

**ESRD Network 11
Frequently Asked Questions
Conditions for Coverage**

Questions and answers compiled by CMS and taken from:

- Comments from the ESRD Interpretive Guidance Distributed 8/4/2008
- Questions submitted at the State Surveyor Training, Dallas, 9/2008

Comment/question	Response
Infection Control	
Must staff always change gloves and do hand hygiene when moving between a specific patient and that specific patient's machine?	During initiation and termination of treatment, CMS realizes it may not always be possible to change gloves and do hand hygiene while protecting the patient's access and maintaining patient safety. The intent is to minimize contact with the patient with the same gloves that have contacted potentially contaminated surfaces, such as the patient's dialysis machine.
Gloves: should staff change gloves between "setting up" the machine and initiating the patient?	Yes. Initiation of treatment is a point where there is high risk for contamination of the vascular system. The staff member needs to use fresh clean gloves when they initiate treatment with the patient.
Do gowns worn for PPE need to be impermeable?	Yes. Gowns, which cover the individual from chest to knees and the arms, must be worn whenever there is potential for blood exposure. 115
Can intravenous medication vials labeled for single use be used multiple times?	No. CMS is following the guidance of CDC, as published in the CDC's 2001 document on recommendations for dialysis facilities and the CDC's August 15, 2008 document, which clarified CDC's previous communication on parenteral medication vials.
How is a "dialysis station" defined?	A dialysis station is defined as the dialysis machine, a purified water connection, the dialysate concentrate container(s) or connections(s), and the treatment chair.
What is the appropriate method of disinfection of the patient station between patient shifts?	Clean all surfaces without visible blood following the low-level disinfection protocol using soap, detergent or detergent germicide. For visible blood, follow the intermediate-level disinfection protocol. Immediately clean the area with a cloth soaked with tuberculocidal disinfectant or 1:100 dilution of bleach (300-600 mg/dL free chlorine) following the manufacturer's directions for contact time. Wear gloves and place the used cloth in a leak proof container. After cleaning up all visible blood, apply disinfectant a second time using a new cloth or

	towel.
Define low level vs. intermediate disinfection.	“Low-level disinfection” means disinfection that kills most bacteria and is accomplished by using general-purpose disinfectants. “Intermediate-level disinfection” means disinfection that kills most bacteria and most viruses and is accomplished by using a tuberculocidal “hospital disinfectant” or a 1:100 dilution of bleach.
Can a disposable wipe be used to clean equipment or does a cloth soaked in bleach need to be used?	The requirement is that the equipment be cleaned and disinfected; the type of cloth or wipe to use is not specified.
Can hemostats be wiped clean or soaked with bleach?	After use, all equipment should be considered as potentially contaminated with blood, and should be handled with caution, disinfected or discarded.
Do fistula clamps have to be assigned for use on only one patient?	Not necessarily. Items taken to the patient hemodialysis station which can be adequately disinfected (i.e. immersing in disinfectant solution for sufficient time) may be used on more than one patient. V116
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 2/9/2009 is required to have an isolation room unless granted a waiver of this requirement by CMS. Existing facilities currently using an area may continue to use that “isolation area.” Existing facilities that begin caring for HBV+ patients after 2/9/2009 may designate an area for such use, unless they are expanding the physical location, in which case they must add an isolation room or obtain a waiver of the requirement. An isolation “area” is separated from other stations by a space at least equivalent to that of another dialysis station.
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.
If an existing clinic currently uses an area for HBV+ patients expands their physical capacity, may they continue to use an isolation area?	No. If an existing facility that is currently uses an isolation area for HBV+ patients expands their physical capacity, they must add an isolation room.
What process will be used for determining whether or not a facility can be granted a waiver for an isolation room?	The waiver process has not yet been defined. When defined, the waiver process will be distributed.

