DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-56

DATE: **September 4, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Frequently Asked Questions (FAQs) Related to the New End Stage Renal Disease (ESRD) Conditions for Coverage (CfCs): Wave One

Memorandum Summary

- A template of FAQs related to the new ESRD CfCs is attached to this memorandum. These Questions are organized around the respective Condition(s) and V-tag(s) for easy reference.
- The FAQs will be distributed in a series of releases. This is Wave One of the series.
- These FAQs are being shared broadly in order to facilitate common understandings and consistency of standards/expectations. We encourage further questions about the Conditions to be addressed to the Centers for Medicare & Medicaid Services (CMS) mailbox: ESRDsurvey@cms.hhs.gov.

CMS wants to promote common understandings about the regulatory process and the specific rules that guide the CMS survey and certification process. In order to promote common understandings and consistency of standards and expectations regarding the new ESRD CfCs, we are distributing a series of FAQs that are related to those CfCs. The first of this series of Questions and Answers (Wave One) is attached to this memorandum.

We will continue to publish series of FAQs as new questions arise. We encourage those who have further questions to submit them to our CMS mailbox: ESRDsurvey@cms.hhs.gov.

For questions regarding this memorandum, please contact Judith Kari at judith.kari@cms.hhs.gov.

Date: This clarification is effective immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: This information should be shared with all appropriate survey and certification staff, surveyors, their managers, and applicable staff.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments

ESRD Conditions for Coverage
Frequently Asked Questions (FAQs)
September 2009

V Tag	Question	Answer
	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	**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. V464 can also be considered.
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

V Tag	Question	Answer
		that some State licensing rules may be more stringent.
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):** 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 for potential splashes.
115	**PPE:** How are masks expected to be worn—over the staff member's nose, under their chin, or where?	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:** 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.

V Tag	Question	Answer
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 clamps 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.
117	**Saline bags at chairside:** Can qualified staff members use a patient's bag of saline to draw up saline at the patient's chairside?	Yes. Qualified staff members may use a patient's bag of saline as a source to draw up saline at the patient's chairside. Careful attention to infection control techniques is expected to prevent any potential contamination of the saline bag. Facilities that reprocess dialyzers must not use the saline bag used for rinsing the dialyzer free of germicide as a source for saline irrigation and flushing.
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 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.

V Tag	Question	Answer
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 or a 1:1000 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.
126	**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. See V127 also.
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 they do 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 spur a reconsideration of the need for an isolation room.
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 room be used for HBV- patients?	No. According to the CDC, the isolation room can only be used for surface antigen positive patients. Hepatitis B virus can survive on surfaces in the environment for at least 7 days and transmission can occur through direct or indirect contact with contaminated surfaces. These

V Tag	Question	Answer
		surfaces can be contaminated with high levels of hepatitis B virus without evidence of visible contamination (thus creating a challenge to 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:** When do the regulations related to HBV+ isolation rooms and areas take effect?	For existing facilities, the requirements for isolation were effective October 14, 2008. For new facilities, the requirements were effective February 9, 2009.
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 containing 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.
129	**Isolation:** Initial surveys have been delayed for several months due to our budget constraints. If these facilities are not surveyed until after February 9, 2009 will a waiver be granted for an isolation room?	Facilities that had building permits or completed plan reviews before October 14, 2008 are not required to obtain a waiver or to have an isolation room.
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." 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 clinic 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	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

V Tag	Question	Answer
	an isolation room?	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 clinic 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+. A 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 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. 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.

V Tag	Question	Answer
		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. 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 State Agency will consult with the CMS Regional Office 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 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.
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.
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.
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 central catheters, must the ESRD facility follow the hospital policy?	An ESRD facility is responsible for developing its own policies and procedures. If appropriate, the ESRD facility may adopt the hospital policies. The ESRD staff should routinely monitor the site of the

V Tag	Question	Answer
	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?	catheter each treatment for swelling or redness; depending on the size of this dressing, 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. *Considerations for Accessing the Bloodstream Using Catheters* provides this recommendation.
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.
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. 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?	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. Active TB would require airborne infection isolation precautions. Outpatient dialysis facilities are not

V Tag	Question	Answer
		required to have the capacity to provide this level of isolation.
	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?	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. 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.
"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.
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.
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 differentiation 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/banks with a sample port between them for the daily and each shift testing for chlorine/chloramine. A sample port after the second carbon tank/bank 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 carbon must be disposed of in accordance with the local waste management requirements. The 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 ≤0.5mg/L (ppm), and the maximum allowable level for chloramine is ≤ 0.1

V Tag	Question	Answer
		mg/L (ppm). If a facility is doing only one test, and that is for total chlorine, then the ≤0.1mg/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 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 at less than 0.1 mg/L (ppm). If State requirements are more stringent, those requirements would need to be met.
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 0.5 mg/L (ppm); the allowable level for chloramine is 0.1 mg/L (ppm). Free chlorine is different from total chlorine: total chlorine includes both free and combined chlorine. Tests for total chlorine include free chlorine. If the facility uses two tests, the tests would be for total chlorine and free chlorine; the result for free chlorine is subtracted from the result for total chlorine to determine the result for chloramine. If only one test is performed, the test must detect both total chlorine and free chlorine, and be sensitive to levels less than 0.1 mg/L (ppm). If only one test is performed, the facility must set the target value for that single test at less than 0.1 mg/L (ppm).
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? At V196 under “additional guidance” regarding test strips, the guidance says "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	The facility is expected to have a method in place to validate the strips; this could be using the field validation

V Tag	Question	Answer
	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?	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).
197	**Chlorine/chloramines test:** If one of the two carbon tanks has been exhausted, can the facility operate with one carbon tank until the exhausted carbon tank is replaced?	V197 allows dialysis to continue with one exhausted carbon tank for up to 72 hours as long as test results after the remaining functional tank remain below the accepted limit of $\leq$0.1 mg/L (ppm) of chloramine.
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 $\leq$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.
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 established (V253). It is acceptable for a new (or

