should include a record of the start and end dates of the leave of absence. This can serve as documentation for an exception to the 18-month deadline.</p>
695	Patient-care dialysis technician (PCT) certification: If a PCT worked in dialysis then left to work in a different field and later returned to work in dialysis, how long would he/she have to become certified?	<p>A PCT who has a gap in employment as a PCT for <18 months has a total of 18 months from his/her original hire date to obtain PCT certification. Changing jobs from one facility to another even across State lines does not restart the 18-month clock on obtaining PCT certification.</p> <p>However, if a PCT did not work as a PCT at any dialysis facility for >18 months, he/she would have 18 months from his/her rehire date to obtain certification.</p>
695	Proctored exam: What is a proctored exam? Who can proctor? Could the exam be offered at a dialysis provider corporate office?	<p>A “proctored exam” means that an outside, independent person receives and protects the exam; provides oversight of the test administration (ensures candidates sit at a 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. The proctor must be independent of the dialysis facility. The exam can be offered at a dialysis facility or corporate office if the site is proctored by an independent examiner.</p>
695	Standardized test: What does CMS mean by a “standardized test?”	<p>For the purposes of these regulations, a “standardized” exam must:</p> <ul style="list-style-type: none"> • Be developed by a group of experts representing more than one provider entity; • Be reviewed by a qualified entity (e.g., university, State licensing board, or test development company) for internal consistency and to ensure the test covers both common and critical tasks; • Test similar information under the same testing conditions. For example, all test takers (with the exception of those with certain disabilities) must be given the same amount of time to complete their exams and must have a quiet, controlled testing environment; • Measure a student’s performance against specific standards; in this case, against the required curricula items for a patient care technician and the knowledge and skills a PCT must demonstrate; • Produce consistent scores among different testing conditions or versions used; • Work the same way for all test takers. For example,

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		<p>the language and wording of test questions must be free of cultural, racial, ethnic, gender, and other forms of bias that may inappropriately affect students' performance;</p> <ul style="list-style-type: none"> • Be scored and have a set passing score; and • Be protected from casual distribution
695	<p>PCT certification: How many times may a PCT take one of the national certification exams?</p>	<p>The three currently approved national certification organizations have different limits for the number of times their exams may be repeated:</p> <ul style="list-style-type: none"> • NNCC Web site does not include a limit for the number of times the exam could be repeated but requires a new application for any retake; • BONENT allows 3 retakes in any 12 months, then requires the applicant to present evidence of having completed a nephrology related continuing education session(s) or attend and complete a nephrology education program prior to retaking the test after the third unsuccessful attempt. • NNCO Web site states their exam may be taken "as often as desired upon filing a new application."
695	<p>Patient care dialysis technician (PCT) certified: What States have PCT certification exams that have been approved by CMS?</p>	<p>Eleven State programs have been approved by CMS as of 12/2010. See S&C-ESRD-10-03 for more detail and the list of States.</p>
N/A	<p>LPN/LVN: If a facility requires LPNs to function as patient care technicians, do the LPNs need to be certified as patient care technicians?</p>	<p>No. The CMS requirement for PCT certification applies to unlicensed/unregistered/uncertified individuals providing direct patient care.</p>
N/A	<p>Patient care dialysis technician (PCT) certified: Does a reuse technician have to be certified?</p>	<p>The Federal regulations do not require reuse technicians to be certified as long as that reuse technician does not provide direct patient care.</p>
	<p>Condition: Medical Director</p>	
711	<p>Role: Is there a limit to the number of facilities for which a physician can be medical director?</p>	<p>The CfC does not limit the number of facilities where an individual physician can function as medical director. If a physician is functioning as the medical director for multiple facilities, and there are survey findings in areas which could affect the safety of patients or quality of care, those findings might be attributed to the inability of the medical director to devote sufficient time to meeting all of his/her responsibilities, and that her/his absence and lack of guidance may have contributed to the findings.</p>
711	<p>Role: How often must the medical director be physically present at the facility?</p>	<p>The medical director should devote sufficient time to ensure that safe and effective care is delivered to all patients. This requires the medical director be actively involved in the oversight of the facility: attending care plan meetings (if he/she has patients in the facility), QAPI committee meetings, guiding development of performance improvement/action plans, and assuring that staff are sufficiently trained to perform their assigned roles. As a guide, each facility's financial cost report, filed with CMS, considers the Medical Director</p>

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		role as 0.25 FTE.