<p>How should concentrate containers be handled for isolated HBV+ patients?</p>	<p>Refillable concentrate containers must be surface disinfected at the completion of each treatment. Refillable acid concentrate containers should be kept in the isolation area and refilled at the door. Refillable bicarbonate concentrate containers may be removed for cleaning and disinfection. In the disinfection area, the isolations containers(s) and pick-up tubes(s) must be segregated in a dedicated area away from all other containers and pick-up tubes. If the container/pick-up tube is to be rotated out of the isolation area, it must be bleached before subsequent use.</p>
<p>Are dietitians, social workers, physicians, APRN, PA required to have routine HBV screening?</p>	<p>There is no requirement for routine screening of any staff members. The only screening required for employees is after completion of the vaccine series. All staff are required to be offered vaccine.</p>
<p>Water/Dialysate Treatment</p>	
<p>Does the use of an extra filter in the water distribution path or dialysate flow pathway on-line at the point of use constitute ultrapure dialysate?</p>	<p>No. Ultrapure dialysate is defined as having a bacterial content of less than 0.1 CFU/mL and an endotoxin count of less than 0.03 EU/mL using sensitive assays. Placing an extra filter in the water or dialysate pathways may or may not result in the production of ultrapure dialysate.</p> <p>CMS only monitors for the requirements of conventional dialysate. Use of these extra filters or other attempts to provide more pure dialysate is seen as a “best practice” and is not required.</p>
<p>Are water systems installed before 5/30/1997 subject to these regulations?</p>	<p>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 rules.</p>
<p>When the facility is going to be using the water in the storage tank at the start of the day, does the water system have to run for 15 minutes before testing?</p>	<p>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. (V196) Testing the water being “made”, even if the water in the storage tank is currently being used, ensures water safety as the “new”</p>

	water fills the tank.
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.
When must machines be tested for conductivity and pH?	Each machine must be tested for pH using a hand-held meter or other appropriate testing device, e.g., adequately-sensitive testing strips, before every dialysis treatment and whenever a different composition of acid concentrate is used. If the dialysis machine manufacturer requires testing for conductivity, there must also be testing using an independent testing device prior to each treatment and before using a different composition of acid concentrate in the same treatment.
Can pre-packaged (by the manufacturer) bicarbonate jugs be “topped off” when partially empty?	No. Topping off partially filled bicarb jugs is rarely appropriate, due to the high propensity for microbial growth, and combining pre-packaged liquid medications, which could have different lot numbers, is not an acceptable nursing practice.
How many dialysis machine/dialysate cultures must be done each month?	2 dialysis machines per month, and each machine must be cultured annually, at a minimum.
Should dialysate cultures be collected at the end of dialysis?	Cultures of water and dialysate should always be taken at the “worst-case” time: product water samples prior to disinfection, dialysate samples from the dialysate port of the dialyzer at the end of dialysis.
What are acceptable levels of chlorine and chloramine in water used for dialysis treatment? Are free chlorine and total chlorine the same thing?	<p>The allowable level for chlorine is 0.5 ppm; the allowable level for chloramine is 0.1 ppm.</p> <p>Free chlorine is different from total chlorine; tests for total chlorine include free chlorine. If the facility is using two tests, they would test for total chlorine and free chlorine, and subtract the result for free chlorine from the result for total chlorine to determine the result for chloramine.</p> <p>If only one test is performed, the test must detect both total chlorine and free chlorine, and be sensitive to levels less than 0.1 ppm. If only one test is performed, the facility must set the target value as less than 0.1 ppm.</p>

Is it acceptable for facilities to use the powder or tablet reagents to test water for chlorine/chloramine rather than testing strips?	Yes. The expectation is that facilities use a testing method that is approved by the FDA for testing of water for chlorine/chloramines and they use a test method that is sensitive to the levels required. The DPD methods using tablets/powders would meet this requirement.
Is there a regulation stating where in the water treatment system the water should be tested for chlorine/chloramine?	Yes. V192 requires 2 carbon tanks/banks with a sample port between them for the daily and each shift testing for chlorine/chloramine. It also requires a sample port after the second port after the second tank/bank for testing if the first test exceeds limits.
Can test strips sensitive to .5 be used to test for residual bleach after rinsing?	Yes.
Reuse	
Can an advanced practice registered nurse or physician assistant sign treatment orders for whether or not a patient will participate in the reuse program? Can the Advance practice registered nurse or physician assistant 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.
If the dialyzer reuses labels are affixed to individual patient reprocessing records, must those logs be filled in the patient's medical record?	The reprocessing records have to be treated as a medical record, but may be maintained separately. When the patient is no longer treated at the facility, the facility might choose to combine these records with the other records of that patient's care.
Physical Environment	
Are physicians, advance practice registered nurses, and physician assistants required to maintain current CPR certification?	No. CMS will not regulate whether physicians maintain current CPR certification. If advanced practice registered nurses and physician assistants are functioning as medical staff in lieu of physicians, CMS will not monitor whether they maintain current CPR certification.
Emergency Drugs: If the medical director states no drugs are needed, what is the recourse? Is there a minimum number or list of emergency drugs that must be available?	V411 requires that the nursing staff be trained in the use of emergency drugs. V413 requires that emergency drugs be present. The emergency drugs to be present may be defined by the medical director and cannot simply be no drugs are required. Minimally, the drugs expected are to be available include Benadryl, 50% dextrose,

