

ESRD Survey Training

ESRD Core Survey Field Manual

Version 1.7

- *"The new Core Survey Process changes the approach to ensuring safe care for Medicare beneficiaries....One of the most important messages for me was the need for all dialysis providers to develop and maintain a "culture of safety" that allows for open and honest communication between patients and facility staff as well as among the facility staff."* – Nephrology Nurse
- *"I love the Core!!! It really keeps us focused on the most important things."* – ESRD Surveyor
- *"I think the Core Survey is great. It really streamlines the survey process yet picks up areas of concern."* – ESRD Surveyor
- *"I think the way the surveyors are focusing on outliers, allowing everyone to see the interface between QAPI and Interdisciplinary Care is very instructive and useful. I can see how post survey we will focus on ways to make the tie between care planning and QAPI even closer."* – Medical Director
- *"The new core ESRD survey stresses the importance of hearing the patient voice, and making sure the patient's perspective is evident when assessing the operations of each dialysis facility—what patients need, what we worry about, what makes our lives better relative to our dialysis treatments. The way the Core Survey is being administered encourages partnering with our care providers to identify and address concerns, so we can be vigilant together and continually improve the quality of care for everyone."* – Dialysis Patient
- *"I feel the new CORE survey process has created improved feelings that both providers and surveyors are working to improve patient care as well as keep patients safe and in a 'Culture of Safety'."* – ESRD Surveyor



Revision History

Revision	Effective Date	Author	Description of Change
1.6	04/30/2014	Helen Blakey	This document had internal changes previously recorded by the ESRD team and so identified with this version number. This table is for the purpose of recording future changes. This version is being released for the class offering beginning June 23, 2014.
1.7	10/22/2014	Darin Tambascio	Multiple changes to the internal documents and cover were made.

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ESRD Core Survey Field Manual

Tab 1: ESRD Core Survey Process

ESRD Core Survey Process

Purposes:

The ESRD Core Survey process is intended to efficiently utilize survey resources to identify deficient facility practices which most impact patient safety and clinical outcomes. The Core Survey focuses on clinical areas where performance improvement is indicated at the individual facility based on facility-specific data and information.

Facility-based survey: The ESRD Core Survey process is intended to assess if the individual dialysis facility (i.e., single Medicare certification number) and the on-site staff who routinely deliver care and monitor patients, clinical outcomes, and facility operations are sufficiently qualified, knowledgeable, and equipped to provide safe and effective patient care in compliance with all applicable ESRD Conditions for Coverage. The staff interviews included in the survey must be with facility-based staff who routinely perform the care/duties in that area. The facility record reviews must be for that facility only. The review of the facility-based (not corporate-based) Quality Assessment and Performance (QAPI) program must be conducted with on-site administrative personnel. The expectation of a facility QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care for and monitoring facility operations of their individual facility. The facility-based staff are expected to recognize when performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.

Audits of personnel practice: The Core Survey process includes the expectation that the dialysis facility will continuously monitor their operations, including auditing staff competency and compliance with implementation of technical and patient care procedures, to assure patient safety. The Core Survey supports the requirements of the ESRD Conditions for Coverage (CfC) and recommendations of the Centers for Disease Control and Prevention (CDC) in that facility staff must be periodically, but not less than annually, audited through direct observation while performing water testing, dialysate mixing and testing, dialysis equipment operation (V260), dialyzer reprocessing/reuse procedures (V360, 367, 368), and direct patient care infection prevention practices (V132, 142, 147). During the course of a Core Survey, surveyors should expect to see that the required staff practice audits are conducted by observers who possess the qualifications and training to evaluate the accuracy of the specific procedure implementation. The practice audit documentation must clearly show that the observed staff demonstrated competency in the procedure(s), or what lapses in practice were observed. When lapses in practices are observed, facility documentation must demonstrate evidence of follow up with investigation and performance improvement actions.

Methods for Conducting the ESRD Core Survey: The ESRD Core Survey may be conducted using the narrative instructions in this document, along with the Core Survey worksheets associated with specific survey tasks, or surveyors may use **STAR** version 3.7 or later. STAR is the automated, tablet-based ESRD survey software which has been provided to all State Survey Agencies (SA). When using STAR to conduct a Core Survey, the surveyor must also use Sections II and III of the “ESRD Core Survey Data Worksheet” for the current fiscal year, to assure the use of the most current data for the survey.

Using this Narrative ESRD Core Survey Process: The ESRD Core Survey process is organized by survey tasks/ review areas specific to the dialysis facility environment and the care of ESRD patients. The “core” activities and guidance for each ESRD Core Survey task are listed, followed by a list of survey “triggers” pertinent to that area of review. *Triggers* indicate the presence of adverse conditions/situations and/or deficient practice. If a surveyor identifies a trigger during an ESRD Core Survey activity, a citation may be warranted or more investigation into that area should be conducted to determine if and what level

of citation is appropriate. The additional investigation may be limited to the specific issue or may include expansion of that survey task, referred to as “extending” that task. Guidance for extending a Core Survey task appears after the applicable tasks or triggers in the Core Survey.

Throughout this ESRD Core Survey document, a triangle (▲) is inserted into areas of review where there is an ESRD Core Survey worksheet to guide the surveyor conducting the survey task.

➡ **TASK: Presurvey Preparation ▲**

Purpose - To determine the preliminary data-driven focus area(s) for the survey

Review the most current Dialysis Facility Report (DFR): *Note how the facility is ranked on the State Profile/Outcomes List. Follow the guidance in the Presurvey Preparation section of the current fiscal year “ESRD Core Survey Data Worksheet” for review of the DFR, and comparison of the facility outcomes and trends with national averages. If the facility outcomes in an area are worse than the national average, plan to include that area as a **preliminary data-driven focus area**.*

Review the facility complaint and survey history for the current 12-18 months. *Look for trends in patient and/or staff complaint allegations, and survey citations.*

Copy the Entrance Conference Materials List/Clinical Outcomes Tables section of the “ESRD Core Survey Data Worksheet” for the current fiscal year to present to the facility person in charge during “Introductions.” *Gather other documents needed to conduct the survey (e.g., 3427, survey worksheets).*

Contact the ESRD Network: *Ask about any quality concerns at the facility, information regarding involuntary discharges and transfers, and patient complaints.*

➡ **TASK: Introductions**

Purpose – To announce the survey, introduce the survey team, and give the facility person in charge notification of the materials needed from the facility to conduct the Entrance Conference.

Contact the person in charge: *Introduce the survey team; give that person the copy of the Entrance Conference Materials List/Clinical Outcomes Tables from the ESRD Core Survey Data Worksheet for the current fiscal year. Explain that the document lists the items the survey team will need to conduct the survey and that the facility should provide much of the information within 3 hours (e.g. current facility and patient-specific outcomes) for discussion during the Entrance Conference.*

➡ **TASK: Environmental “Flash” Tour**

Purpose - To observe the patient care-related areas for conditions which may have immediate impact on patient safety in infection control, physical environment hazards, serious lapses in equipment and building maintenance, and availability of emergency equipment.

Observe four patient-related areas of the facility as listed: *This is a “flash” look at the patient-related areas listed below, looking for observable indicators of patient safety concerns. This “flash tour” begins immediately after the Introductions task.*

Ask staff about the facility “culture of safety” *in the patient-related areas listed below. Early in the survey is a key time to begin to look for evidence of a culture of safety in the facility. Begin to determine if*

the facility culture supports open communication, clarity for staff on the expectations of their roles, and if all levels of staff are engaged in identifying and addressing risks and errors. These determinations are important in evaluating the strength of the QAPI program and how well patients are protected from recurring medical errors. Begin to understand the role the direct care and technical staff play in this process. Ask technicians and nurses about actions taken when errors or “near misses” occur. These conversations can demonstrate if the facility “culture of safety” program is active and effective.