V Tag	Question	Answer
		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:** V228 requires concentrate jugs to be labeled with sufficient information to identify the contents. Does this mean both acid and bicarb jugs? How extensive does the labeling need to be, especially for bicarb jugs?	Both bicarb and acid jugs must be labeled. Labeling for bicarb jugs would need to include "Bicarb" and, if the facility does not discard all bicarb at the end of each day, the label must include the date and time the bicarb was mixed to allow discard within the manufacturer's guidelines. For acid jugs, the label should include sufficient information to allow determination of any differences in the acid concentrates available in the clinic. The more acid "choices" available, the more extensive the labeling required. If the choices in a clinic are more limited, (e.g., only one level of calcium available), the labeling may be less extensive. 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.
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.
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

V Tag	Question	Answer
		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.
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.
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: • 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). Note that conductivity alarms are always important to troubleshoot immediately and effectively.
249	**Conductivity/pH:** If the bicarbonate level in the dialysate is changed from one patient to another, does this affect the conductivity reading on the machine? Should staff be expected to know the "safe range" for variability of the conductivity with different bicarbonate levels?	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 hand-held readings with machine readings. 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?	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 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.
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

V Tag	Question	Answer
		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.
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.
253	**Testing:** Should dialysate cultures be collected at the end of dialysis?	Yes. Effluent dialysate samples should be collected from the Hanson connector or a sample port in the dialysate line exiting the dialyzer at the end of dialysis.
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	**Compliance:** The Millipore manufacturer’s directions for use (DFU) require incubation at 25-37	The regulatory requirements are within the manufacturer’s DFU. The expectation is that the facility would meet the AAMI requirement which is incorporated

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	degrees C for 48-72 hours, but the AAMI language at V256 regarding these samplers requires incubation at 35 degrees C for 48 hours. Why the difference and which is expected?	into CMS regulatory language.
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. When publications/standards from non-government entities are adopted as regulation, subsequent updates are not automatically adopted. Each update must go through the rule-making process to be adopted as regulation.
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 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 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 sites are not certified

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	Centralized Reprocessing Center need to be surveyed if the Center is owned by a company that is not related to the user dialysis facility?	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.
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 reuse 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 reuse to be done within the patient treatment room.
320	**PPE:** Is it a deficient practice if the reuse tech wears the gown worn in 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?	These regulations do not prohibit a reuse technician from using the same gown in the reuse room to go into 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 suffices for this requirement.
331	**Refrigeration:** What is the expected temperature for refrigerators used to store used	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

V Tag	Question	Answer
	dialyzers until reprocessing begins?	expected to be refrigerated, and 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 l to control the risk of microbial growth, while preventing freezing.
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.
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 first 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?	There are 2 requirements for this testing: 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). 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 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	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,

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	patient's treatment being started?	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.
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 different State survey agencies who oversee user facilities using the same centralized reprocessing center is vital and expected.
	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.
403	**"Dummy drip chambers":** Why does the use of "dummy drip chambers" present an Immediate Jeopardy situation?	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 use of dummy drip chambers is acceptable in the machine maintenance area only.
403	**Refrigerators:** What are the expectations for refrigerators for medication storage?	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.
403	**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?	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.
403	**Equipment preventive maintenance:** May a technician be asked to open up a machine that has recently had preventative maintenance to allow inspection for	Yes. This sort of inspection is usually reserved for occasions when a problem is suspected.

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	leaks, cleanliness, etc?	
403	**Equipment preventive maintenance:** Is there a maximum number of dialysis machines for which one biomedical technician can be responsible for maintenance and repair?	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 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	**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	**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 would be able to be seen by staff throughout the treatment, and it is expected that video surveillance would not be an alternative to visualization 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.
407	**Visibility of patients:** If patients refuse to keep their vascular	Patients have the right to refuse aspects of their treatment plans. If the patient refuses to keep his/her

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	accesses uncovered, is having the patient sign a waiver acceptable?	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, advance practice registered nurses (APRN), and physician assistants (PA) required to maintain current CPR certification?	No. CMS will not regulate whether physicians maintain current CPR certification. If APRN and PA are functioning solely as medical staff in lieu of physicians, CMS will 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 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.
	Life Safety Code (LSC)	
417	**Life Safety Code (LSC):** What Life Safety Code requirements apply to dialysis clinics located in hospitals?	Hospital LSCs are more stringent than those in the ESRD CfCs. An ESRD facility located in a hospital must either be in compliance with the hospital LSC or be appropriately separated from the hospital by a 2-hour firewall.
417	**Life Safety Code (LSC):** Must a freestanding home dialysis training unit meet the requirements of the LSC for Ambulatory Health Care facilities?	Yes. Home dialysis training and support facilities must meet the new ESRD Conditions for Coverage which includes Life Safety Code requirements.
417	**Life Safety Code (LSC):** If a portion of the dialysis facility is used for other, but related purposes, such as physician offices and exam	No. The Life Safety Code requirements of the dialysis facility may encompass other, related services that lease space from the dialysis facility, such as physician offices/exam rooms.