711	Role: What provision is there for a group of physicians to collectively serve the facility as medical directors?	Under the CfC, each facility must have a single medical director identified to CMS as responsible for carrying out the duties of the 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 one facility medical director and are under the same QAPI program and governing body oversight.
711	Role: In facilities that have co-medical directors now, can one be the medical director and the other be an associate medical director?	CMS requires that a single medical director takes responsibility as outlined in the regulations. The governing body may assign job titles and distribute medical tasks or oversight required by the facility as it deems appropriate; however, one physician must be designated as Medical Director for the purpose of CMS accountability.
712	Role: Can an APRN or PA serve on the IDT for plan of care and QAPI?	<p>The medical director of an ESRD facility must be a physician. The Conditions for Coverage are specific about the qualifications and role of the medical director, including having overall responsibility for monitoring the QAPI program.</p> <p>Other services that are required to be performed by a physician may be performed by a non-physician practitioner functioning as a physician, i.e. APRN or physician assistant, as long as they are legally authorized to do so by the State in which the services are performed; and if the non-physician practitioner works in collaboration with a physician.</p>
715	Initial assessment: What is the definition of the “initial” assessment?	“Initial” assessments are “admission” assessments of patients admitted to the dialysis facility, 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. physician, advanced practice RN, or physician assistant, 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, and 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.
715	Initial assessment: 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	A physician, APRN or PA must conduct an initial assessment (or evaluation) in order to establish admission treatment orders and to promptly identify urgent patient medical needs (e.g., anemia <10 gm/dL, fluid overload, hyperkalemia) that must be addressed prior to completion of the initial comprehensive

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	met?	<p>interdisciplinary assessment. This evaluation requirement could be met by reviewing various medical records (from primary care physicians, hospitalizations, etc.) and verbal consultations rather than actually seeing the patient in the dialysis facility prior to treatment. The surveyor would expect to see a medical staff note or other evidence of this evaluation, as well as orders for admission and treatment of the patient.</p> <p>In addition, the RN on duty must evaluate and document the patient's immediate needs prior to that first treatment. The expectations for this evaluation are listed at V715 and could be documented on the treatment record (note, this evaluation requires review of areas not routinely addressed in a pre-treatment assessment), in a nurse's note, or on a form developed for this purpose that could become a part of the comprehensive interdisciplinary patient assessment.</p> <p>In contrast, V516 refers to the Initial Interdisciplinary Comprehensive Assessment that must include the input of all members of the IDT and be completed within 30 days/13 treatments of admission.</p>
715	Initial assessment: What is the role of the nurse in the initial patient evaluation?	<p>An RN is expected to review the medical admission orders and evaluate the patient prior to initiation of the first treatment for potential immediate needs. The evaluation should determine the patient's:</p> <ul style="list-style-type: none"> • Level of alertness/mental status, orientation, identification of sensory deficits • Subjective complaints • Pain status • Ambulation status, support needs, fall risk • Vascular or peritoneal access status • Respirations description, lung sounds • Heart rate and rhythm; presence and location of edema • Fluid gains, blood pressure and temperature pre-treatment • Skin color, temperature and, as needed, type/location of wounds
715	Initial assessment: Does the initial patient evaluation by the RN need to be completed prior to the patient beginning his/her HD treatment?	Yes. The initial RN assessment of a new patient must be completed prior to initiation of the first treatment of that patient in the facility.
	Condition: Medical Records	
726	Accessible: 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 record in less than four hours. Inactive records stored off site should be able to be retrieved within 24-48

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		hours.
