

Compendium of Comments and Responses Related to the Interpretive Guidance

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V113	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.
V118	Infection control: 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.
V118	Infection control: 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.
V122	Infection control: 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 connection(s), and the treatment chair.
V122	Infection control: What is appropriate method of disinfection of the patient station between patient shifts?	Clean all surfaces without visible blood following the low level disinfection protocol using soap, detergent or detergent germicide. For visible blood, follow the intermediate-level disinfection protocol immediately clean the area with a cloth soaked with tuberculocidal disinfectant or 1:100 dilution of bleach (300--600 mg/L free chlorine) following the manufacturer's directions for contact time. Wear gloves and place the used cloth in a leak proof container. After cleaning up all visible blood, apply disinfectant a second time using a new cloth or towel.
V127	Infection control: How can you tell if patients/staff have responded to the hepatitis B vaccine?	The CDC defines an adequate response to vaccination as a laboratory result of $\geq 10\text{mIU/mL}$ anti-HBs. The laboratory performing the testing for anti-HBs must be able to define a 10mIU/mL

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		<p>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 10mIU/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.</p>
V128	<p>Infection control: When is an isolation room required for hepatitis B + (HBV+) patients? When is an isolation area acceptable? How is an isolation area defined?</p>	<p>Any facility constructed after February 9, 2009 is required to have an isolation room unless granted a waiver of this requirement by CMS. Existing facilities currently using an area may continue to use that “isolation area.” Existing facilities that begin caring for HBV+ patients after February 9, 2009 may designate an area for such use, unless they are expanding the physical location, in which case they must add an isolation room or obtain a waiver of the requirement. An isolation “area” is separated from other stations by a space at least equivalent to that of another dialysis station.</p>
V130	<p>Infection control: 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 “isolation” container(s) and pick-up tube(s) must be segregated in a dedicated, designated area away from all other containers and pick-up tubes. If the container-pick-up tube is to be rotated out of the isolation area, it must be bleached before subsequent use.</p>
V181	<p>Water/dialysate treatment: 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>

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		<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>
V184	<p>Water and dialysate: 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>
V210	<p>Water/dialysate treatment: 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?</p>	<p>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.</p>
V249	<p>Water/dialysate treatment: What are some safeguards for the risky business of changing from one dialysate proportioning ratio to another?</p>	<p>The best practice is to restrict use of all machines in a facility to one proportioning ratio. The medical director and the responsible staff person must be knowledgeable about the mixing ratio that the machines are set up to use.</p> <p>If different ratios are in use in the same facility, supplies for the different ratios must be segregated and labeled clearly to avoid a mismatch; staff must be carefully instructed on the risks of mismatch; and audits must be frequently done to assure these safeguards are effective.</p>
V250	<p>Water/dialysate treatment: When must machines be tested for conductivity and pH?</p>	<p>Each machine must be tested for pH using a hand-held meter or other appropriate testing device, e.g. adequately-sensitive</p>

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		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.
V311	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 which 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.
V410	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.
V417	Life Safety Code (LSC): If a portion of the dialysis facility is used for other, but related purposes, such as physician offices and exam rooms, do these areas need to be separated from the dialysis unit by a one-hour firewall?	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.
V417	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.
V417	Life Safety Code: 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.
V420	Life Safety Code: Can the Life Safety Code be uniformly waived	This regulation provides CMS the authority to waive specific provisions of the LSC. A

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	for dialysis providers? If enforced, the LSC would mean significant financial hardship on smaller facilities	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.
V455	Patients’ 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 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.
V455	Patients’ rights: What rights do patients have relative to their own medical records?	Patients have the right to read their own medical record, to have corrections made to their record, and to obtain a copy of their record, for which a nominal fee may be charged.
V456	Patients’ rights: 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.
V462	Patients’ rights: How should patients be informed of charges for services that are not covered by Medicare?	If a facility plans to bill a patient for items and/or services which are usually covered by Medicare but which are not considered “reasonable and necessary” in a particular situation (according to section 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.
V501	Patient assessment: What is the difference between a “multidisciplinary” assessment	“Multidisciplinary” team members work sequentially and use the medical record as the chief means of communication.

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	and an “interdisciplinary” assessment?	“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.
V501	Patient assessment: 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 they are congruent rather than disparate. The regulations do not specify.
V505	Patient assessment: What does “respond promptly” to laboratory results mean?	The IDT must evaluate laboratory results as they become available and take action, as indicated.
V506	Patient assessment: Can an alternative to the tuberculin skin test (TST) be used to test for tuberculosis?	The CDC recommends that all dialysis patients be tested at least once for baseline TST results. For individuals who are unable to tolerate use of the TST, chest x-rays may be used to test for tuberculosis.
V510	Patient assessment: Who is qualified to evaluate psychosocial needs?	A “qualified social worker,” as defined by the Conditions at V691, is the IDT member who is qualified to evaluate psychosocial needs.
V512	Patient assessment: The CfC require that facilities need to document reasons why patients cannot receive care at home. How extensive does the documentation need to be?	The rules do not specify the mechanism for the documentation. The intent of this regulation is to ensure that each patient receives information about the modalities of home dialysis, and that each patient who is capable of doing home dialysis is given the opportunity to choose home dialysis if he/she desires. If a facility does not provide the option of home dialysis, patients have the right to know about other facilities that offer this option. The survey process will expect to find that patients receive information on the home dialysis option; and that eligible patients are offered a choice of home versus in-center dialysis.
V514	Patient assessment: What rules apply to staff talking with family/support members about a patient?	While the IDT may not discuss a patients protected health information (PHI) with family members/others without the patient’s permission, it is not a violation of