V Tag	Question	Answer
	rooms, do these areas need to be separated from the dialysis unit by a one-hour firewall?	
417	**Life Safety Code (LSC):** If a facility is relocating, must a Life Safety Code survey be conducted?	Yes.
417 403	**Life Safety Code (LSC):** The NFPA for Ambulatory Surgery Centers requires back-up generators. Will ESRD facilities be required to have a back-up generator?	No. The Federal regulations do not require ESRD facilities to have emergency generators because the ESRD facility does not continually use life support equipment. Generators would be required if there was an ongoing need for general anesthesia or life support equipment. However, if a back-up generator is used for emergency lighting purposes, then the generator must be maintained in accordance with manufacturer's recommendations.
417	**Life Safety Code (LSC):** Will CMS offer specific training to State agencies for LSC for ESRD?	It is expected that the LSC surveys will be very like the Ambulatory Surgery Center (ASC) LSC surveys and that the training provided in the CMS/LSC courses will address the ESRD LSC survey process.
417	**Life Safety Code (LSC):** What is the effective date for the LSC surveyor to begin conducting LSC surveys in ESRD?	Beginning February 9, 2009 initial surveys require a LSC survey to be completed prior to a "new" facility being able to be recommended for certification. A "new" facility is defined as one that has not received approval of all of its building permits (or alternatively, completed all of its plan reviews in jurisdictions that do not require building permits) on or before February 9, 2009. Beginning February 9, 2009, complaints with allegations related to the LSC requirements will need to be investigated. Please refer to S&C Letter #09-24 for LSC survey timelines.
417	**Life Safety Code (LSC):** Will the LSC survey occur in conjunction with the ESRD survey?	The LSC survey will generally be conducted at a separate time from the ESRD survey.
417	**Life Safety Code (LSC):** Where are deficiencies for Life Safety Codes cited?	The deficiencies for LSC are written on CMS Form 2786, Fire Safety Report Form for Ambulatory Health Care. This form is available on the CMS website for forms. Although CMS does not require that LSC deficiencies ("K" tags) be cited on the ESRD Survey Report Form 2567, some States require that these deficiencies be included as a part of the ESRD survey (citing at V417).
417	**Life Safety Code (LSC):** The new regulations incorporate NFPA's Life Safety Code 2000. The code has been updated in 2006. Will CMS utilize this newer version or stay with the 2000 version?	CMS will use Chapter 20 (for new dialysis facilities) and Chapter 21 (for existing dialysis facilities) of the 2000 edition of the National Fire Protection Association's Life Safety Code for Ambulatory Health Care Occupancies.
420	**Life Safety Code (LSC):** Can the Life Safety Code be uniformly waived for dialysis providers? If enforced, the LSC would mean significant financial hardship on smaller facilities.	This regulation gives CMS the authority to waive specific provisions of the LSC, but not a facility's compliance with the entire LSC. A waiver may be granted if the facility is unable to comply with a certain requirement of the LSC, and if complying with that requirement would cause an "unreasonable hardship"

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		for the facility. An "unreasonable hardship" can include a financial hardship. The waiver will only be granted if it is determined that the health and safety of the dialysis facility's patients are not adversely affected by the waiver. In some cases, the waiver may be time-limited.
N/A	**Life Safety Code (LSC):** What are the qualifications required for a Life Safety Code surveyor?	To qualify as a LSC surveyor, the State or Federal employee must take a Principles of Documentation course; observe a LSC survey; and either take an online LSC course or attend the Basic LSC training course (4.5 days).
	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.
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.
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 plan of care?	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 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

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		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:** 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+.
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 clinics 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 regulation expects "a physician treating the patient"

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	the medical director substitute for the "treating physician" in the IDT?	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	**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 equal one assessment of the patient. The regulations do not specify the format for the assessments.
501 541	**Interdisciplinary Team (IDT):** How often are social workers and dietitians required to see patients and document progress notes?	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.
501 516	**Interdisciplinary Team (IDT):** What is the definition of "comprehensive initial interdisciplinary" assessments?	"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.
502	**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?	If the transferred H&P is complete and current, it may be used as part of the next 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. The transferred H&P could possibly be used as part of that reassessment. 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.
502	**Current health status:** Are ESRD facilities required to have the capacity to test blood glucose?	Provision must be in place to ensure safe care of diabetic patients who may experience hypoglycemic episodes during treatment. This could include having blood glucose monitoring available for use in

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		emergencies.
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?	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). 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-you would need to include their policy requiring physician's orders to be followed); or V758, (sufficient staffing of RNs to meet the patient needs).
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 dialysate affect the blood pressure and comfort of the patient? Is there a limit to the allowable change?	A slightly cooled dialysate may prevent hypotension during treatment. Cooled dialysate may result in patient 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

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		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 cycler 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 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 4th 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?	The surveyor generally begins by looking at 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	**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

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		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 is 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?	Facility policy should define when the patient's catheter site is assessed. 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, dependent on facility policy.
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 rules apply to staff talking with family members or significant others about a patient?	While the IDT may not discuss a patients protected 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.
516	**Frequency:** Discuss the expectation for "compliance within a year" for the patient assessment and plan of care requirements. Should all existing patients have a comprehensive assessment and plan of care in their medical record on October 14, 2008? Or does this mean facilities are not required to comply with this part of the regulations for the first year?	Every facility is being allowed up to a year from October 14, 2008 to fully comply with the two Conditions, Patient assessment and Patient plan of care. To avoid citations in this area, facilities are expected to have developed and operationalized a plan to convert all patients to a system for care planning that meets the new requirements by October 14, 2009, with some patients converted each month. Unstable patients require monthly assessments. Patients new to dialysis (or returning from transplantation, or changing modalities) must have an assessment within 30 days/13 treatments of admission, and a POC immediately implemented. Records of patients who are not yet included in the "new" system must have evidence that the IDT is monitoring their outcomes and updating their care plans to address identified needs.
516	**Frequency:** Do transfer and transient patients need an initial comprehensive interdisciplinary assessment in 30 days or 13 treatments?	Requirements for transferred patients 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