Examples of questions for staff:

- What is the system of communication like here? How does administration ask for your input?
- Are you comfortable bringing issues and concerns to administration’s attention? Does the administration listen?
- How are you involved in the QAPI program? How are QAPI plans for improvement communicated to you?
- What can someone in your position do to prevent or reduce treatment errors?
- What errors or near misses are you expected to report? Do you feel comfortable reporting errors?
- How and to whom would you report an error or near miss that you observed or were involved in?
- How would you expect the error or near miss to be addressed? What is your role in follow up?

In-center dialysis patient treatment area - *Observe the general environment and atmosphere of the treatment area. Observe a sample of 25% (minimum of 3) dialysis stations with patients undergoing treatments. Observe the patient, their vascular access, and the surroundings of the dialysis station. This is a “flash” look, and not a verification of their dialysis prescription delivery, which is done during “Observations of Hemodialysis Care and Infection Control Practices.” Observe the availability and functionality of emergency resuscitation and evacuation equipment.*

Triggers for citation or more investigation of concerns:

- Dummy drip chambers present in the patient treatment area (V400, 403)
- Patients' vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Evidence of poor staffing, e.g., machine alarms not answered, patients not regularly monitored, no dietitian or social worker currently on staff (V757)
- Blood spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood (V122)
- HD machine transducer protectors wetted with blood not changed - *observe/interview staff regarding the practice of inspecting the internal transducer for blood prior to machine use for another patient* (V120)
- Insufficient space to prevent cross-contamination and use emergency equipment (V404)
- Absence of functional emergency resuscitation equipment (i.e., AED/defibrillator, oxygen, suction, emergency medications, Ambu bag) (V413); emergency evacuation equipment insufficient or unavailable (V415)
- Hemodialysis machines in observable poor repair (e.g., alarms not functional, missing components) (V403)
- If dialyzer reuse, germicide odors noticeable in patient treatment area (V318)
- Disrespectful communication, e.g., rude, demeaning, harassing, name calling, loudly calling out weight; disrespectful or punitive actions toward patients, e. g., physical or chemical restraints, involuntary seclusion (V452, 627)
- Failure to offer patients confidentiality when discussing their condition/treatment; failure to protect the patients' confidentiality by allowing exposure of patients' sensitive body parts during procedures (V454)

Water treatment/dialysate preparation area - *Observe the carbon system, the chlorine testing equipment and reagents, and current day/shift total chlorine test results. Look at the alarm/monitoring systems for the reverse osmosis (RO) and/or deionization (DI) components, and the dialysate concentrate proportioning ratios listed on the packaging.*

Triggers for citation or more investigation of concerns:

- Carbon system: absence of 2 or more carbon tanks, with sampling port between (V192), current shift total chlorine test not done, testing reagents not sensitive to 0.1mg/L total chlorine, expired or don't match testing equipment (V196)
- RO: absence of functioning water quality monitor; no audible alarm in patient treatment area (V200)
- If DI is present: absence of functioning resistivity monitor, no audible AND visible alarm in patient treatment area, absence of automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis stations if resistivity falls <1 megohm, DI not monitored twice/day (V202, 203)
- Water distribution equipment in observable disrepair or contaminated state, e.g., the presence of algae or discoloration of water (V403)
- Acid and bicarbonate dialysate concentrates of different proportioning ratios present - *interview staff regarding the use of the different concentrates and verify only matching ratios are used with machines programmed to that ratio* (V249)
- Acid or bicarbonate dialysate concentrate mixing and distribution equipment in observable disrepair or contaminated state, e.g., algae (V403)

Reuse room - *Observe the condition of the reprocessing equipment, dialyzer storage, and dialyzer refrigerator, if present.*

Triggers for citation or more investigation of concerns:

- Stored reprocessed dialyzers aesthetically unacceptable, e.g., header caps with blood, leaking, port caps off (V343)
- Stored dialyzers not protected from unauthorized access (V321) Not within germicide manufacturer's temperature range (V345)
- Reprocessing room or equipment in observable disrepair (V318, 403)
- Dirty dialyzers kept at room temperature >2 hrs. before reprocessing (V331)
- Dialyzer refrigerator temperature not monitored (V331)

Home dialysis training area - *Observe the physical environment, infection control, availability of emergency equipment and method for summoning immediate assistance.*

Triggers for citation or more investigation of concerns:

- Insufficient space in patient training area to prevent cross-contamination and provide emergency care if >1 patient trained at a time (V404)
- Insufficient methods to provide patient privacy (V406)
- Blood or PD effluent spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood or PD effluent (V122)
- Absence of functional, immediately available emergency resuscitation equipment (V413)
- Absence of method for summoning immediate assistance for patient or solitary staff (V402)

Extending the "flash" tour to other areas of the facility : Consider looking at other patient-related areas of the facility, e.g., waiting room, patient bathrooms, supply storage room, hazardous waste storage, laboratory area if you observe:

- Evidence of serious lack of environmental maintenance that has the potential to impact patient safety, e.g., large areas of water damage, presence of mold in the patient-related areas, uneven/broken floor surfaces creating multiple trip hazards where patients ambulate (V401, 402)

➔ **TASK: Entrance Conference ▲**

Purpose- To communicate with and engage facility administrative personnel in the survey process. To review current facility outcomes and determine the data-driven focus areas of the survey for patient sample selection, clinical care reviews, and QAPI review

Obtain and Review documentation of current facility and patient-specific clinical outcomes data submitted from/on the Entrance Conference Materials List/Clinical Outcomes Tables. *You may wish to review this information prior to the Entrance Conference, to be prepared to ask for clarifications, and discuss possible areas of concern.*

Explain purpose and timeline for the survey

Ask the administrative person the facility-specific questions from the “Entrance Conference Questions” worksheet.

Discuss with the administrative person the current facility and patient outcomes data submitted. **Compare** the current facility outcomes listed in the “% Met Goal” column of the Clinical Outcomes Tables to the applicable “**Threshold for % Met Goal**” on the Clinical Outcomes Thresholds Table in the “ESRD Core Survey Data Worksheet” for the current fiscal year. **Ask** (briefly) about actions being taken for improvement in the areas where national thresholds are not currently achieved.

Determine the data-driven focus areas for the survey (clinical areas for review): The data-driven focus areas for the survey are the clinical areas where improvement is currently needed at that facility. *Discuss the selection of the data-driven focus areas for the survey with the administrative person, to engage them in the process. Note if the survey team selected an area as a preliminary data-driven focus, based on the DFR information, but the facility has attained improvements and are currently meeting the national thresholds listed for that area, you may chose not to include that as a data-driven focus area for review.*

➔ **TASK: Observations of Hemodialysis Care and Infection Control Practices ▲**

Purpose - To identify routine patient care practices which may impact patient safety in the areas of infection control, equipment operation, reprocessed dialyzer use, and patient assessment

1. **Observe the direct care staff delivering care** – *Observe the following activities using the applicable observational checklists from the “Observations of Hemodialysis Care and Infection Control Practices” worksheet:*

Hemodialysis patient care and dialysis station & equipment preparation: *Attempt to capture at least 2 separate observations of each of the procedures listed below. Try to conduct observations on different days and of different staff. It may be possible to observe several of the procedures at one dialysis station during the changeover between patient shifts.*

Observe each procedure listed below one at a time, to assure focus on that activity.