	epinephrine, Solu-Medrol and other drugs as indicated for medications that could result in anaphylactic reactions.
AED requirement: if a hospital-based unit is located in the hospital, may the hospital CPR team respond to a cardiac emergency? Would the dialysis unit need an AED?	The facility would need to determine the average response time of the CPR team, and if that response time is less than~ four 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 get an AED.
Life Safety Code	
Will the Life Safety Code (LSC) survey occur in conjunction with the ESRD survey?	The LSC survey will generally be conducted at a separate time from the ESRD survey.
The new regulations incorporate the NFPA's Life Safety Code 2000. The code has been updated in 2006. Will CMS use this newer version or stay with the 2000 version?	CMS will use chapter 20 (for new dialysis facilities) and chapter 21 (for existing facilities) of the 2000 edition of the National Fire Protection Association's LSC for Ambulatory Health Care Occupancies.
Can the LSC be uniformly waived for dialysis providers? If enforced, the LSC would mean significant financial hardship on smaller facilities.	This regulation provides CMS the authority to waive specific provisions of the 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" for the facility. The waiver will only be granted if it is determined that the health and safety of the dialysis facility's patients are not adversely affected by the waiver. In some cases, the waiver may be limited to a specific time period.
If a dialysis center is located in a hospital, what LSC requirements apply?	Hospital LSC are more stringent than those in these regulations, and an ESRD located in a hospital must comply with the hospital LSC.
Will a freestanding home dialysis-training unit be required to meet the requirements of the LSC for Ambulatory Health Care facilities?	Yes. The home dialysis-training unit must meet the new ESRD Conditions for Coverage, which includes the Life Safety Code.
Patient Rights	
Under HIPAA rules, is a facility permitted to contact another entity about a patient that the facility is trying to place following an involuntary discharge without the permission of the patient?	A signed release is not required by HIPAA to share protected health information for continuity of care, such as but not limited to, providing emergency care, contacting other dialysis facilities as a part of the protocol for involuntary discharge, termination of treatment, or when asking police to help locate a patient so that he/she can receive dialysis.
What rights do patients have	Patient have the right to read their own medical

relative to their own medical record?	record, to have corrections made to their record, and to obtain a copy of their record, for which a nominal fee may be charged.
Is it acceptable to do chair-side review of the patient's plan of care?	Chair-side review of the patient's plan of care is acceptable if sufficient privacy can be provided. Other alternatives include the patient participating in the care plan meeting either in person or by teleconference from home. Patients also have the right to decline to participate in care planning.
How should patients be informed of charges for services that are not covered by Medicare?	If a facility plans to bill a patient for items and/or services which are usually covered by Medicare but are not considered "reasonable and necessary" in a particular situation (according to section 1862 of the Social Security Act), the patient should be informed and be offered an Advance Beneficiary Notice (ABN) to sign pursuant to section 1879 of the Social Security Act.
Can a dialysis facility refuse to treat a patient who is in the country illegally and has misrepresented their status by using a false SSN, etc.?	There is no federal law that denies health services to undocumented individuals. The regulation at V166 allows a dialysis facility to transfer or discharge a patient who is unable to pay. There should be evidence that the facility attempted to resolve payment issues, including verifying that state Medicaid will not cover the expenses (some states only use state funds to treat undocumented individuals) and notifying the undocumented individual about hospitals where he/she can get emergency dialysis. The federal law Emergency Medical Treatment and Active Labor Act (EMTALA) ensures that public access to emergency services provided by hospitals, physicians, and ambulance providers to stabilize the individual regardless of his/her ability to pay. Routine outpatient dialysis is not considered an "emergency" under EMTALA.
Patient Assessment	
What is the difference between a multidisciplinary assessment and an interdisciplinary assessment?	Multidisciplinary team members work sequentially and use the medical record as the chief means of communication. Interdisciplinary team members work collaboratively with regular meetings to discuss patient status and the evolving plan of care. Interdisciplinary teams work together toward common goals, pool their expertise, and use one another as a forum for problem solving.
Must the assessments, e.g. nutritional, psychosocial, medical history, be in one document or	The assessments may be either in one document or in separate documents, the key is that they are congruent rather than disparate. The regulations