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		transferred PA/POC initially. The IDT would need to conduct a reassessment within three months of the patient's admission to the new facility 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 and immediately implement the plan of care.
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.
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.
518	**Adequate dialysis:** What procedure is used to draw blood samples for calculating "adequate" dialysis or Kt/V for hemodialysis patients?	The facility must ensure that the method/procedure for drawing the blood sample to measure Kt/V will produce accurate results. At the time of 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: • 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", stop flow may be substituted; • After 15 seconds, staff should draw the post dialysis BUN sample from the arterial port closest to the patient. All staff members should be using the same method, as described above. Home hemodialysis patients should be instructed to draw their samples in this same way.
519 520	**Annual/monthly assessments:** What is required for updating an assessment?	Complete updates of the patient assessment are required annually for stable patients and monthly for 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

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		adjustment or change in the plan of care.
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" 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 of these conditions or two of these conditions at the same time would not automatically be considered "unstable."
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	**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 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. 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; having 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	To facilitate full Interdisciplinary team participation, any member, including the physician or the patient, may

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	present at the IDT meeting, or can he/she attend by conference call?	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. "dry" weight. The "dry" weight is the weight at which the patient attains normotension for most of the interdialytic period, while avoiding orthostatic hypotension or postural symptoms either during or after dialysis. Each patient should be weighed before and after each treatment, and a target weight identified for each patient. 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 hypertension should be recognized and addressed 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 receiving standard treatment results.
544	**Adequate dialysis:** Why are the Kt/V values different for in-center HD, home therapies, and in PD	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

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	patients?	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:** Are there new Kt/V guidelines for PD?	The KDOQI PD Adequacy Guideline was updated in 2006 and states the measure for adequate peritoneal dialysis as a weekly Kt/V of 1.7. The Measures Assessment Tool (MAT) updates the values as guidelines change.
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:** 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.

V Tag	Question	Answer
550	**Vascular access:** How can dialysis facilities be responsible for vascular access results?	The Department of Health and Human Services' Breakthrough Initiative on Fistula First website 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: • Considering the outcomes of various surgeons used for vascular access and preferentially referring patients to surgeons with good outcomes in fistula placement; • 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.
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 to meet this requirement. 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 http://gim.med.ucla/kdqol/. You must register (free) 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.
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	"Area transplant centers" refers to all transplant programs in the geographical area of the dialysis facility.

V Tag	Question	Answer
	centers?	
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	**Interdisciplinary team (IDT):** If the patient does not wish to participate in the IDT, what documentation is expected in their medical record?	The patient has the right to refuse to participate in the IDT discussions about his/her care, and the IDT should document their attempts to include the patient in such discussions and the refusal. Because the patient's situation and/or outlook may change, the IDT should continue to make and document good faith attempts to include the patient in the IDT discussions. If the patient chooses not to sign their plan of care, this choice must be documented along with the reason for not signing.
558 559	**Interdisciplinary team (IDT):** Does the IDT have to meet monthly to discuss patient status?	While the IDT is expected to meet at least monthly for QAPI, they are not required to meet monthly to discuss patient status. The IDT is expected to work collaboratively to assess patients and to plan each patient's care. This goal could be achieved using weekly or monthly rounds, or other meeting times and methods to facilitate their communication.
559	**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?	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,

V Tag	Question	Answer
		progress notes, changes in orders, or adjustments in the treatment records.
559	**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?	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. The team must review the patient outcomes regularly. 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.
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?	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.
560	**Monthly physician visits:** How is CMS going to reconcile the CfC home patient visit requirement vs. the home patient MCP guidance?	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.
560	**Monthly physician visits:** What are the "acceptable reasons" for a home patient not to be seen by a physician every month?	If a home patient chooses not to be seen by a physician every month, 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.
560	**Monthly physician visits:** Clarify when a physician is required to direct or provide care for patients, vs. an APRN or PA.	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

V Tag	Question	Answer
		requirement for a specific level/number of visits/number of hours that the physician must be involved. 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.
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

V Tag	Question	Answer
		by a physician or a practitioner functioning in lieu of a physician. "Self monitoring" data (dialysis treatment sheets) from home patients must be retrieved and reviewed by the facility at least every two months.
589	**Home visits:** For home hemodialysis, does an RN have to make the home visits or can an LVN/LPN do these?	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.
591	**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?	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 or by teleconference, 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.
595	**Water/dialysate:** 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 all home hemodialysis patients.
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 clinic'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	**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. Surveyors make contact with the administrator or director of nursing at the LTC facility to explain the purpose of their visit, but permission to visit the LTC facility is not requested or required. Each patient would

V Tag	Question	Answer
		be asked for permission for the interview, and the patient 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 certification.
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.
/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. 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.
	Condition: QAPI	
626-638	**Measures Assessment Tool (MAT):** How is the Measures Assessment Tool (MAT) used for QAPI?	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. Facilities are expected to use CROWNWeb, Dialysis Facility Reports, and Network reports to determine comparison or "average" values associated with clinical outcomes. If a facility has areas of QAPI that do not meet target levels (per MAT) or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving those outcomes. The important aspects of the QAPI program are appropriately monitoring data/information; prioritizing areas for improvement; determining potential root causes; and developing, implementing, evaluating and revising plans that result in improvements in care.
626	**Interdisciplinary team (IDT) documentation:** Is there a	V626 requires the facility to "maintain and demonstrate evidence" of the QAPI program for review by CMS. This

V Tag	Question	Answer
	requirement for documentation of the QAPI program activities?	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 will we expect to see?	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. Signatures on lab reports or similar data summaries alone are not sufficient when data falls below community standards or is "worse than expected."
626	**Interdisciplinary team (IDT):** Since there is no time frame mentioned in the regulations, how often should we expect the QAPI meetings to take place?	The scheduling of these meetings must be sufficient to address the facility's QAPI needs. Data must be reviewed as it becomes available. 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 the QAPI all 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, 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 since some 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	Facilities are expected to track patient/staff injuries, treatment errors (e.g., wrong dialysate, wrong dialyzer,