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		<p>HIPAA for staff to ask family members/others for information that would help the IDT provide care for the patient. HIPAA does not prohibit a staff member from educating a family member or other support person about how to help the patient with diet, medications, and coping with kidney disease.</p>
V516	<p>Patient assessment: What is the difference between “initial” assessments and “comprehensive initial interdisciplinary” assessments?</p>	<p>“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 review of medical records and consultation with the referring 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 at the Condition of Patient assessments.</p>
V516	<p>Patient assessment: Do transfer 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 in transfer, the receiving patient’s IDT must conduct a reassessment within three</p>

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		<p>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>
V518	<p>Patient assessment: What procedure is used to draw blood samples for calculating “adequate” dialysis or Kt/V for hemodialysis patients?</p>	<p>The facility must ensure that the method/procedure for drawing the blood sample to measure Kt/V will produce accurate results. At the time of the publication of these regulations, the stipulated method for drawing blood samples to measure Kt/V included the following:</p> <ul style="list-style-type: none"> • Pre- and post-samples are drawn at the same treatment; • Pre-sample is drawn just prior to the start of treatment; • Slow flow/stop pump technique is used for the post-sample; staff should slow the blood pump speed to 50-100 mL/min for 15 seconds before drawing blood. In the event the equipment in use does not allow for “slow flow”, stop flow may be substituted; • After 15 seconds, staff should draw the post dialysis BUN sample from the arterial port closest to the patient. <p>All staff members should be using the same method as described above.</p> <p>Home hemodialysis patients should be instructed to draw their samples in this same way.</p>
V540	<p>Patient plan of care: How is the Measures Assessment Tool (MAT) to be used?</p>	<p>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</p>

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		<p>explanation should be provided by the IDT 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.</p>
V543	<p>Patient plan of care: How is volume status measured?</p>	<p>Volume status is measured in terms of the dialysis patients “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. Excess fluid accumulation may have adverse effects, e.g. hypertension, left ventricular hypertrophy, cardiovascular complications, and hospitalizations. Removal of too much fluid in one dialysis treatment or going below the patient’s target weight may cause hypotension, cramping, and clotting of the vascular access. Each patient should be weighed before and after each treatment, and a target weight identified for each patient.</p>
V544	<p>Patient plan of care: What if the patient misses or shortens treatment time or gains excessive fluid between treatments resulting in an inability to achieve an “adequate” dialysis?</p>	<p>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.</p>
V545	<p>Patient plan of care: 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 which 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</p>

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		<p>expected should demonstrate continuing efforts which are tailored, implemented, assessed, and revised to address individual challenges.</p>
V550	<p>Patient plan of care: How can dialysis facilities be responsible for vascular access results? What does the dialysis facility do if records are not available from the surgeon regarding the decision and placement for the current vascular access?</p>	<p>The Department of Health and Human Services' Breakthrough Initiative on Fistula First describes actions that dialysis centers can take to both increase fistula use in dialysis patients and decrease the inappropriate use of catheters.</p> <p>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.</p>
V552	<p>Patient plan of care: 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?</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 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.</p>
V552	<p>Patient plan of care: What is the schedule for administering the standardized mental and physical assessment survey tool?</p>	<p>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.</p>
V552	<p>Patient plan of care: What survey tool for mental and physical functioning should be used for pediatric patients?</p>	<p>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.</p>
V560	<p>Care at home: How is CMS going to reconcile the CfC home patient visit requirement vs. the home patient MCP guidance?</p>	<p>The monthly capitation payment (MCP) sets a specific rate to reimburse physicians who manage ESRD home patients as a single monthly rate, regardless of the number of face-to-face physician or practitioner visits. Although a frequency of required visits does not apply to home</p>