726	Accurate: Are physicians required to sign, date and time all verbal orders? Was this a requirement prior to the new ESRD CfCs?	Yes. Verbal orders must be signed, dated and timed by the responsible physician, signifying review, acknowledgement, and approval of the verbal order. This was a requirement prior to the new ESRD CfCs.
727	Medical record privacy & security: If a chart room has locks on any doors to deter unauthorized entry, is it against HIPAA regulations for nurses and other IDT members to go into the locked chart room and retrieve charts and read them? Is it against regulations for the billing personnel to use the patient charts to check insurance status or for coding and/or billing?	Physicians, nurses, dietitians, social workers, and other authorized staff, including billing personnel, who have a need to know should be given ready access to patients' medical records for continuity of care and billing purposes. Here is a summary of the HIPAA law: www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html This 6-page document specifically addresses the HIPAA law related to treatment, payment, and healthcare operations: www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/sharingfortpo.pdf
732	Retention: How long should a dialysis facility maintain dialysis machine disinfection logs?	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 patients who are dialyzed on them. The logs should be maintained separate from patient records; be accessible; and retained at least 6 years after the discharge of the last patient on service at the time the records were created or per medical record retention requirements under State regulation or facility policy, whichever is more stringent.
	Condition: Governance	
752	Facility administrator: Can a medical director also act as facility administrator?	Yes. A facility administrator can act in these two roles if he/she meets the qualifications as a medical director and fulfills the duties and responsibilities outlined for both positions.
752	Facility administrator: What are the qualifications required for the facility administrator?	The regulation does not specify the qualifications for the administrator. Qualifications should be defined by facility policy, which would need to address sufficient educational and practical experience to fulfill the responsibilities assigned to this position in the Condition for Governance (V753-V773).
752	Facility administrator: Can an administrator function in that role for two or more facilities?	Yes.
752	Facility administrator: Can a facility administrator also be the social worker?	Yes. To function in both roles, the person would need to meet the required qualifications for the social worker and fulfill the duties and responsibilities outlined for both positions.
752	Facility administrator: If the CEO/administrator is an RN, can he/she also be the Chief Nursing Officer?	Yes. To function in both roles, the person would need to meet the required qualifications for the nurse manager and fulfill the duties and responsibilities outlined for both positions.
757 758	Patient/staff ratios: Are there any CMS required patient-to-staff ratios?	No. The CMS regulations, at V757, require an "adequate" number of qualified personnel be present so that the patient/staff ratio is appropriate to the level of

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		dialysis care given and the care meets the needs of the patients. In addition, V758 requires that the registered nurse, social worker and dietitian members of the IDT are available to meet patient clinical needs. Surveyors may use these tags to cite a facility which does not meet any State staffing ratios that are more stringent than these requirements.
759	RN presence: If no patients are on treatment, but are in the waiting room, must a registered nurse be present?	While the regulation requires that a registered nurse, responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated, it is expected that an RN would be present as long as patients are in the building. If a patient in the waiting room experienced a medical emergency before or after treatment, the facility would be expected to render emergency care, which would require an RN.
763	QAPI responsibility: Are all medical staff members required to attend QAPI meetings?	While there is no requirement that all medical staff members attend QAPI meetings, the governing body is responsible to ensure that all medical staff who provide care in the facility are informed of the facility's QAPI program. The medical director is responsible for the QAPI program and could require attendance at QAPI meetings of some or all of the medical staff members under certain circumstances. If a surveyor found a pattern of inadequate anemia management in one physician's patients, it would be expected that this issue would have included review of this physician's patient outcomes in QAPI, and that review would include attendance of that physician at that meeting.
767	Involuntary discharge: 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 medical practice acts, which generally require that some notice be given to patients to avoid the charge of patient 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.
767	Physician discharge orders: Do the medical director and treating physician have to sign a discharge order if a patient is being involuntarily discharged for lack of payment?	Yes. Both the Medical Director and the patient's attending physician must sign orders for ALL involuntary transfer/discharges.