V Tag	Question	Answer
	medical injuries and errors?	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 website for Patient Safety sponsored by the Renal Physician's Association.
636 765	**CAHPS In-center Hemodialysis Survey (CAHPS):** Are facilities expected to use the CAHPS (a standardized experience of care assessment survey) to track patient satisfaction/grievances?	Since there is a significant cost to having the Consumer Assessment of Healthcare Providers and Systems (CAHPS) In-center Hemodialysis Survey scored, CMS is reconsidering this requirement. At this time (6/2009), facilities should use a self-selected instrument to measure patient satisfaction. Facilities are required to monitor and track patient complaints and grievances, including meeting a timeline for response and providing feedback to the patient/ complainant regarding the outcome of the facility investigation.
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. This survey is only validated for adult in-center hemodialysis patients. At this time (6/2009), a facility does not need 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.
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. However, some State 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	
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.

V Tag	Question	Answer
	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 training program in nephrology, but is not Board certified, continue as the medical director?	In addition to completing a board-approved training program in nephrology, and having at least 12 months experience in nephrology, the medical director must be certified in internal medicine, pediatrics, or nephrology. If a person, as specified above, is not available, the Secretary of the 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 can 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.

V Tag	Question	Answer
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.
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 roles, 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 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

V Tag	Question	Answer
		clinic, 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 nursing care to patients on maintenance dialysis" to qualify as the charge nurse?	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 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	**Dietitian:** Can a dietitian use protocols or algorithms to direct dosage changes of medications?	The 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.
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. CMS recognizes that some States have specific qualifications for a "clinical social worker."
692	**Patient-care dialysis technicians (PCTs):** Who is classified as a "patient care dialysis technician?"	Technicians are described using a variety of terms, including "biomedical technician" and "machine technician." The CMS requirements for the "patient care dialysis technician" apply to any technician who has any

V Tag	Question	Answer
		responsibility for direct patient care, including setting up the dialysis machine for patient use. A technician who maintains or "takes down" machines after use without direct patient contact is not considered a "patient care dialysis technician."
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.
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?	"Experienced" PCTs, (i.e., those PCTs who have been employed as a PCT for more than two years as of the effective date of these regulations) who 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.
693 694	**Patient-care dialysis technicians (PCTs):** How is the content of PCT training verified when their 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 they meet the certification criteria?	If there is documentation that the course taken meets the curricula requirements, or if the PCT has been working for more than two years as a PCT and passes a test over the content of the curricula, the training course requirement would be met. Every PCT must successfully complete a certification exam from a qualified entity in order to meet the certification criteria.
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 intends to "count" experience from one facility to another in determining the 18 months time limit for completing certification, unless the PCT has at least an 18 month break in employment as a PCT.
695	**Proctored exam:** What is a proctored exam? Who can proctor? Could the exam be offered at a dialysis provider corporate office?	A proctored exam means that an outside, independent person receives and protects the 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

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		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.
695	**Standardized test:** What does CMS mean by a "standardized test?"	For the purposes of these regulations, a "standardized" exam must: • 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, 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; • Be scored and have a set passing score; and • Be protected from casual distribution
N/A	**LPNs as patient-care dialysis technicians (PCTs):** If a facility requires LPNs to function as patient care technicians, do the LPNs need to be certified as patient care technicians?	No. The CMS requirement for PCT certification applies to unlicensed individuals providing direct patient care.
	Condition: Medical Director	
711	**Role:** Is there a limit to the number of facilities for which a physician can be medical director?	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.
711	**Role:** How often must the medical director be physically present at the facility?	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),

V Tag	Question	Answer
		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 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.
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 nurse, 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:** Can the registered dietitian write orders to adjust medications for anemia and CKD MBD management?	The scope of practice for all of the professional staff, including the registered dietitian, is dependent on the State practice acts where the individual is practicing. The Federal regulations do not address specifics about the scope of practice for dietitians.
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 met?	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 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

V Tag	Question	Answer
		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. 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. 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.
715	**Initial assessment:** What is the role of the nurse in the initial patient evaluation?	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: • Level of alertness/mental status, orientation, identification of sensory deficits • Subjective complaints • Pain status • Ambulation status, support needs, fall risk • Access assessment • 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 patient evaluation by the RN need to be completed prior to the patient beginning his/her HD treatment?	The initial RN assessment of a new patient must be completed prior to initiation of the first treatment of that patient in the facility. Facility policy may guide the time of routine pre-treatment evaluations, and policy may outline parameters that the patient must meet in order to be initiated on treatment prior to the nursing evaluation being completed. For example, the policy could allow PCTs to start treatment if the patient's vital signs and history since the last treatment are within set parameters, while requiring an RN's assessment if the data collected are outside those set parameters.
	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.

V Tag	Question	Answer
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 by the responsible physician, signifying review, acknowledgement, and approval of the verbal order. This was a requirement prior to the new ESRD CfCs.
732	**Retention:** How long should a dialysis clinic 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. The person must 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. The person must 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 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?	No. 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.
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

V Tag	Question	Answer
		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	**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 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 clinic know this so they 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, then the involuntary discharge procedure could be considered.
767	**Involuntary discharge:** If a patient brings a knife to the clinic and is screaming and yelling, threatening staff, what can the staff do?	Call 911 and ask the police for assistance to protect the other patients and the staff. This may result in an abbreviated 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

V Tag	Question	Answer
		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 facility provisions for emergency medical care are expected?	The patients should be able to contact a call service for a responsible staff member, physician, or on-call staff for dialysis-related emergencies 24 hours a day, 7 days a week. In cases of need for emergent medical care, e.g., severe chest pain, loss of consciousness, 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 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 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**	Dialysis facilities are not restricted from dialyzing "non-