can they be in separate forms?	do not specify.
What does “respond promptly” to laboratory results mean?	The interdisciplinary team must evaluate laboratory results as they become available and take action, as indicated.
Who is qualified to evaluate psychosocial needs?	A qualified social worker as defined by the Conditions at V691 is the interdisciplinary team member who is qualified to evaluate psychosocial needs.
The CfC requires that facilities need to document reasons why patients cannot receive care at home. How extensive does the documentation need to be?	The rules do not specify the mechanism for the documentation. The intent of this regulation is to ensure that each patient receives information about the modalities of home dialysis, and that each patient who is capable of doing home dialysis is given the opportunity to choose home dialysis if he/she desires. If a facility does not provide the option of home dialysis, patients have the right to know about other facilities that offer this option. The survey process will expect to find that patients receive information on the home dialysis option, and that eligible patients are offered a choice of home vs. incenter dialysis.
What rules apply to staff talking with family/support members about a patient?	While the IDT may not discuss a patient's protected health information (PHI) with family members/others without the patient's permission, it is not a violation of HIPPA for staff to ask a family members/others for information that would help the IDT provide care for the patient. HIPPA 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.
What is the difference between “initial” assessments and “comprehensive interdisciplinary” assessments?	“ Initial” assessments are assessments that are described under the Condition of Responsibilities of the medical director at V715. An “initial” assessment must be done by a member of the medical staff, i.e. 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 a review of medical records and consultation with the referring

	<p>physician without medical staff “seeing” the patient in the facility prior to the first treatment.</p> <p>“Comprehensive initial interdisciplinary assessments” are described in detail as the Conditions of Patient assessments.</p>
<p>Do transfer patients and transient patients need an initial comprehensive interdisciplinary assessment in 30 days or 13 treatments?</p>	<p>Each patient new to dialysis must have an initial comprehensive interdisciplinary assessment within 30 days or 13 treatments after admission. This requirement applies to all new dialysis patients, without regard to the modality of treatment. If the comprehensive assessment and plan of care for an experienced dialysis patient transferring from one dialysis facility to another is received with the patient transfer, the receiving patients IDT must conduct a reassessment within three months of the patient’s admission to the new facility. This same provision i.e., completion of a reassessment within 3 months of admission, applies to transient patients who are received with the sending facility’s comprehensive assessment and plan of care.</p>
<p>Discuss the expectation for “compliance within a year.” Does this mean, “don’t cite” for one year?</p>	<p>Allowing facilities up to a year from October, 14 2008 to come into compliance with these two Conditions for current patients does not mean “don’t cite” these requirements for a year. Patients new to dialysis (or returning from transplantation, or changing modalities) are expected to have an assessment within 30 days/13 treatments of admission, and a POC immediately implemented. When a transferred patient is received with a PA/POC from the transferring unit, the receiving unit is expected to reassess the patient within 3 months of admission. The requirements discussed above are expected to be “met” at the time of surveys during the first year of implementation. In addition, the facility should have a plan for completing PA/POC for all current patients within the year and have begun accomplishment of that plan.</p>
<p>Does an acute patient who dialyzes in an outpatient facility require the full assessment and care plan process? This patient has been discharged from a hospital and is coming to the outpatient facility until kidney</p>	<p>Every patient is expected to receive the same level of care. If an “acute” patient is treated in the outpatient facility longer than 13 treatments/30days, the PA/POC would be expected to be completed.</p>

function is regained.	
Is there any specific format required to document the patient assessment and plan of care? Can these both be included in one form?	There is no required; both the assessment and the POC can be included in the same form.
Discuss the mechanism of updating an assessment: what would the document look like, a series of assessments?	If a patient is stable, but does not achieve or maintain the goal for one or more areas in the POC, the facility would need to update that portion of the POC. This could be done on the assessment form, or in the progress notes of one or more of the IDT members. The form of the documentation is not specified.
Patient Plan of Care	
How is the Measures Assessment Tool (MAT) to be used?	The MAT is a reference guide for current professionally accepted standards and values for listed clinical elements. The listed elements are community-accepted standards and target levels. Each patient should be treated individually. When a specified target is not met, either the plan of care should be adjusted to achieve the community-accepted standard or an explanation should be provided by the interdisciplinary team member or group. Initially, goals for some patients may need to be different from these targets and then incrementally changed to the standard value as the patient outcomes improve.
Are facilities required to hold care plan meetings with all disciplines and patients at the same time as opposed to passing around the document and each person signing off on it?	The patient assessment and POC are required to be developed by the IDT, which includes the patient. These can be accomplished many ways; best practice would have to be face-to-face meetings of the team including the patient; other options would be do accomplish part of the assessment/POC during chair-side rounds; having each discipline work with the patient and collaborate with their findings. The POC must demonstrate collaboration and congruence, which is not likely to happen if a piece of paper is just passed around among the team.
Can the medical director substitute for the “treating physician” in the IDT?	The regulation expects “ a physician treating the patient” to be a member of the IDT. If the medical director is not one of the physician’s treating the patient, he/she would not be allowed to routinely substitute on the IDT.
When the IDT develops the POC, is it expected that all the	The IDT members are expected to interact and share information for the comprehensive