767	Involuntary discharge: May a facility involuntarily discharge a patient who does not come for treatment for an extended period, for example, 3-4 weeks?	The regulations specifically address the involuntary discharge process in an effort to reduce its occurrence. Facilities should work to avoid the need to involuntarily discharge any patient. In the situation described, a better resolution would be if the facility sent the patient a certified letter expressing concern about their absence from treatment and a willingness to talk with the patient about why s/he is not coming for treatment. In the letter, they could tell the patient that s/he has the right to

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		discontinue treatment, that doing so will likely result in his/her death, and that if s/he chooses to resume dialysis, to call to let the facility know this so the facility can schedule the dialysis treatment. The facility should provide names and phone numbers of key people s/he could talk with including the physician, social worker, and nurse manager or facility administrator. If the patient is unable to be reached, or does not respond to these efforts, the patient may be voluntarily discharged, as the patient has chosen to discontinue treatment.
767	Involuntary discharge: If a patient brings a knife to the facility and is screaming, yelling, and 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 involuntary discharge procedure.
767	Involuntary discharge: What is an “abbreviated involuntary discharge procedure?” What should be included in an “abbreviated involuntary discharge” procedure? Are facilities required to help patients find new facilities 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.” An angry verbal outburst or verbal abuse is not considered to be an immediate severe threat. In instances of an “immediate severe threat,” facility staff may determine to use “abbreviated” involuntary discharge or transfer procedures. These immediate procedures may include taking immediate protective actions, such as calling “911” and asking for police assistance. In this scenario, there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer. After the emergency is addressed and staff and other patients are safe, staff must notify the patient’s physician and the medical director of these events; notify the State and Network of the involuntary discharge; and document this contact and the exact nature of the “immediate severe threat” in the patient’s medical record. When the abbreviated discharge process is used, the patient is discharged from the facility.
768	Emergency coverage: What provisions for emergency medical care after the facility operating hours 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, uncontrollable bleeding, patients and families should be instructed to call “911” for immediate medical care.
770	Hospital agreement for inpatient care: 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 care, routine and emergency dialysis, and other hospital services with emergency services available 24/7. The agreement must ensure that hospital services are available promptly to dialysis patients when needed and include

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		reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.
N/A	Contract for water treatment services: Must the facility have a contract for water treatment?	No. Water treatment services may be provided by facility employees who use supplies and equipment purchased from vendors. If the facility uses a contract service, the responsibilities of the contractor should be developed in writing. There is no requirement for a facility to have a contract for water treatment services.
N/A	Contract for pest control services: Does the facility need a pest control contract?	The facility must be maintained to provide patients, staff, and the public a safe, functional, and comfortable environment. If there is a need for pest control, the facility must address the problem.
N/A	“On the premises”: Give examples of when “services provided on the premises” applies.	All services have to be provided at the single physical location of the ESRD facility, with the exception of the delivery of home therapies. If the in-center hemodialysis unit and the home training department are located at different addresses, each facility would require a separate CCN. If a hospital has an ESRD facility on the campus and another facility off campus, the off campus facility would be considered a "satellite," and each facility would require its own CCN.
	Acute Kidney Failure	
N/A	Treating patients with acute kidney failure: Are there any restrictions for treating patients with acute kidney failure (patients who are expected to recover kidney function) in an outpatient facility?	Dialysis facilities are not restricted from dialyzing “non-ESRD” patients. The payment for their care would be outside of the Medicare ESRD system.
N/A	Acute care units: Do these regulations have any affect on acute care hospital dialysis units?	No. These regulations are Conditions for Coverage for programs that are a part of the ESRD Benefit, including ESRD facilities that provide out patient in-center dialysis or home training and support. The hospital-based acute care units are a part of the hospital prospective payment system (PPS) Benefit; are covered by hospital Medicare Conditions of Participation; and would be surveyed as a part of the hospital survey.