- Initiation of hemodialysis for a patient with a Central Venous Catheter (CVC)
- CVC Exit site care

- Discontinuation of hemodialysis and post-dialysis vascular access care for a CVC
- Initiation of hemodialysis for a patient with an arteriovenous fistula (AVF) or arteriovenous graft (AVG)
- Discontinuation of hemodialysis and post-dialysis access care for an AVF or AVG
- Cleaning and disinfection of the hemodialysis station between patients
- Preparation of the hemodialysis machine and extracorporeal circuit
- Dialysis Supply Management: *Observation checklist 9 is intended for completion after the surveyor has conducted the other activity observations, to document assessment of the facility practices in supply management and contamination prevention.*

Triggers for citation or more investigation of concerns:

- Observed trends of breaches in infection control patient care practices:
 - Poor hand hygiene and glove use practices (V113)
 - Supplies taken to station not disposed, disinfected or dedicated to that patient (V116)
 - Clean dialysis supplies not protected from potential contamination (V119)
 - Breaches in aseptic practices for CVC (V147) or AVF/AVG care (V550)
- Not adequately disinfecting the HD station & equipment between patients (V122)
- Using dummy drip chamber to set up HD machine for patient treatment (V400, 403)-*This practice has been determined to be a serious risk to patient safety, and should be considered as an IJ*
- Not testing hemodialysis machine alarms (V403)
- Not testing dialysate pH/conductivity with independent method or lack of staff knowledge of acceptable parameters for pH/conductivity (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers according to manufacturer's DFU (V352, 403)
- Not assessing patients before and after treatment or monitoring during treatment according to facility policy (V504, 543, 550, 551, 715)

Medication preparation and administration: *Observe this process using the applicable observational checklist. Attempt to capture 2 observations of different staff preparing and administering medications for 1-2 patients.*

Triggers for citation or more investigation of concerns:

- Medications not prepared in a clean area away from the dialysis stations (V117)
- Single dose medication vials punctured more than once or used for multiple patients (V118)
- Multidose medication vials punctured with previously used syringe or needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared and/or administered by unqualified personnel (V681)

Extending *any of the above direct care and medication preparation/administration observations should not be necessary if poor practices were identified during either or both of the 2 observations of each procedure. If the surveyor determines that more observations are indicated, 2 additional observations of the applicable procedure(s) should be sufficient to determine the presence of deficient practice.*

2. Review Facility Isolation practices: If there is a hepatitis B positive (HBV+) patient on in-center hemodialysis at the facility:

- **Observe** the isolation room/area, and the equipment and supplies contained within it. If possible, **observe** the care delivery for an HBV+ patient for the observations of direct care procedures in the section above. Observe for separation of care practices from the HBV susceptible patients.
- **Review** staff/patient assignments for the current week, looking at which patients are concurrently assigned to the staff caring for HBV positive patient.
- **Ask** staff on duty how staff assignments are made when an HBV+ patient is dialyzing.

Triggers for citation or more investigation of concerns:

- HBV+ patient(s) not isolated (V110, 128, 129)
- Observed trends of breaches in infection control practices when caring for HBV+ patients (V113, 116, 117, 119, 121)
- Staff assigned/delivering care to HBV+ patient and HBV susceptible patients on same shift- *Investigate the extent of the practice* (V110, 131). (**Note:** Exceptions to this should be rare. If this is occurring, the facility's efforts to avoid this situation should be explained and clarified for the surveyor. Examples of such efforts are to schedule patients in a manner to avoid overlap between HBV+ and HBV-susceptible patients or scheduling HBV+ patients on shifts when there are 2 Registered Nurses (RN) on duty so that one RN may access the HBV+ patient's CVC and administer their medications, while the other RN does so for the other patients. Emergency medical situations may be a justifiable exception.)
- Isolation equipment not dedicated for use on HBV+ patients (V130)
- Non-HBV+ patient(s) dialyzing in the isolation room/area when an HBV+ patient is on in-center HD census (V110, 128, 130)

3. Verify dialysis treatment prescription delivery: Review and compare the dialysis prescription delivery (dialysate, dialyzer, blood flow rate, dialysate flow rate) to patients' dialysis orders for 4-5 patients during their treatments.

Trigger for citation or more investigation of concerns:

- 1 or more patients not dialyzed on ordered prescription, e.g., wrong dialysate, dialyzer type, blood flow rate, dialysate flow rate (V543, 544)

➡ TASK: Patient Sample Selection:

Purpose - To select a core patient sample for clinical care review that represents clinical areas where facility data indicates improvements are needed (i.e., data-driven focus areas) as well as areas pertinent to quality patient care/management and patients' rights that are not represented by available data

Review the patient-specific information submitted by facility from the Entrance Conference Materials List/Clinical Outcomes Tables.

Select at least 10% of the total number of patients on census (minimum 4) representing all dialysis modalities provided at the facility. Attempt to include in-center hemodialysis patients from different days/shifts. Select patients using the criteria below:

Criteria for patient selection:

- **Not meeting outcome goals (“outliers”) in the data-driven focus areas** for the survey. Refer to the patient-specific information submitted from the Entrance Conference Materials List/Clinical Outcomes Tables, i.e., the lists of patients, hospitalization logs, infection logs. Select patients with trends of not meeting outcome goals in the data-driven focus areas for the survey.
- **Unstable** - To look at interdisciplinary team (IDT) activation and functionality for assessing and planning care for the most fragile patients

- **New admission <90 days** - *To look at facility processes for assuring timely evaluation and appropriate care of patients new to the facility prior to and during their first treatment and first weeks at the facility.*
- **Long Term Care (LTC) residents receiving home hemodialysis (HHD) or peritoneal dialysis (PD) at the LTC facility** - *If the dialysis facility supports long term care (LTC) residents who receive home dialysis at their LTC facility, select at least one patient to sample and follow the process as outlined in the current CMS Survey and Certification guidance for review of the care of the home dialysis LTC resident.*
- **Observed patients:** *You may also sample patients you have observed with possible concerns during the survey.*
- **Complaints:** *Patients involved with a complaint being investigated during the survey may also be included in the patient sample. This should be limited to no more than 25% of the patient sample.*
- **Involuntarily discharged (IVD) in the past 12 months, if applicable** - *To review facility actions taken in attempt to avert the IVD prior to the patient's discharge. **An IVD of a dialysis patient is a grave situation, because the patient has no reliable means for obtaining their dialysis treatments, and may expire as a result.** Note: Do not include patients who voluntarily or involuntarily transferred to other dialysis facilities.*

Minimum patient sample: If there are fewer than 10% of patients on census who fit into any of the criteria listed above, the survey team should select at least 10% of the total number of patients on census (minimum of 4) representing every dialysis modality provided at the facility, for Patient Interviews and Medical Record Reviews.