members be present and document their presence?	assessment and to develop the POC. This may be accomplished in an IDT conference or use 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.
What documentation of the work of the IDT will we expect to see?	For individual patients: look at the patient assessment, the plan of care, progress notes, physician orders, treatment records, and for home patients, clinic visit reports. For the facility, expect to see participation of the IDT in QAPI.
If the patient does not wish to participate in the IDT, what documentation is expected in their medical record?	The patient has a right to refuse to participate in the IDT discussions about his/her care, and the IDT should document their attempts to include the patient in such discussions and the refusal. Because the patient's situation and/or outlook may change, the IDT should continue to make and document good faith attempts to include the patient in the IDT discussions, or those with individual members, to assess the patient's care needs.
Should the POC be one shared document or can each discipline have its own POC?	The written plan of care can be one document or composed of separate sections, but must be congruent and reflect the integration of the comprehensive assessments contributed by all members of the IDT.
What criteria from a transplant center are supposed to be used to screen patients as potential transplant candidates?	Transplant centers are required to develop "selection criteria" and share these on request with potential candidates and dialysis facilities. These often read like "exclusion criteria" as they list diagnoses or conditions that would exclude a patient from consideration for transplantation.
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.
If a stable patient does not meet one quality indicator in the POC does the entire team need to reassess or can only one member of the team update and revise the POC?	If the patient does not meet the expected goal, the IDT must reassess that specific area. POC does not "require" a patient to meet every goal. Any member of the team including the patient may document why goals are not met. In some areas, such as rehabilitation, volume status and nutritional status the majority of the actions taken might be developed by one team member.

<p>V560 requires that every dialysis patient is to be seen by a physician/APRN/PA monthly and periodically while the patient is receiving dialysis (if the patient is on in-center HD). For patients in remote areas, would seeing their primary care provider, who would then be in contact with the nephrology physician team, be sufficient to meet this requirement?</p>	<p>The POC would need to address specific hardships patients might have in being able to see their physicians monthly. The expectation is that a member of the medical team of the dialysis provides routine care including monthly visits.</p>
<p>What if the patient misses or shortens treatment time or gains excessive fluid between treatments resulting in an inability to achieve and “adequate” dialysis?</p>	<p>The interdisciplinary team is responsible for ensuring that each patient understands the consequences of his/her behavior in terms of treatment results. In addition, the staff should work with the patient to address behaviors that result in poor treatment results, such as missing and shortening treatments. Ultimately, the patient can choose to continue behaviors that result in lessened treatment results. With documentation of educational efforts, the patient’s choice can be an explanation on a plan of care for not receiving standard treatment results.</p>
<p>What happens if the patient has wasting disease (cachexia) or chronic inflammation, which contribute to poor nutritional status?</p>	<p>The plan of care should acknowledge those factors that limit the achievement of nutritional status goals.</p> <p>Each patient may not meet all target standards developed for the elements in the plan of care. However, the medical records of patients with outcomes lower than expected should demonstrate continuing efforts, which are tailored, implemented, assessed and revised to address individual challenges.</p>
<p>Regarding heparin doses administered that do not match physician orders, some manufacturers allow a difference of +/- 200 units. At what point would this be considered a deficient practice?</p>	<p>The physician order is the dose that must be delivered. If the dose is different from the order, there should be an explanation for the treatment where the delivered dose is different, and evidence of discussion with the physician to adjust the dose if indicated.</p>
<p>The regulation states that the facility should use a standardized mental and physical assessment tool “chosen by the social worker”, but the National Quality</p>	<p>Facilities can use any standardized survey of physical and mental functioning, including the KDQOL-36 to comply with the regulation. In the future, facilities will need to report electronically in CROWNWeb the percentage of eligible patients</p>