N/A	Acute care units: Can an acute inpatient dialysis unit dialyze chronic patients at the same time as acute patients are being treated?	Yes. Acute and chronic patients may be dialyzed at the same time. However, in order to bill for routine chronic outpatient dialysis services, a unit would have to be certified as an ESRD facility. While hospitalized, the reimbursement for dialysis of ESRD patients is included in the hospital rate.
	Survey & Certification	
588	Certification for home: Can a provider be certified to offer PD or HD home support only with the training provided by another facility that is certified to offer training?	The service of home training and support is ONE service. A dialysis facility must be prepared to offer both training and support in order to be certified for home services. A home dialysis training facility must also furnish home dialysis support services.
588	Certification for home: If a facility is adding the service of home	CMS does not require home dialysis equipment be present in the facility prior to adding the service of home

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	therapies or a new facility is offering home therapies, must the home dialysis equipment (e.g., PD cyclor, home HD machine, etc.) be present at the facility when the survey is done?	dialysis training and support, but CMS does expect at least one patient to have been admitted for any service being requested.
N/A	Effective date for new rules: What is the effective date for the new Conditions for Coverage (CfCs)/regulations/rules?	In general, the regulations were effective on October 14, 2008, and surveys after that date used these regulations. There are different dates for some sections of the regulations: V128-V129 state February 9, 2009 as the effective date for isolation stations for new facilities; V417 states February 9, 2009 as the effective date for Life Safety Code; and V695 states the dates for certification of technicians based on their hire date, with PCTs employed prior to October 14, 2008 being required to be certified by April 15, 2010.
N/A	Interpretive Guidance: Is the Interpretive Guidance for the CFCs available electronically?	Yes. See the Dialysis Survey & Certification site: www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp
N/A	ESRD surveyor training: Are State surveyors required to take an ESRD training course prior to doing ESRD surveys?	Yes. In order to independently survey an ESRD facility, the surveyor must first attend a Basic or Advanced Technical ESRD course.
N/A	Different locations: If a hospital has 2 outpatient ESRD facilities in different off-site locations, does each need a separate certification number?	Yes. Each location is required to be separately certified (i.e., have a separate CNN). Hospitals may have satellite facilities, owned and operated by the same hospital but located away from the main campus. Each satellite facility would have a separate CCN.
N/A	Home patient presence for initial survey: Is the facility required to have a current patient in training at the time of an initial survey for HD and PD home training and support so the surveyor can observe the care that staff members render?	No. A patient must have been admitted to each service being requested. There is no requirement that a patient be in training at the time of the survey.
N/A	Initial surveys: How are initial surveys of ESRD facilities prioritized?	ESRD initial surveys are prioritized higher than initial surveys of other provider types. Statutorily-required surveys (for long term care and home health), complaint investigations, and surveys focused on facilities with poor outcomes receive a higher priority than initial ESRD surveys.
N/A	Initial surveys: Does a facility need to demonstrate an “access to care issue” in order to have an initial survey?	Depending on the resources available for surveys (surveyor time and money) in a specific State, the CMS Regional Office may require applicants for an initial survey of any provider type to demonstrate an access to care issue. CMS has defined this process in the following memorandum: S&C-08-03.
N/A	Initial surveys: How many patients are required to be on service for initial certifications?	Every initial certification survey requires the facility to have admitted at least one patient to each service being requested and to be delivering on-going care. If only in-center hemodialysis is requested, one in-center hemodialysis patient is required to be on service. If in-center hemodialysis and home hemodialysis training

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		and support is requested, an in-center hemodialysis patient must be on service and a home hemodialysis patient must have been admitted.
N/A	Different locations: If a facility relocates its home programs away from the in-center location (at a different physical address), could both the home program and the in-center location share the same CCN?	No. Each physical address requires a separate CMS certification number, and would have to separately meet the requirements of the Conditions for Coverage for ESRD facilities. If a facility chooses to relocate their home training program to another physical address, they would need to make application as an initial facility at the new address and successfully pass a full initial survey in order to be eligible for reimbursement for the services provided at the new location.