Record the patient sample - *Record the criteria used for selecting each patient. Note that when patients fit more than one criterion above, they may only be counted once in the core patient sample of 4-10 patients.*

➡ **TASK: Water Treatment and Dialysate Review** ▲

Purpose - To verify that systems in use and facility oversight of water and dialysate quality are able to protect patients from harm

Review critical water treatment components with on-site staff routinely responsible for the activity and daily monitoring of the component:

- **Observe total chlorine test and interview** *about maximum allowable level of 0.1mg/L total chlorine, chlorine “breakthrough” procedure, and the amount of carbon in the system (empty bed contact time-EBCT). Note the alternate form of carbon, block carbon, may only be used in the outpatient setting with a single portable reverse osmosis unit supplying a single hemodialysis machine. The block carbon system must include 2 carbon “blocks” with a sample port between. The manufacturer of the block carbon must demonstrate equivalency to the required EBCT of 10 minutes. If the facility is using a continuous on-line chlorine monitor, **ask** about periodic (usually daily) validation testing with an alternate method.*

Triggers for citation or more investigation of concerns:

- Absence of 2 or more carbon tanks with sample port between (V192)
- Insufficient carbon empty bed contact time (<10 minutes total EBCT) or equivalency documentation for block carbon used with portable RO-*verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)*
- Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equipment (V196)

- Staff assigned total chlorine testing has inadequate knowledge of maximum allowable level of 0.1mg/L total chlorine and/or breakthrough procedures (V260)

Extending may include an additional observation of another staff member conducting the chlorine test, or additional staff interviews. **Note** that the absence of 2 carbon tanks with a sample port between in an outpatient water treatment system is citable on identification and should be considered an immediate jeopardy situation.

- **Observe reverse osmosis (RO) unit, water quality monitor and alarm and interview** about monitoring RO function by % rejection, and product water quality by total dissolved solids (TDS) or conductivity.

Trigger for citation or more investigation of concerns:

- RO % rejection and product water conductivity or TDS not monitored and recorded daily, water quality alarm non-functional, not audible in patient treatment area (V199, 200)

Extending should include an interview with technical administrative staff. **Note** that the absence of accepted methods for monitoring RO function and warning staff of problems is citable on identification. If the water treatment components appear in observable disrepair, consider reviewing the pre-treatment and water distribution components for compliance with the applicable V-tags (V188-191, V198-215).

- **Observe deionization (DI) and resistivity monitor and alarm**, if present. **Interview** about the DI system, and determine if there is a plan to use DI as back-up. If DI is present or included in a back-up plan, **ask** about the presence of an automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis stations, ultrafilter (UF) post DI, how monitoring is conducted, what the minimum allowable resistivity level is, and what actions are taken when resistivity falls <1 megohm (i.e., STOP dialysis). **Note:** DI should not be used as the primary water purification component in a centralized water treatment system except on a temporary basis due to RO failure (V205).

Triggers for citation (Note if DI is part of a backup plan, all of the items below must be included):

- Absence of functional resistivity monitor or alarm; alarm not audible **and** visible in patient treatment area; resistivity not monitored/recorded at least twice per treatment day (V202, 203)
- Absence of functional automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis machines (V203)
- Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion (i.e., stop dialysis) (V260)
- No ultrafilter in-line post DI (V204)

All of the above DI triggers are citable on identification, due to the serious safety hazard poorly managed and monitored DI systems present to patients.

Interview the person responsible for microbiological sampling and monitoring of water and dialysate regarding system disinfection, sample sites, collection methodology, sample timing (before disinfection) and how often dialysate cultures are done for each HD machine.

Interview the person responsible for bicarbonate and acid dialysate concentrate mixing regarding verification of proper mixing, testing of acid concentrate, bicarbonate concentrate time frame for use (24 hours or per manufacturer's DFU) and "spiking" (inserting additives) into individual dialysate containers.

Triggers for citation or more investigation of concerns:

- Water/dialysate samples not drawn before disinfection (V254)

- Water distribution system not disinfected at least monthly (V219)
- Each HD machine not cultured at least annually (V253)
- Staff unaware of correct dialysate concentrate mixing, acid concentrate batch testing, “spiking”, duration of bicarbonate usability, etc. (V233, 235, 236, 260)

Extending may include additional interviews with staff responsible for applicable water & dialysate activities, observations of dialysate mixing and acid concentrate batch testing (V229, V232), and review of dialysate mixing and bicarbonate system disinfection logs (V230,239).

Review facility documentation of oversight of water & dialysate systems in the following areas:

- **Chemical and microbiological monitoring**
 - Total chlorine testing-2 months
 - RO monitoring by % rejection and product water quality by TDS or conductivity, **NOT** all gauge and component readings-2 months
 - If DI present or has been used in past 12 months: 2 months of resistivity readings at least twice per treatment day
 - Product water chemical analysis-12 months
 - Microbiological monitoring of water, including in the reuse room, and dialysate; both colony forming units (CFU) and endotoxin units (EU)-6 months
- **Practice audits of the operators' compliance with technical procedures** - *Look at 12 months of facility documentation of observations of staff conducting water testing, dialysate mixing, pH/conductivity testing, etc. (V260)*

Triggers for citation or more investigation of concerns:

- Total chlorine results exceeding 0.1mg/L without documentation of appropriate actions taken (V197)
- Chemical analysis of product water not done at least annually (V201)
- Irregularities, trends of omitted tests (V178, 180, 196, 199, 200, 202, 203, 213, 252, 253)
- Microbiological results of water or dialysate exceeding action or maximum levels without documentation of appropriate actions taken (V178, 180)
- Practice audits of staff conducted less than annually (V260)

Extending should include technical administrative staff interview and may include review of an equal number of additional logs, e.g., 2 more months of total chlorine logs or RO logs, 12 more months of chemical analysis.

➡ **TASK: Dialyzer Reprocessing/Reuse Review** ▲

Purpose - To validate that dialyzer reprocessing and the clinical use of reprocessed dialyzers are conducted safely, and facility QA oversight of the reuse program assures ongoing patient protection

Observe the following high risk components of dialyzer reprocessing, and interview the reuse technician:

- **Transportation of used/dirty dialyzers to the reprocessing area** – *how promptly reprocessing occurs; if refrigerated, ask about procedures for refrigeration and maximum refrigeration time.*
- **Pre-cleaning procedures** - *if manual pre-cleaning, header removal/cleaning and/or reverse ultrafiltration are conducted, observe these processes for 1-2 dialyzers and interview about the procedures, the water source for pre-cleaning, and the maximum allowable water pressures at the pre-rinse sink.*

Interview the reuse technician about germicide mixing, storage and spill management; dialyzer labeling/similar names warnings; reprocessing procedures; and dialyzer refrigeration and storage.

Review the documentation of facility oversight of dialyzer reprocessing/reuse program in the following areas:

- **Quality Assurance (QA) audits - Review 12 months of facility documentation of the following reuse observational audits. For clarification about the audits, you may need to interview a technical administrative person, instead of the reuse technician:**
 - Observations of reprocessing procedures -each reuse technician observed at least semi-annually
 - Observations of preparation of dialysis machines with reprocessed dialyzers for patients' treatments, i.e., germicide tests, priming, 2 persons identification of patient/dialyzer quarterly
 - Dialyzer labeling, including similar names labeling quarterly
- **Reprocessing equipment preventative maintenance - Briefly look at 12 months of documentation, to verify adherence to manufacturer's directions for daily calibration of automated equipment (this may be located on a daily "start-up" log) and routine maintenance procedures.**
- **Reuse adverse events/dialyzer "complaint" log - Look at 12 months for actions taken in response to occurrences possibly related to reprocessing.**

Triggers for citation or more investigation of concerns:

- Improperly performed dialyzer pre-cleaning, header removal/cleaning (V334)
- Water used for pre-cleaning dialyzers not purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V319, 321,339)
- Reuse tech unaware of requirements in key patient safety areas per interview guide (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)
- Reprocessed dialyzers stored for extended periods (V345)
- QA audits listed above not done or incomplete - **Extend** to review all of the required QA audits for reuse (V360-368)
- Noticeable strong germicide odors and/or patient or staff complaints regarding germicide odors- review the last 12 months of ambient air vapor testing for the germicide (V318)
- Serious adverse events possibly related to dialyzer reprocessing/reuse, e.g., **dialyzing patient on another patient's dialyzer**, without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)-**Extend** to include reuse as a focus area for QAPI Review.