V Tag	Question	Answer
	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?	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 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 and 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?	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 ESRD patients is inclusive 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 furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company.
588	**Certification for home:** If a facility is adding the service of home therapies or a new facility is offering home therapies, must the home dialysis equipment (e.g., PD cycler, home HD machine, etc.) be present at the facility when the survey is done?	CMS does not require home dialysis equipment be present in the facility prior to adding the service of home dialysis training and support, but CMS does expect at least one patient to be on census 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 S&C 09-01 (October 3, 2008) www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf
N/A	**ESRD surveyor training:** Are State surveyors required to take an	Yes. In order to independently survey an ESRD facility, the surveyor must first attend a Basic or Advanced

V Tag	Question	Answer
	ESRD training course prior to doing ESRD surveys?	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., separate CNN). Hospital units may have satellite facilities, owned and operated by a 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?	Every initial certification survey requires the facility to have at least one dialysis patient on census. CMS expects that a patient would be on every service being offered; e.g., if home HD is being added or initiated, there would be a home HD patient on service. If PD is being added or initiated, there would be a PD patient on service. 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 a least one patient on each service being requested. 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 and support is requested, an in-center hemodialysis patient and a home hemodialysis patient must be on service.
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?	Yes: this form is "good for" one year after the date of the signature and would need to be updated prior to payment being made if the form "expired" before the initial survey was done. The need to update the form would not delay the survey or the effective date of certification.

V Tag	Question	Answer
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.
	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?	No. There are many surveyors who have yet to train in the software and many States have not yet purchased the PC Tablet hardware.
N/A	**Updating:** Has the STAR program been updated to reflect the new regulations and the updated survey process?	The STAR program has been updated to reflect the new tags of the new regulations. Work is currently being done to incorporate all of the components of the new regulations into the STAR system.
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.

V Tag	Question	Answer
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 will accommodate both programs.
	General	
N/A	**Updating Clinical Performance Measures (CPMs):** Will the data on the Dialysis Facility Compare (DFC) website be changed to "% of Hct >30%" instead of "% of Hct >33%" to conform to the Measures Assessment Tool (MAT)?	The DFC website will be updated to follow the updated CMS Clinical Performance Measures (CPMs) of April 2008. The CMS CPMs guide the information on the DFC website, the information distributed in the Dialysis Facility Reports (DFRs), and the information summarized in the MAT.

Acronyms & Abbreviations

AAKP	American Association of Kidney Patients
AAMI	Association for the Advancement of Medical Instrumentation
ACIP	Advisory Committee on Immunization Practices
ACLS	Advanced Critical Life Support
ACTS	Aspen Complaint Tracking System
AED	automated external defibrillator
AHFSA	Association of Health Facility Survey Agencies
AHRQ	Agency for Healthcare Research and Quality
AIA	American Institute of Architects
AIDS	acquired immunodeficiency syndrome
AIR	American Institute for Research
ALJ	administrative law judge
ALT	alanine aminotransferase, also called SGPT
ANNA	American Nephrology Nurses' Association
ANP	advanced nurse practitioner
ANSI	American National Standards Institute
Anti-HBc	antibody to hepatitis B core antigen
Anti-HBe	antibody to hepatitis B e antigen
Anti-HBs	antibody to hepatitis B surface antigen
Anti-HCV	antibody to hepatitis C virus
Anti-HDV	antibody to hepatitis D virus
AOR	adverse occurrence report
APD	automated peritoneal dialysis
APN	Advanced Practice Nurse
APRN	Advanced Practice Registered Nurse
AST	aspartate aminotransferase, also called SGOT
AV	arteriovenous
AVF	arteriovenous fistula
AVG	arteriovenous graft
AWP	average wholesale price
BBA	Balanced Budget Act
BCG	bromcresol green—laboratory method for measuring albumin
BCP	bromcresol purple—laboratory method for measuring albumin
BFP	backflow preventer
BFR	blood flow rate
bid	twice daily
BMI	body mass index
BP, B/P	blood pressure
BSA	body surface area
BSI	blood stream infection
BUN	blood urea nitrogen
C	celsius
c/o	complaint of
CAD	coronary artery disease; cadaver transplant donor (deceased donor)
CAH	critical access hospital, Condition for Care at Home
CAHPS	Consumer Assessment of Healthcare Providers and Systems In-Center Hemodialysis Survey
CAPD	continuous ambulatory peritoneal dialysis
CAVH	continuous arteriovenous hemofiltration
CAVHD	continuous arteriovenous hemodialysis

Acronyms & Abbreviations

CAVHFD	continuous arteriovenous high-flux hemodialysis
CCBT	Certification in Clinical Biomedical Technology
CCHT	Certified Clinical Hemodialysis Technician
CCN	CMS certification number
CCNT	Certification in Clinical Nephrology Technology
CCPD	continuous cycling peritoneal dialysis, also called APD
CD	compact disk
CDC	U.S. Centers for Disease Control and Prevention
CDN	Certified Dialysis Nurse
CD-ROM	compact disk read only memory
CEO	chief executive officer
CEU	continuing education units
CfC	Conditions for Coverage
CFR	Code of Federal Regulations
CFU	colony -forming unit
ch/chl	chlorine/chloramine
CHF	congestive heart failure
CHOW	change of ownership
CHr	reticulocyte hemoglobin
CHT	Certified Hemodialysis Technologist/Technician
CIP	Core Indicators Project
CKD	chronic kidney disease
CI	confidence interval
CLIA	Clinical Laboratory Improvement Amendments
cm	Centimeter
CME	continuing medical education
CMS	Centers for Medicare & Medicaid Services
CNA	certified nursing assistant
CNE	continuing nursing education
CNN	certified nephrology nurse
CNN-NP	Certified Nephrology Nurse-Nurse Practitioner
CNS	coagulase negative staphylococci; central nervous system, or clinical nurse specialist
CO	CMS Central Office
CO2	carbon dioxide, bicarbonate (on labs)
COBRA	Consolidated Omnibus Budget Reconciliation Act
CoP	Conditions of Participation
CPM	Clinical Performance Measures
CPR	cardiopulmonary resuscitation
CPT	current procedural terminology
CQI	continuous quality improvement
CrCl	creatinine clearance
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CRP	C-reactive protein
CRRT	chronic renal replacement therapy
CHT	Certified Hemodialysis Technologist/Technician
CTC	certified transplant center
CVA	cerebrovascular accident
CVC	central venous catheter
CVD	cardiovascular disease