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		<p>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, an advance practice registered nurse, or a physician assistant. This visit may be conducted in the dialysis facility, at the physician’s office, or in the patient’s home.</p>
V560	<p>Care at home: What are the “acceptable reasons” for a home patient not to be seen by a physician every month?</p>	<p>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 IDT should assure that he/she is not unstable according to the definition in these regulations and address the lack of medical oversight with the patient through the “plan of care” process.</p>
V580	<p>Care at home: Can dialysis facilities that are certified to provide home care to patients residing in long-term care facilities continue to provide that service under these new regulations?</p>	<p>Yes. CMS will issue an updated Survey and Certification Letter with instructions regarding this service under the new regulations.</p>
V587	<p>Care at home: How frequently should data be reviewed for home patients?</p>	<p>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.</p> <p>“Self monitoring” data from home patients must be retrieved and reviewed by the facility at least every two months.</p>
V626	<p>QAPI: How is the Measures Assessment Tool (MAT) used for QAPI?</p>	<p>The MAT is a reference for community-accepted standards and values for listed elements of QAPI. Within their individual QAPI program, facilities are expected to use the MAT for community-accepted standards/values associated with clinical outcomes. Facilities are expected to use CROWNWeb and Dialysis Facility Reports</p>

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		<p>to determine comparison or “average” values associated with clinical outcomes.</p> <p>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.</p> <p>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.</p>
V634	QAPI: 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.
V636	QAPI: Are facilities expected to use the CAHPS (a standardized experience of care assessment survey) to track patient satisfaction/grievances?	V636 and V765 require facilities to monitor and track patient grievances. Effective 4/1/2008, CMS endorsed the measurement of in-center hemodialysis patient satisfaction using the CAHPS survey as a CPM.
V661	Special purpose dialysis facilities: Do peritoneal dialysis camps need to be certified as “special purpose renal dialysis facilities?”	Camps that provide only peritoneal dialysis on-site are not required to be certified as the treatment provided is considered a “home” treatment, and the dialysis facility providing training and support is expected to continue in the support role.
V682	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 (DHHS) may “approve” another physician to direct the facility. An alternative

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		<p>“Secretarial approval” process is expected to be rare and related to physician accessibility. A time-limited “approval” may be issued in some cases to give an individual physician time to qualify as a medical director.</p>
V683	<p>Personnel: Does the nurse manager need to be available 24/7 for on-call coverage?</p>	<p>The nurse manager can share on-call coverage with other qualified staff.</p>
V684	<p>Personnel: What qualifies as “experience” for the nurse manager, self-care training nurse, and charge nurse?</p>	<p>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.</p>
V684	<p>Can an RN serve as the nurse manager if all of her related experience (the 1-year requirement) was obtained overseas?</p>	<p>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.</p>
V690	<p>Personnel: What happens if the dietitian does not have at least one year in a clinical setting?</p>	<p>The dietitian must have one year of clinical experience to be categorized as the qualified dietitian required at each dialysis facility. A dietitian with less than one year of clinical experience can not 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.</p>
V691	<p>Personnel: What does “specialization in clinical practice” mean in the qualifications’ statement for masters-prepared</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</p>

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	social workers?	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.”
V692	Personnel: Who is classified as a “patient care dialysis technician?”	Technicians are described using a variety of terms, including “biomedical technician” and “machine technician.” The CMS requirements for the “patient care dialysis technician” apply to any technician who has any responsibility for 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.”
V692	Personnel: 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.
V693	Personnel: 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?	For “experienced” PCTs, meaning 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(s) over the required content and a skills checklist completed by observation of the PCT’s skills by a registered nurse. These PCTs would be expected to achieve certification within the specified time period.

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V692	Personnel: 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.
V695	Personnel: 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.
V711	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.
V727	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.
V758	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 IDT. The medical director may serve as the medical staff representative for the QAPI program.
V767	Governing body: What happens when a staff physician determines that he/she can no longer care for a particular patient?	If there is no other physician on the staff who is available or willing to accept responsibility for the care of the patient, attention must be paid to State practice boards for physicians, which generally require that some notice be given to patients to avoid the charge of 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.,

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		during the physician’s period of notice to the patient.
V767	<p>Governance: What is an “abbreviated involuntary discharge procedure?” Who determines what is contained in an “abbreviated involuntary discharge” procedure? Are facilities required to help patients find new facilities if this “abbreviated involuntary discharge” procedure is used?</p>	<p>The regulations state that in the case of an “immediate severe threat” to the health and safety of others, the facility may utilize an abbreviated discharge procedure instead of following the required procedures for an involuntary discharge. An “immediate severe threat” is considered to be a threat of physical harm. For example, if a patient has a gun or a knife or is making credible threats of physical harm, this would be considered an “immediate severe threat.” An angry verbal outburst or verbal abuse is not considered to be an immediate severe threat. In instances of an “immediate severe threat,” facility staff may determine to use “abbreviated” involuntary discharge or transfer procedures. These immediate procedures may include taking immediate protective actions, such as calling “911” and asking for police assistance. In this scenario, there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer. After the emergency is addressed and staff and other patients are safe, staff must notify the patient’s physician and the medical director of these events, notify the State and Network of the involuntary discharge, and document this contact and the exact nature of the “immediate severe threat” in the patient’s medical record.</p>
V768	<p>Governing body: What facility provisions for emergency medical care are expected?</p>	<p>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 be instructed to call “911” for immediate medical care.</p>