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?	who have taken the KDQOL-36 annually. Using the KDQOL-36 starting with the implementation date of these regulations will allow tracking of comparable historical data.
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.
What survey tool for mental and physical functioning should be used for pediatric patients?	The 4/1/2008 CMS CPMs do not specify what survey to use with pediatric patients <18 years. The social worker should choose an age-appropriate standardized mental and physical assessment survey for pediatric patients.
Care at Home	
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.
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 rate to reimburse physicians who manage ESRD home patients as a single monthly rate, regardless of the number of face-to-face physician or practitioner visits. Although a frequency of home visits does not apply to home patients in the MCP, the CfC require equivalent care among facility-based and home patients. Therefore, a monthly visit is required for each home visit by either a physician, and advance practice nurse or a physician assistant. This visit may be conducted in the dialysis facility, at the physician's office, or in the patient's home.
What are the "acceptable reasons" for a home patient not to be seen by a physician every month?	If a home patient himself/herself chooses not to be seen by a physician every month, that is an "acceptable" reason because patient choice is a hallmark of these ESRD regulations. However, if there is a pattern of a home-based patient consistently not seeing a physician, the patient's interdisciplinary team should assure that he/she is not unstable according to the definition in the regulations and address the lack of medical oversight with the patient through the "plan of care" process.
Can dialysis facilities that are	Yes. CMS will issue an updated Survey and

certified to provide home care to patients residing in long-term care facilities continue to provide that service under these new regulations?	Certification letter with instructions regarding this service under the new regulations.
How frequently should data be reviewed for home patients?	Time-sensitive data and information, such as radiology, pathology, and laboratory results, along with hospitalization reports should be reviewed upon receipt by a physician or a practitioner functioning in lieu of a physician. “Self monitoring” data from home patients must be retrieved and reviewed by the facility at least every two months.
Quality Assessment and Performance Improvement	
Is there some way to get a copy of the CAPHS survey?	Yes. You can go to www.caphs.ahrq.gov and download a single survey or the entire CAPHS kit. This survey is validated for adult in-center hemodialysis patients.
Where would tracking for blood loss, machine malfunction, clotting, prolonged bleeding and allergic reactions be reviewed under the requirements of QAPI? Some seem like infection control issues and some seem like medical errors?	The facility may decide in what portion of the QAPI program to discuss these issues; the important point is that each of the problems listed must be included in the QAPI program, and those that may be related to infection control would need to be tracked and trended as part of the infection control auditing.
How is the Measures Assessment Tool (MAT) used for QAPI?	The MAT is a reference for community-accepted standards and values for listed elements of QAPI. Within their individual QAPI program, facilities are expected to use the MAT for a community-accepted standards/values associated with clinical outcomes. If a facility has areas of QAPI that do not meet target levels (per MAT) or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving those outcomes. The important aspects of the QAPI program are appropriately monitoring data/information; prioritizing areas for improvement; determining potential root causes; developing, implementing, evaluating and revising plans that result in improvements in care.

Can the IDT for the QAPI team all be “corporate” people as opposed to facility staff? Can the QAPI all be done at the corporate level?	The facility’s IDT must be responsible for the facility’s QAPI. Corporate staff (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 meetings jointly, but records of each facility’s trends, analysis, plans, timetables, and accountability must be maintained.
If the facility incident reports are sent to the corporate risk management department rather than being kept onsite, is it acceptable to only review the aggregate data kept by the facility? Are we authorized to request actual incident reports?	By virtue of the facility signing a Medicare agreement, a surveyor has the right to review any and all records of the facility, including adverse occurrences or incident reports. The facility must provide the actual incident report (or a copy) on the surveyor’s request.
Since there is no timeframe mentioned in the regulations, how often should we expect the QAPI meetings to take place?	The scheduling of these meetings must be sufficient to address the facility’s QAPI needs. Data must be reviewed as it becomes available; most data is available monthly. If immediate action is required, there must be a system to allow such action to be taken.
What should be trended and tracked for medical injuries and errors?	Facilities are expected to track patient/staff injuries, treatment errors, medication errors, hospitalizations, deaths, cardiac arrests in the facility, acute allergic-type reactions, and major blood loss, at a minimum.
Are facilities expected to use the CAHPS (a standardized experience of care assessment survey) to track patient satisfaction/grievances?	V636 and V765 require facilities to monitor and track patient grievances. Effective 4/1/2008, CMS endorsed the measurement of in-center hemodialysis patient satisfaction using the CAPHS survey as a CPM.
Personnel	
What happens when a physician has completed a board approved training program in nephrology, but the person is not board approved, and the person has been serving as medical director for an extensive period of time?	In addition to completing a board-approved training program in nephrology, and having at least 12 months experience in nephrology, the medical director must be certified in internal medicine, pediatrics, or nephrology. If a person, as specified above, is not available, the Secretary of the Department of Health and Human Services may “approve” another physician to direct the facility. An alternative “Secretarial” process is expected to be rare and related to physician accessibility. A time limited “approval” may be issued in some cases to an individual physician time to qualify as the medical director.