Extending the facility-based reprocessing/reuse review may include: Observing the complete dialyzer reprocessing procedures, i.e., pre-rinse, automated cleaning, testing, germicide instillation, and labeling for at least 2-3 dialyzers (V327-345); and additional interviews with reuse technicians and/or technical supervisory personnel.

Note: If centralized dialyzer reprocessing is conducted with the dialyzers transported to an off-site location for reprocessing, refer to the current CMS Survey and Certification guidance in the State Operations Manual.

➡ TASK: Dialysis Equipment Maintenance Review: ▲

Purpose - To verify that facility programs for dialysis-related equipment preventative maintenance (PM) protect patients from harm due to avoidable equipment malfunction

Interview machine/equipment maintenance technician – *Ask: about the hemodialysis machine manufacturer's directions for PM and repair and the prescribed intervals for PM, i.e., per operating hours or calendar.*

Review PM documentation for 10% of hemodialysis machines (minimum 3) *for 12 months: include 10% of the home hemodialysis machines maintained by the facility in the total 10% sample. If there are multiple types of machines, i.e., from different manufacturers, include a sampling of each type. Review for adherence to manufacturer's directions for PM. You may wish to verify what the manufacturer's directions include, which may be obtained in the machine operator's manual.*

Review documentation of calibration of equipment used for dialysis machine maintenance and dialysate pH and conductivity testing: *Briefly look at 2 months of logs for pH and conductivity meters and at the most recent documentation of calibration of the equipment/ meters used to conduct the hemodialysis machine maintenance and repairs.*

Triggers for citation or more investigation of concerns:

- Trends of non-adherence to hemodialysis machine manufacturer's directions for PM (V403)
- No calibration of pH and conductivity meters or equipment calibration meters or not per manufacturer's directions (V403)
- Observations of serious lack of maintenance of ancillary equipment, e.g., scales, chairs, infusion pumps, oxygen concentrators, that has the potential to impact patient safety (V403)

Extending *review of dialysis equipment maintenance may include review of the PM logs for an additional 10% of HD machines; review of 2-3 additional months of calibration meter logs, or review of maintenance documentation of equipment that is in observable disrepair (V403).*

➔ TASK: Home Dialysis Training and Support Review: ▲

Purpose - To verify that patients/caregivers receive adequate training and subsequent support to facilitate safe and successful home dialysis. If the dialysis facility provides only home dialysis training and support, the survey must include all applicable survey tasks, e.g., Presurvey Preparation, Entrance Conference, Patient Sample Selection, Environmental “Flash” Tour, Water/dialysate Review, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review.

Interview the home training nurse(s) *about the home training and support program in evaluating patient candidacy, training patient/caregiver, demonstration of patient/caregiver comprehension; providing IDT support and QAPI oversight. You may need to interview different home training nurses for home hemodialysis and peritoneal dialysis.*

Observe the direct care of home dialysis patient(s) *if the opportunity arises during the survey when a home dialysis patient is being treated or trained at the facility. Look for adherence to infection control standards.*

Interviews and medical record reviews with/of home dialysis patients are conducted during Patient Interviews and Medical Record Reviews.

Triggers for citation or more investigation of concerns:

- Home training nurse(s) interview or observation of care identifies concerns about knowledge, infection control practices or other aspects of the home training program-*for infection control*

concerns, refer to the applicable triggers for infection control listed at Observations of Hemodialysis Care and Infection Control Practices task.

- Patient/caregiver interviews identify concerns about the adequacy of training, competency and support from the IDT, i.e., registered dietitian and master's prepared social worker, physician, home training nurse (V581, 585, 586, 592)
- Medical record reviews of home dialysis patients identify concerns related to training or monitoring of home dialysis patients, including monitoring water/dialysate quality for HHD patients, if applicable (V585, 586, 593-595).
- The facility does not evaluate home program outcomes separately in QAPI (V626, 628).

***Extending** review of the home dialysis training and support program may include review of the patient/caregiver training materials (V585), sampling additional home dialysis patients for interview or medical record review, and further evaluation of the surveillance of the home dialysis environment, i.e., home visits (V589).*

***Note:** If there are long term care (LTC) residents on census of the ESRD facility who are receiving HHD or PD treatments at their LTC facility, the surveyor is expected to **extend** the review of the care of these residents. Follow the current CMS Survey and Certification guidance for review of the care of the home dialysis LTC resident.*

➡ **TASK: Patient Interviews:** ▲

Purpose - To listen to the patients' voices as recipients of the care provided at the facility, to determine if patients receive unbiased and adequate information on modality choice, to evaluate patients' understanding of their rights and responsibilities, to determine how comfortable patients feel to voice concerns or make suggestions, and to assess their satisfaction with their care at the facility

Interview the sampled patients selected during “Patient Sample Selection.” *To ensure the survey process includes sufficient attention to the point of view and care experience of the patients, attempt to interview as many of the “interviewable” sampled patients as possible, i.e., they are alert, oriented, and not mentally impaired to the point that the interview would yield unreliable results.*

*After attempting to interview the sampled patients, if the survey team is not able to interview at least 4 of the sampled patients, **interview additional alert and oriented patients to obtain a minimum of 4 patient interviews representing all dialysis modalities provided at the facility.** Enter these additional patients on the Patient Roster and designate that they were interviewed. Unless their interview indicates a reason to do so, you are not required to review their medical records.*

Patients may be interviewed in person or by phone. The surveyor should offer each patient the choice to conduct the interview by phone. Expect that some patients may not feel fully comfortable being interviewed in the patient treatment or waiting areas, where staff may overhear what is said. For home dialysis patients not in the facility, ask the home training nurse to contact the patient to alert him/her that the surveyor will be calling them for an interview.

*Individualize patient interviews to focus on each patient's issues and the criteria for sampling them, however **ask** at least the “core” questions listed on the applicable ESRD Core Survey Interview Worksheet. For patients sampled due to being involuntarily discharged, some of the Interview Guide “core” questions may not be applicable.*

Triggers for citation or more investigation of concerns:

Patients express concerns regarding:

- Patients' rights and responsibilities (V451)
- Education about transplant and all options of dialysis modalities and settings, including those not offered at the facility (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- How to prevent infections and protect their dialysis access (V562)
- The safety and comfort of the physical environment of the facility (V401, 402)
- Disaster preparedness at home and how to evacuate the facility in an emergency (V409, 412)
- Communication with the IDT and involvement in planning their care (V501, 541)
- Staff proficiency in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff, e.g., nursing, dietitian, social worker, patient care technicians (V757-759)
- Culture of Safety: freedom to report care concerns, ask questions, make suggestions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training and IDT support of home dialysis patients and caregivers to facilitate successful home dialysis (V585, 592)

Extending patient interviews may include asking questions of additional applicable patients focused on the specific area(s) of concerns.