N/A	Form CMS 855A: Is a CMS 855A required for address changes caused by changes to the “911” system or post office changes?	Yes, a CMS-855a is required for any address change (whether or not the facility actually relocated).
N/A	Form CMS 855A: Does the CMS 855A “expire” if the initial survey is delayed?	No. The 855A does not expire it would simply need to be updated. Based on instructions in the <i>Program Integrity Manual, Chapter 10, Section 5.5.5 State Surveys and the CMS-855A</i> , it states that “...information on the CMS-855A is still considered to be valid notwithstanding a delay in the State survey. However the provider will be required to submit an updated CMS-855A application to the contractor...”
N/A	Immediate jeopardy (IJ): Are there directions for identification of IJ findings in ESRD facilities?	The Interpretative Guidance at each Condition tag provides examples of findings that could result in Condition-level non-compliance. In addition, the automated ESRD survey process, Surveyor Technical Assistant for Renal disease (STAR), identifies potential immediate jeopardy situations in an ESRD facility. For more information on immediate jeopardy situations, refer to Appendix Q.
N/A	Compliance penalties: Has CMS considered implementing a system of financial penalties/fines for facilities found out of compliance at the IJ or Condition level?	There is no “enforcement” language in the ESRD regulation, so currently there is no regulatory basis for such penalties.
N/A	Complaints & Networks: Are surveyors expected to contact the applicable Network prior to initiating a complaint investigation?	Although not mandated by regulation, the new ESRD survey protocol specifies that the surveyor “contacts the applicable ESRD Network for current information related to compliance with Network goals, complaints, and monitoring” (V772). It is CMS’ intent that Networks and State survey agencies work together and not duplicate efforts, particularly with complaint investigations.
N/A	Training: When/where are the Annual ESRD Update Courses held?	Annual ESRD Updates are generally held in conjunction with either the National Kidney Foundation or the American Nephrology Nurses’ Association meetings in April or May. The Annual ESRD Update is held in conjunction with a large professional meeting in order for CMS surveyors to use the meeting Exhibit Hall as a learning laboratory regarding new technologies, equipment, and devices.

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	STAR	
N/A	National program: Is the automated ESRD survey program, Surveyor Technical Assistant for Renal (STAR), a national program? Is the use of the STAR program limited to specific States?	The STAR program is nationally-available for use in all States.
N/A	Mandated use: Is there a date when STAR will be mandated for use?	While there is not yet a date when STAR usage will be mandated, CMS encourages its use as an efficient and effective survey tool. States are encouraged to purchase PC Tablets and send ESRD surveyors to the STAR training.
N/A	Updating: Has the STAR program been updated to reflect the new regulations and the updated survey process?	Yes. The STAR program has been updated to reflect the new tags of the new regulations. STAR is continuously update to improve its usability.
N/A	Keeping the STAR PC Tablet clean: How are surveyors expected to keep the PC Tablet clean during a STAR survey in a facility?	Surveyors are not delivering direct care to patients and have a very low risk of blood exposure. Surveyors using the STAR tablet should use care and attention to avoid contamination of their computer.
N/A	Printing: How can the findings recorded in STAR be printed?	The "notes" section of STAR can be printed by using the "Ctrl+A" command. Each page of STAR can be printed with the "Ctrl+P" command. If the Windows Journal is used to record survey findings in STAR, the usual print options in Windows may be used. Refer to the STAR "job aids" for directions on printing.
N/A	PC Tablet: If a State is using a PC Tablet computer for QIS surveys, can the STAR program be loaded onto the same computer?	Yes. STAR and QIS can share the same PC Tablet if the PC Tablet computer is sufficiently powered to accommodate both programs. The Mission and Priority Document (MPD) annually contains information regarding the PC Tablet hardware requirements for both STAR and QIS programs for surveys.