Clarify when a physician is required in the care of patients, vs. an APRN or PA.	<p>A physician is expected to participate in the IDT. An APRN/PA may provide treatment orders, assess patients, respond to emergencies, etc. Look at outcomes: if the outcomes indicate that patients are receiving safe and effective care, there is no requirement for a specific level/number of visits/number of hours that the physician must be involved.</p> <p>Recognize that the Medicare reimbursement regulations base payment on the physicians seeing the patient at least monthly; additional monies are paid for 4 X month. Three of those visits may be done by an APRN/PA.</p>
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.
Must the facility have a nurse manager?	The facility must employ a full-time manager who is available all hours that the facility is open.
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” of the qualifications of the charge nurse are in “providing nursing care. These experiences may be in either a chronic or acute setting.
Is there a definition of the job duties of 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 guide this.
If the CEO is an RN, can he/she also be the Chief Nursing Officer?	Yes.
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. RNs 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 has shown that an RN from his/her country is “equivalent” to an RN in the U.S., then experience in another country will meet the regulatory requirement.
Would it be acceptable if the	If all the nurses are qualified as nurse managers,

nurse manager changed each day, i.e., the charge nurse of the day or the shift is considered the nurse manager that day?	there is no regulation to prohibit this. Look at outcomes: consider turnover of staff; whether new staff are oriented prior to being assigned responsibilities for care of patients or support roles; QAPI re patient outcomes, medical errors/injuries, patient satisfaction. Cite the problems you identify under Governance not providing adequate resources and not assuring staff have sufficient time to meet the needs of the patients.
Can there be a different charge nurse on MWF and TTS?	A charge nurse must meet the qualifications in the regulations but can work different days and shifts.
Can an LPN/LVN be “on call” for home patients?	This depends on your state nurse practice act and the policy of the facility. If your state nurse practice act does not allow an LPN/LVN to assess the patient, that the individual could not take call, or would have to triage calls, referring assessment to an RN, but handling calls not requiring assessment such as calls for assistance with equipment or supplies.
What happens if the dietitian does not have at least one year in a clinical setting?	The dietitian must have one year of clinical experience to be categorized as the qualified dietitian required at each dialysis facility. A dietitian with less than one year of experience cannot do the patient assessments plans of care, QAPI program review, or care at home components of the regulations. The facility may define other tasks for a dietitian with less than one year of experience in a clinical setting.
Could there be some “grandfathering” for registered dietitians who are currently working but did not have the year of experience as required in the new regulations?	These requirements for personnel qualifications are applicable to persons being hired after 10/14/08 and to those RDs who do not yet have a year clinical experience as of 10/14/08. The regulation does not have a grandfather clause or any exception for this requirement. A dietitian who does not have one year post-RD clinical experience may be able to obtain that experience working under an RD who does meet these requirements.
Can a facility administrator also be the social worker?	Yes.
How often are social workers required to chart in the progress notes?	There is no requirement for the frequency of SW progress notes-the documentation by the SW should be as needed to show assessment, planning, and implementing care to meet the needs of the patient.

<p>What does “specialization in clinical practice” mean in the qualifications statement for master’s-prepared social workers?</p>	<p>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.”</p>
<p>Who is classified as a “patient care dialysis technician”?</p>	<p>Technicians are described using a variety of terms, including “biomedical technician” and “machine technician.” The CMS requirements for the “patient care dialysis technician” apply to any technician who has any responsibility for 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 technician.”</p>
<p>Some experienced patient care technicians (PCTs) do not have evidence of a high school diploma or GED. How will this be handled?</p>	<p>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 10/14/2008 who are lacking evidence of a high school diploma may use that work experience as an “equivalency” to a high school diploma.</p>
<p>With the new regulations, PCTs are expected to complete a training program focused on the operation of the kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills. What is expected of experienced technicians?</p>	<p>For “experienced” PCTs, meaning those who have been employed as a PCT 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 a successful completion of a written exam(s) over the required content and a skills checklist completed by observation of the PCTs skills by a registered nurse. These PCTs would be expected to achieve certification within the specified time period.</p>
<p>How do we verify content of PCT training when a facility personnel file only includes a certificate from the corporation and the training is done at a corporate off-site</p>	<p>Each facility must make available the content of the training program for the surveyor to validate that the program covers the specific topics required.</p>