➡ TASK: Medical Record Review: ▲

Purpose - To verify the provision of safe, effective, interdisciplinary care through the documentation in the patients' medical records

Review the medical records for all the sampled patients selected during Patient Sample Selection - All of the medical record reviews are focused reviews, looking at the care provided to each sampled patient related to the criteria used to select them. Review each sampled patient's dialysis/medication orders, and the documentation of their dialysis treatments. The remainder of each patient's medical record review should be focused on the components of the record related to the criteria for sampling that patient, using the following guidelines:

For all sampled patients, Review dialysis prescription/medication orders and dialysis treatment records (except closed records of patients involuntarily discharged): **Review the patient's current dialysis prescription and medication orders and compare to the documentation of the dialysis treatments delivered:**

- **In-center HD patients** - Look at 2-3 consecutive weeks of hemodialysis treatment records for machine safety checks, treatments & medications delivered as ordered, blood pressure/fluid management and patient monitoring per policy.
- **Home HD patients** - Look at 2-3 consecutive weeks of hemodialysis treatment records for staff monitoring of the patient's adherence to treatment & medication orders, machine safety checks, blood pressure/fluid management and recognizing and addressing issues. **Note:** For the sampled home HD patient, also review documentation of water/dialysate chemical and microbiological quality, as applicable for the hemodialysis equipment in use.
- **PD patients** - Look at 8-12 consecutive weeks of PD documentation e.g., flowsheets for staff monitoring of the patient's adherence to treatment & medication orders, blood pressure/fluid management, and recognizing and addressing issues.

Patients sampled due to not meeting goals (“outliers”) in the data-driven focus areas for the survey: *Review the patient's trend in outcomes in that data-driven focus area, e.g., 3 months of labs. Look at the physician's orders, interdisciplinary progress notes, patient care plans, and other applicable medical record components to assess the facility's actions.*

- Expect to see that one or more IDT members were monitoring the patient's outcome in that area, recognized that the patient was not attaining their goal or had a problem in that area, and responded with meaningful interventions aimed at improvement/resolution. When the interventions were unsuccessful, the IDT continued to attain improvement by changing strategies with alternate interventions.

*Note: This is a focused review intended to look at facility systems for addressing poor patient outcomes in the data-driven focus areas. You are not expected to **search** each patient's record for all of their outcomes. If, during your review of the data-driven focus areas used for selecting that patient, you **discover** poor outcomes for the patient in another area, use your judgment about whether reviewing the additional area would be of value, and follow the guidance above for that area, as well.*

Guidance for review of patients sampled due to anemia management concerns as a data-driven focus area of the survey: **Patients with Hgb <10 g/dL:** *Look for evaluation of the patient for: treatable causes of the anemia, e.g., infection, inflammation, GI blood loss; iron studies such as ferritin, transferrin saturation; symptoms of anemia; erythropoiesis stimulating agent (ESA) prescribed or increased; avoidance of transfusion*

Guidance for review of patients sampled due to fluid management concerns as a data-driven focus area: **Patients with >5% average intradialytic fluid removal:** *Look for evaluation and interventions into causes of fluid gains between treatments, and interventions to mitigate the effects of rapid fluid removal during dialysis (e.g. BP drops, cramping, loss of consciousness). Expect to see IDT recognition of the potential risks to the patient posed by both failure to control fluid gain between treatments and consistent rapid fluid removal (e.g. >5% target weight in treatment <4 hours or >15mL/kg/hour in any treatment length), and interventions to minimize those risks.*

Patients sampled as “Unstable” - Review the IDT documentation in progress notes, physician's orders, assessments, results of physical and mental functioning surveys (age-appropriate Healthcare Related Quality of Life-HRQOL survey), plans of care, etc. pertaining to the two most recent patient assessment and plan of care periods. The IDT process and content of the patient assessments and plans of care are more important than the format or timelines.

- Expect to see that an assessment of the patient was conducted and the clinical and psychosocial issues that contributed to the patient’s instability were addressed through revised plan of care interventions. There should be evidence of a functional IDT process, including substantive contributions from and communication among all required IDT members.

Patients sampled as newly admitted (<90 days) - Review the admission orders, labs and progress notes. Look at the process for assuring the new patient was appropriately evaluated on admission, prior to the first dialysis treatment, and during his/her first weeks receiving care at the facility.

- Expect to see that the patient had written orders by a physician or non-physician practitioner (if allowed by state law) and was evaluated by an RN prior to their first dialysis treatment at the facility. The patient must be evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccination and pneumococcal vaccination, if indicated. The facility staff should have evaluated and addressed the issues related to the patient’s labs, fluid management, dialysis-related problems, as well as other clinical, nutritional, and psychosocial needs. For home dialysis

patients and their partners, their training and home dialysis environmental needs must be evaluated and addressed.

Patients sampled as LTC residents receiving home dialysis at the LTC facility: *Follow the current CMS Survey and Certification guidance for review of the care of the LTC resident receiving home dialysis at the LTC facility.*

- Expect to see coordination and communication between the LTC and ESRD IDT to assure the dialysis treatments are delivered in a safe environment, by adequately qualified, trained, and competent caregivers, with on-site oversight by a qualified RN (LPN for PD). The ESRD facility is responsible for monitoring the dialysis care and condition of the resident, in accordance with all applicable requirements in the CfC (e.g. Water/dialysate quality, Infection control, Patients' rights, Physical environment, Patient assessment, Patient plan of care, Care at Home)

Patients sampled due to observations: *Focus review on the circumstances pertinent to the concerns raised from your observations and/or random interview(s) regarding the patient.*

Patients sampled as part of a complaint investigation: *Follow the applicable complaint investigation process. Note: To preserve the intention of the Core Survey Patient Sample Selection process, patients sampled as part of complaint investigations must not make up more than 25% of the survey patient sample.*

Patients sampled as involuntarily discharged (IVD) - *An IVD of a dialysis patient, i.e., no transition of their dialysis care to another outpatient dialysis provider, is a grave situation, because the patient has no reliable means for obtaining their dialysis treatments, and may expire as a result. The primary focus of your investigation for a patient who has been involuntarily discharged should be on the meaningful actions taken by the facility in attempt to avert the IVD, and to preserve the health and safety of the patient.*

Note: The ESRD Conditions for Coverage severely limit the option of involuntarily discharging a patient without transferring the patient's care to another outpatient dialysis facility. When one of the criteria for consideration of involuntary transfer/discharge listed at V766 is identified, the facility and ESRD Network are fully expected to exhaust all resources to address the problems and prevent the patient's transfer or discharge. If there is no resolution, the facility must make meaningful attempts to transfer that patient's care to another outpatient dialysis facility without regard to facility ownership. The only exception to this expectation is in the case of an immediate severe threat to the health and safety of others when the facility may utilize an abbreviated IVD procedure.

*Review the documentation pertaining to the actions taken in attempt to avert the IVD, to locate and arrange for the transfer of the patient's care to another dialysis provider, and, if all meaningful efforts are unsuccessful, the procedures followed prior to discharging the seriously abusive/disruptive patient. You should **interview** the facility qualified social worker, other applicable staff, and the patient to supplement and/or support the medical record review.*

Guidance for review of IVD of the seriously abusive/disruptive patient: *Note: Patients' rights protect a patient's right to refuse treatment. Therefore, skipping or shortening treatments and/or failing to meet facility set goals for clinical outcomes, as well as verbal outbursts that do not express a credible threat are not acceptable reasons for involuntary discharge.*

Review of the medical record and other documentation must show written evidence of/that:

- The IDT took meaningful actions to attempt to avert the IVD. *At a minimum, these efforts must include a full IDT reassessment of the patient involving the professional IDT, the medical*

*director, and patient's attending physician to investigate and determine the root causes of the patient's disruptive or abusive behavior and actions to resolve the issues **before** considering involuntary discharge of the patient. The facility investigation should include evaluation of possible roles mental illness, cognitive impairment, cultural or language differences or staff behaviors and interactions with the patient may play in the patients' problematic behaviors, with interventions implemented to address and resolve the conflict(s).*

- The facility staff contacted and collaborated with the applicable ESRD Network to resolve the problems, avert the discharge, and, if unsuccessful, facilitate a transfer to another facility.
- The facility staff contacted other dialysis facilities including those outside their corporation to attempt to transfer the patient before considering IVD. The patient's information shared with the contacted facilities was limited to the medical record contents per HIPAA requirements.
- The facility fully implemented/conducted ALL of the above actions **before** proceeding with the procedures for IVD.
- Once the decision for IVD was made, the facility notified the patient at least 30 days before the IVD, notified the applicable ESRD Network, obtained a written physician's order for the IVD, signed by the medical director and the patient's attending physician, and notified the State survey agency of the IVD.