Acronyms & Abbreviations

CVVH	continuous venovenous hemofiltration
CVVHD	continuous venovenous hemodialysis
CVVHFD	continuous venovenous high-flux hemodialysis
DFC	Dialysis Facility Compare
DFO	deferoxamine
DFR	Dialysis Facility Report; dialysate flow rate
DFU	directions for use
DHD	daily hemodialysis, also SDHD (short daily hemodialysis)
DHHS	Department of Health and Human Services
DI	Deionization; Deficiency Index
dl	deciliter
DM	diabetes mellitus
DME	durable medical equipment
DMO	disease management organization
DNA	deoxyribonucleic acid
DNR	do not resuscitate
DON	director of nursing
DOPPS	Dialysis Outcomes and Practice Patterns Study
DOQI	Dialysis Outcomes Quality Initiative
DP	dialysate pressure
DTaP	diphtheria & tetanus toxoids & acellular pertussis vaccine
EAA	essential amino acid
EBCT	empty bed contact time
ECF	extra cellular fluid
EDs	emergency departments
EDW	estimated dry weight
EGHP	employer group health plan
EIA	enzyme immunoassay
EIPD	extended intermittent peritoneal dialysis
EKG	electrocardiogram
eKt/V	equilibrated Kt/V (see Kt/V)
EPA	U. S. Environmental Protection Agency
EPO	epoetin; erythropoietin
ER	emergency room
ESA	erythropoiesis-stimulating agent
ESR	erythrocyte sedimentation rate
ESRD	end stage renal disease
ETO	ethanol
EU	endotoxin units
EUR	European Region
F	fahrenheit
FBV	fiber bundle volume
FDA	U. S. Food and Drug Administration
FI	fiscal intermediaries
FSGS	focal segmental glomerulosclerosis
ft	foot; feet
FTE	full time equivalent (staffing)
GAC	granular activated carbon
GAO	Government Accountability Office

Acronyms & Abbreviations

GB	governing body
GED	General equivalency diploma
GFI	ground fault interruption
GFR	glomerular filtration rate
GI	gastrointestinal
GISI	glycopeptide-intermediate Staphylococcus aureus
GN	glomerulonephritis
H&P	history & physical
H&S	health & safety
Hb	Hemoglobin, also abbreviated Hgb
HBcAg	hepatitis B core antigen
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HBV DNA	hepatitis B virus deoxyribonucleic acid
HCFA	Health Care Financing Administration (now known as CMS)
HCQIP	Health Care Quality Improvement Program
Hct	hematocrit
HCV	hepatitis C virus
HCV DNA	hepatitis C virus deoxyribonucleic acid
HD	hemodialysis
HDF	hemodiafiltration
HDV	hepatitis D virus
HG	human granulocytic
Hg	mercury
Hgb	hemoglobin, also abbreviated Hb
HHA	home health agency
HHD	home hemodialysis
HICPAC	Hospital Infection Control Practices Committee
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HR	heart rate
hr	hour
HRSA	Health Resources and Services Administration
HTN	hypertension
IA	interagency agreement
IACET	International Association for Continuing Education and Training
IC	infection control
ICD-9	International Classification of Disease, Ninth Revision
ICD-10	International Classification of Disease, Tenth Revision
ICF/MR	intermediate care facilities for the mentally retarded
ICHD	in-center hemodialysis
ICU	intensive care unit
ID	identification
IDPN	intradialytic parenteral nutrition
IDT	interdisciplinary team
IG	Interpretive Guidance
IJ	immediate jeopardy; internal jugular
IM	Intramuscular

Acronyms & Abbreviations

IOM	Institute of Medicine
IPD	intermittent peritoneal dialysis
IR	incident report
IU	international unit
IVC	inferior vena cava
IVD	involuntary discharge
JCAHO	Joint Commission on Accreditation of Healthcare Organizations, now The Joint Commission
K+	potassium
KDOQI	Kidney Disease Outcomes Quality Initiative
KDQOL-36	Kidney Disease Quality of Life
KoA	measure of dialyzer clearance
Kt/V	kinetic modeling for dialysis adequacy reflecting clearance, time, & volume
KUF	ultrafiltration coefficient
L	liter
LAL	limulus amebosyte lysate
LDL	low density lipoproteins
LDO	large dialysis organization
LMRP	local medical review policy
LPN	licensed practical nurse
LRD	living related donor
LSC	Life Safety Code
LTC	long term care
LVN	licensed vocational nurse (used in TX and CA; equivalent to LPN)
M+C	Medicare Plus Choice, called Medicare Advantage or Medicare Part C
MAT	Measures Assessment Tool
MATCH-D	Method to Assess Treatment Choices for Home Dialysis
MCO	managed care organization
MCP	monthly capitation payment
MCV	mean corpuscular volume
MDRD	Modification of Diet in Renal Disease (study)
MDS	Minimum Data Set
mEq	milliequivalent
mg	milligram
MIC	minimum inhibitory concentration
min	minute
mIU	million units
ml	milliliter
mm	millimeter
MMWR	Morbidity and Mortality Weekly Report
MR	medical record
MRB	medical review board (part of every ESRD Network)
MRSA	Methicillin-resistant *Staphylococcus aureus*
MS	morphine sulfate
MSDS	material safety data sheet
MSSW	master of science in social work
MSW	master of social work
MW	molecular weight
MWF	Monday, Wednesday, Friday
N (n)	number