location?	
Will CMS track technicians who do not have appropriate qualifications/certifications, but move from one facility to another?	CMS does not maintain a registry of technicians. However, CMS intends to “count” experience from one facility to another in determining the 18 months time limit for completing certification, unless the PCT has at least an 18 month break in employment as a PCT.
What does CMS mean by a “standardized test?”	A “standardized test” means a test developed and tested to validly and reliably measure the knowledge required to demonstrate competency in an area.
Medical Director	
Many facilities have a group of physicians that collectively serve the facility as medical directors. What provisions are made for this practice?	For these regulations, each facility must have a single medical director identified as responsible for carrying out the duties of this position. The governing body and medical director may designate additional physicians to direct different program components in that facility, e.g., home hemodialysis program, peritoneal dialysis program, as long as all components ultimately report to the facility medical director and are under the same QAPI program and governing body oversight.
Is there a limit to the number of facilities for which a physician can be Medical Director?	There is no restriction on the number of facilities where an individual physician can function as Medical Director. The CfC of Medical Director outlines the responsibilities that the Medical Director fulfill. If the Medical Director is over multiple facilities, and there are survey findings in areas which may affect the safety of patients or quality of care, consider whether the Medical Director is meeting all of the responsibilities, or if his/her absence and lack of guidance have contributed to the findings.
How often must the Medical Director be physically present at the facility?	The Medical Director should devote sufficient time, and be actively involved in the oversight of the facility: attending care plan meetings, QAPI committee meetings, guiding development of performance improvement/action plans, and educating staff. As a guide, each facility’s financial cost report, filed with CMS, considers the Medical Director role a 0.25FTE.
Medical Records	
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?

Governing Body	
Are all medical staff members required to attend QAPI meetings?	The medical director is responsible for the facility's QAPI program; at least one member of the medical staff needs to participate on the interdisciplinary team. The medical director may serve as staff representative for the QAPI program.
What happens when a staff physician determines he/she can no longer care for a patient?	If there is no other physician on the staff who is available or willing to accept responsibility for the care of the patient, attention must be paid to State practice boards for physicians, which generally require that some notice be given to patients to avoid the charge of patient abandonment. The facility would need to follow these steps for involuntary discharge, including the 30-day notice, reassessment of the patient, attempts for placement, etc., during the physician's period of notice to the patient.
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 should call "911" for immediate medical care.
Governance	
What is an "abbreviated involuntary discharge procedure?" Who determines what is contained in an "abbreviated involuntary discharge procedure?" Are patients required to help patients find 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." Any angry verbal outburst or verbal abuse is not considered to be an "immediate severe threat." In instances of an "immediate severe threat," facility staff may determine to use "abbreviated" involuntary discharge or transfer procedures. These immediate procedures may include taking protective actions, such as calling "911" and asking for police assistance. In this scenario, there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer. After the emergency is addressed and staff and

	other patients are safe, staff must notify the State and Network of the involuntary discharge, and document this contact and the exact nature of the “immediate severe threat” in the patient’s medical record.
Does the facility have to contract with a hospital for admission of patients in emergencies?	V770 Requires that each facility have an agreement with an inpatient hospital that provides inpatient dialysis.
Are long term care facilities that provide dialysis in the LTC facility to patients, whose care might be paid for by Medicaid, required to have a contract with an ESRD facility for these patients?	CMS has an S&C letter dated 2004 regarding the dialysis of patients in nursing homes. An updated letter will be developed for this service.
Do facilities need to have a signed transplant agreement?	No. This is not required in the new regulations.
Survey and Certification	
A new facility opens after October 14, 2008, are they expected to be in compliance with these regulations?	All ESRD Facilities must be in compliance with these regulations as of 10/14/08. The LSC requirements in the physical environment CfC have specific dates and requirements for compliance depending on when the building was constructed and/or plans approved.
Is the facility required to have a current patient in training for an initial survey for HD and PD home training and support for the surveyor to observe the care that staff render? Does the patient have to be in training at the time of the initial survey?	Every initial survey requires the facility to have at least one patient on service. If the only service being offered is home training and support, then the patient would need to be a home patient. There is no requirement that a patient actually be in training at the time of the survey.
Initial surveys have been delayed for several months due to our budget constraints. If these facilities are not surveyed until after 2/2/2009 will a waiver be granted for an isolation room?	Facilities that have building permits or completed plan reviews before October 14, 2008 are not required to obtain a waiver nor required to have an isolation room.
When can we start using these regulations?	In general, the regulations are effective on October 14, 2008 and surveys after that date should use these regulations. There are different dates for some sections of the regulations: V128-129 state 2/9/09 as the effective date for the Life Safety Code, and V695 states that dates for certification of technicians based on their hire date.