Triggers for citation or more investigation of concerns in Medical Records Reviews:

- Lack of evidence of a functional IDT process to monitor, recognize and address barriers to attaining identified patient outcome goals in one or more clinical and psychosocial areas
- Home dialysis patient interviews or staff interviews indicate concerns about training program- ***Extend*** to review documentation of patient/caregiver training and demonstration of comprehension (V585, 586)
- Patient or caregiver interviews indicate lack of functional patient education program and patients' rights concerns - ***Extend*** review to documentation of patient education and patients' rights
- Incomplete, inaccurate, inaccessible or insecure medical records-***Extend*** to look at medical records systems (V726)
- Concerns identified in other survey tasks which can be investigated further through medical record review to support or dispel findings

Extending medical record reviews may include review of additional patients' records focused on the area of concern and additional interviews for clarification.

➡ TASK: Personnel Interviews: ▲

Purpose - To assess facility-based (not corporate-based) staff knowledge, competence, and their awareness of expectations for safe and effective care aimed at achievement of optimum patient outcomes; to clarify/verify potential survey findings; and to give staff an opportunity to voice concerns

Interview the following staff: *Interviews may be conducted in-person or by phone. Individualize the staff interviews according to the survey issues and concerns, however **ask** the questions listed as “core” in the corresponding ESRD Core Survey interview worksheets:*

- Medical director
- Nurse Manager - *although it is likely that the facility nurse manager will be engaged in and interviewed throughout the survey process, if this is not the case, include her/him in the personnel interviews*
- 2-3 nursing staff members including at a minimum, 1 RN and 1 PCT
- Registered dietitian

- Master's prepared social worker
- Water treatment personnel - *during “Water Treatment and Dialysate Review”*
- Reuse technician - *during “Dialyzer Reprocessing/Reuse Review”*
- Home training nurse(s) - *during “Home Dialysis Training and Support Review”*
- Machine/equipment technician - *during “Dialysis Equipment Review”*

Triggers for citation or more investigation of concerns:

- Concerns identified from personnel or patient interviews or other survey tasks that indicate the need to extend certain areas of questions for personnel or interview more personnel to support or dispel findings.

➡ TASK: Personnel Record Review: ▲

Purpose - To verify that personnel have the qualifications, training, and demonstrated competencies to provide safe and effective dialysis care

Review the facility-submitted documentation on the “Personnel File Review” worksheet given to the facility administrative person during the Entrance Conference, or equivalent electronic report.

Review selected personnel files: *Select a minimum of 3 personnel files to review using the following criteria:*

- Concerns identified about the qualifications or competency of specific staff during observations of care or interviews with patients or staff
- The facility-submitted documentation is incomplete or show irregularities/variances for specific personnel

Triggers for citation or more investigation of concerns:

- Personnel lack required qualifications or competency verification (V410, 681)
- Verification review indicates inaccurate or incomplete facility-submitted documentation for 1 or more files.
- PCTs listed with no certification expiration date-*check for hire date within 18 months; Note that medical, military, or other approved leave of absence extends the time allowed for certification/recertification (V695)*

Extending *personnel file review may include review of 3 more personnel files to verify accuracy of the facility-submitted documentation or investigate the extent of personnel training and competency issues .*

➡ TASK: Quality Assessment & Performance Improvement (QAPI) Review: ▲

Purpose - To verify that the facility’s QAPI program is sufficiently comprehensive and robust to monitor all facility operations/services, recognize when performance improvement is indicated, respond with effective actions to attain and sustain improvements, and support a facility-wide “Culture of Safety” that assures optimum patient safety

Note on Facility-Based (not Corporate-Based) QAPI: The review of the facility QAPI program must be limited to the information for only the facility being surveyed, and conducted with facility-based (on-site) administrative personnel. The expectation of a facility QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care to and monitoring facility operations of their individual facility. The facility-based staff are expected to recognize when

performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.

The QAPI review is divided into 3 Segments of review:

Segment I: Monitoring care and facility operations to verify that the facility QAPI program has sufficient infrastructure, and continuously monitors all areas as expected, including the technical operations. *Note: The QAPI activities for critical priority areas, and the data-driven focus and survey findings areas for this facility will be reviewed in more detail during Segment II of the QAPI review.*

- **Clinical and operational indicators:** A brief look to assure all expected indicators and areas pertinent to dialysis care are continuously monitored.
- **Oversight of technical operations and practice audits** to verify the presence of consistent QAPI oversight and performance improvement actions for water/dialysate, equipment maintenance/repair, and dialyzer reuse programs

Segment II: Review of QAPI activities in three critical priority areas for ALL facilities and in the data-driven focus areas and survey findings areas of this facility survey. A detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and responding in the critical priority and problematic areas to attain and sustain improvements

- **Mortality review:** Looking at the QAPI activities for evaluating and trending patient deaths, and efforts implemented to address adverse trends potentially related to care received at the facility.
- **Infection prevention and control:** A review of the facility program for infection occurrence tracking/trending, vaccination, personnel infection control education and visual auditing, and patient education in infection prevention, toward the goal of reduction of patient infection rates.
- **Medical error/adverse occurrence/clinical variance tracking and investigation system** to verify the presence of an effective system for responding to events, investigating, and addressing causal factors to prevent occurrence or recurrence. During this review, the surveyor “follows” an error/event and the facility performance improvement actions as recorded in the facility system.
- **Data-driven focus and survey findings areas:** Following through with the focuses and findings of the survey, to determine what the facility QAPI activities were for recognition of the problems/risks, and actions taken to address them.

Segment III: Culture of Safety Review: Verifying the presence of a facility-wide culture that promotes and protects patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/events, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated. A facility-wide culture of safety enables complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients. The culture of safety review has 3 components:

- **Risk identification and reporting:** Looking to see that an effective program exists to identify all risks to patients and facilitate liberal reporting of those risks, including “near misses/close calls” to allow comprehensive investigation and mitigation of risks.
- **Staff engagement:** Looking at the facility's communication systems and role expectations among all levels of staff. The surveyor reviews the facility staff complaint/suggestion log.
- **Patient engagement:** Looking at the facility program for assessing and addressing patients' mental and physical health outcomes. The surveyor also reviews the facility patient grievance/complaint/suggestion system by “following” a patient complaint through the process.

Preparation for QAPI Review: Although portions of the QAPI review may occur throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey. This enables focus of the review during Segment II on the facility's QAPI performance improvement activities in the critical

priority areas, data-driven focus areas, and survey findings areas. Conducting the review after most of the survey is completed allows the surveyor to determine if the facility has identified the same concerns as the survey team, and what performance improvement actions they have taken to address them. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and make a list of areas in addition to the critical priority ones to focus on during Segment II.*

Review the facility-based QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-based (not corporate-based) person.