Acronyms & Abbreviations

N&V	nausea and vomiting
Na	sodium
NANT	National Association of Nephrology Technicians/Technologists
NEISS-AIP	National Electronic Injury Surveillance System-All Injury Program
NF	nursing facility
NFP	net filtration pressure
NFPA	National Fire Protection Association
Ng	nanogram
NH	nursing home
NHD	nocturnal hemodialysis
NHHD	nocturnal home hemodialysis
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDDM	non-insulin dependent diabetes mellitus
NIH	National Institutes of Health
NIPD	nightly intermittent peritoneal dialysis
NKF	National Kidney Foundation
nm	nanometer
NNIS	National Nosocomial Infections Surveillance
NOAA	National Oceanographic Atmospheric Association
NP	not performed; nurse practitioner
NPCR	normalized protein catabolic rate
NVAII	National Vascular Access Improvement Initiative (now known as Fistula First or FF)
NW	ESRD Network
OCSQ	Office of Clinical Standards and Quality
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplant Network
ORDI	Office of Research, Demonstration and Investigation
OSCAR	Online Survey Certification and Reporting System
OSHA	Occupational Safety and Health Administration
OT	occupational therapy; occupational therapist
P&P	policies & procedures
PA	patient assessment, Physician Assistant
PCP	patient care plan, primary care physician
PCR	protein catabolic rate
PCT	patient care technician
PD	peritoneal dialysis
PD-CIS	Peritoneal Dialysis Core Indicators Study
PE	physical exam
PEL	permissible exposure limit
PET	peritoneal equilibration test
PHI	protected health information
PKD	polycystic kidney disease
PM	preventive maintenance
PMMIS	Program Medical Management and Information Systems
PO4	phosphorus
POC	Plan of correction; plan of care
PPE	personal protective equipment
ppm	parts per million
PPS	Prospective Payment System

psi	pounds per square inch
Pt	patient
PT	physical therapy; physical therapist
PT/INR	prothrombin time/international normalized ratio
PTFE	polytetrafluoroethylene—material used to manufacture vascular access grafts
PTH	Parathyroid hormone
PVC	polyvinyl chloride
PVR	peripheral vascular resistance
PY	patient year
QA	quality assurance
QAPI	Quality Assessment and Performance Improvement
QB	blood flow rate
QD	dialysis flow rate
QI	quality indicators; quality improvement
QIES	Quality Improvement Evaluation System
QIS	Quality Indicator Survey
QM	quality management
R/O	rule out
RBC	red blood cells
RD	registered dietitian
REBUS	Renal Beneficiary and Utilization System
REMIS	Renal Management Information System
RIBA	recombinant immunoblot assay
RKF	residual kidney function
RN	registered nurse
RNA	ribonucleic acid
RO	reverse osmosis; regional office
ROM	range of motion
RPGN	rapidly progressive glomerulonephritis
RR	relative risk
RRF	residual renal function
RRT	renal replacement therapy
RT-PCR	reverse transcriptase polymerase chain reaction
RUF	reverse ultrafiltration
Rx	prescription
S&C	Survey & Certification
S/S	scope/severity; signs/symptoms
SSA	State Survey Agency
SC	subcutaneous
SCUF	slow continuous ultrafiltration
SD	standard deviation
SDHD	short daily hemodialysis
Sec	second
SGOT	serum glutamic oxaloacetic transaminase, also called AST
SGPT	serum glutamic pyruvic transaminase, also called ALT
SHR	standardized hospitalization ratio
SIMS	Standard Information Management System
SLE	systemic lupus erythematosus
SMA	simultaneous multiple analysis (of several laboratory tests at once)

Acronyms & Abbreviations

SMR	standardized mortality ratio
SNF	skilled nursing facility
SOB	short of breath
SOM	State Operations Manual
SOW	statement of work: the contract between the ESRD Networks and CMS
SPDF/SPRDF	special purpose dialysis facility; special purpose renal dialysis facility
spKt/V	Single pool Kt/V (see Kt/V)
SRTR	Scientific Registry of Transplant Recipients
SSA	State survey agency
STAR	standardized total admission ratio; Surveyor Technical Assistant for Renal Disease
STD	sexually transmitted disease
stdKt/V	standardized Kt/V (see Kt/V)
STR	standardized transplantation ratio
TB	tuberculosis
TBD	to be determined
TCV	total cell volume
TDS	total dissolved solids
TIA	transient ischemic attack
TMP	transmembrane pressure
TP	transplant
TPE	therapeutic plasma exchange
TQM	total quality management
TSA	tripticase soy agar
TSAT	transferin saturation
TSH	thyroid stimulating hormone
TTS	Tuesday, Thursday, Saturday
Tx	treatment
U	unavailable; urea
UF	ultrafiltration
UFR	ultrafiltration rate (a way of removing fluid during hemodialysis)
UKM	urea kinetic modeling (a way of measuring dialysis adequacy)
UM-KECC	University of Michigan Kidney Epidemiology and Cost Center
UNICEF	United Nations Children's Fund
UNOS	United Network for Organ Sharing
URR	urea reduction ratio
US	United States
USRDS	U.S. Renal Data System
UV	Ultraviolet
VA	Veteran's Affairs
VISA	Vancomycin intermediate *Staphylococcus aureus*
VISION	Vital Information System for Improving Outcomes in Nephrology
VP	venous pressure
VRE	Vancomycin-resistant Enterococcus
WBC	white blood cells
WHO	World Health Organization; waste handling option (direct connection to drain found on certain dialysis machines)
WNL	within normal limits