Segment I: Monitoring Care and Facility Operations

➤ **Clinical and operational indicators monitored**

Review the QAPI documentation to verify that the facility's QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI Team monitors at a minimum all the expected areas of patient clinical management and facility operations. Refer to table of indicators in the "ESRD Core Survey QAPI Review Worksheet." Note that not all areas listed in the table are expected to be monitored monthly.

This is not a detailed review, but a brief look at the facility's QAPI summarizing documentation. You will review the facility QAPI performance improvement activities in the critical priority areas, survey data-driven focus areas and survey findings/concerns areas in more detail during Segment II.

- Expect to see that the facility is routinely monitoring and trending all of the expected areas. For the clinical areas, that the facility has identified outcome goals which reflect community standards from the current Measures Assessment Tool (MAT). The QAPI documentation must show the active involvement of all personnel necessary to adequately address and resolve problems/issues, including all members of the interdisciplinary team, i.e., medical director, nurse manager, masters-prepared social worker, registered dietitian, and other personnel such as technical staff and patient care staff (V626, 628).

➤ **Oversight of technical operations and practice audits:**

Review the facility's QAPI documentation to ensure routine audits in these areas are conducted and discussed, and performance improvement actions taken, when indicated. The following are expected:

Water and dialysate quality

- Review of monthly water and dialysate cultures/endotoxin results, annual product water chemical analysis, and other microbiological monitoring as indicated for the equipment in use (V628)
- Audits at least annually of staff mixing dialysate concentrates; testing batches of acid concentrate; testing dialysate pH/conductivity; testing water for total chlorine and microbiological sample collection; operating equipment (V260)

Dialysis equipment: Review of monthly dialysis machine, equipment and ancillary equipment maintenance and repair (V628)

Reuse: Review and verification that all required reuse audits are conducted at the applicable intervals and adverse occurrences related to reuse addressed. The Reuse QA audits include visual practice audits of staff reprocessing dialyzers, and staff preparing reprocessed dialyzers for patients' treatments (set up) (V635)

- Expect to see evidence that all of the above reviews and audits were conducted. When problems were identified, evaluation was done to determine the cause(s) of the issue, and actions taken to resolve it. Note that the cycle of elevated water or dialysate cultures, “addressed” with disinfection, only to have elevated cultures the following month, “addressed” with disinfection, repeated over and over is not effective performance improvement and may be risking patient safety.

Segment II: Review of QAPI activities in three critical priority areas for ALL facilities and in the data-driven focus and survey findings areas of this facility survey (identified areas of patient risk).

For ALL facilities, review the mortality, infection prevention and control, and medical error/adverse occurrence investigation systems (i.e., critical priority areas). Individualize your review of the data-driven focus areas and survey findings pertinent to this facility survey. In all areas, conduct a sufficiently detailed review to determine the quality and effectiveness of the facility QAPI actions for addressing problematic areas and attaining and sustaining improvements in outcomes.

➤ **Mortality review:**

Review, with the responsible facility-based person, the QAPI documentation for evaluation of the facility mortality data. Focus the discussion on the analysis and trending of causes of patient deaths and the relationship to the care received at the facility.

For all facilities, ask: What information do you collect about patient deaths? How does the QAPI Team conduct analysis of individual patient deaths, and recognize trends in causes and contributory factors to deaths?

- Expect to see evidence that the facility reviewed and evaluated all patient deaths, and analyzed trends in causes of patient deaths (V628).

For facilities with poor mortality outcomes as noted from the Dialysis Facility Report review during Presurvey Preparation: Ask: What trends in causes of mortality have you identified? How did you investigate them? What performance improvement strategies have you implemented to address the high mortality ratio and/or adverse trends?

- Expect to see, for identified trends in cause of deaths, that the QAPI Team investigated the issues and conducted QAPI review focused on the aspects of care related to specific-cause categories. Examples are: for high rates of deaths due to **infection causes** the facility should have looked at the CVC rate and CVC reduction efforts, hospitalization patterns, water/dialysate cultures, staff compliance with infection control practices, etc.; for high rates of death due to **cardiac causes** the facility should have looked at HD ultrafiltration rates, length of HD treatments, the use of low potassium (“0K+” or “1K+”) dialysate, patients' serum bicarbonate levels, etc.(V628)

➤ **Infection prevention and control:** *Infections are a leading cause of death in dialysis patients, and protection from infection is vital to their health and safety. This review is intended to assure that the facility’s QAPI activities facilitate a multifaceted and effective facility-wide program for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare associated infections (HAI) acquired at the facility.*

There are 4 areas of the infection prevention and control review :

Infection occurrence tracking/trending/surveillance: Ask: What types of infections do you record? What information do you record about each infection?

Review the infection tracking logs.

- Expect to see that all positive culture results, dialysis access, blood stream infections (BSI), and peritonitis episodes, if applicable, are recorded with sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic use); That trends in infections were recognized, evaluated/investigated, and performance improvement strategies implemented and monitored for effectiveness (V637).

Vaccination: high risk disease management: *Refer to the facility vaccination information obtained from the Entrance Conference Materials List. Ask:* The responsible facility-based person to show you the QAPI documentation of oversight for surveillance and vaccinations including:

- Hepatitis B patient surveillance; susceptible patients and personnel offered vaccination (V125-127)
- Tuberculosis surveillance of patients on admission or exposure
- Influenza vaccinations offered to patients and personnel seasonally
- Pneumococcal pneumonia vaccination offered to patients
- New Hepatitis C infections (i.e. antibody elevation for facilities that test for HCV) or unexplained ALT elevations
- Expect to see evidence of active QAPI oversight of the high risk disease surveillance and vaccination programs listed above. If trends of lapses in surveillance or vaccination were identified, that the QAPI Team responded to thoroughly investigate the problem, implement performance improvement actions, and monitor them for effectiveness (V637).

Staff education and visual practice audits for infection control: *Ask:* What are staff taught about the patient care practices for prevention of infections? How often are they re-educated in infection prevention? What methods does the facility use to visually audit patient care staff infection control practices? How often are the visual audits of patient care staff conducted? If visual audits identify a problem with staff, how do you involve those staff in the development and implementation of the solution?

Review the documentation visual audits of personnel infection control practices while delivering care to patients.

- Expect to see evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff member providing care to patients (e.g. initiation and discontinuation of hemodialysis, vascular assess care, medication preparation and administration, hand hygiene, etc.). There should be evidence of actions taken for improvement when lapses in practices were observed, i.e., involved staff included in the investigation into issues surrounding the poor practices (e.g. low staffing) and development and implementation of improvement plans, rather than just counseling or reeducating (V637, 132, 142, 147).

Patient education for infection prevention: *Ask:* How are patients educated about infection prevention? How are patients encouraged to be engaged in knowing what infection prevention actions (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment) they and staff should follow? How are the patients encouraged to speak up if they have concerns about personnel infection control practices?

- Expect to see that the facility's infection prevention and control program includes educating patients and families about strategies for remaining infection-free (V637, 562, 585).

For facilities with high rates of infection, high rates of CVC >90 days, or patterns of survey findings in infection control: *Ask:* What investigation have you conducted into your facility's problematic

infection issue? What QAPI strategies have you implemented to improve the problem? What improvements have you achieved?

- Expect to see that a facility with high patient infection rates has fully investigated for trends and causes of the infections, including but not limited to staff care practices, water/dialysate and dialyzer reprocessing sources. For high rates of CVC >90 days, there should be evidence of meaningful strategies implemented for reducing CVC rates. When reductions in infection rates or CVC >90 days rates are not attained, there should be evidence of revisions and changes in performance improvement actions until improvements are achieved (V637).

➤ **Medical error/adverse occurrence/clinical variance tracking and investigation system:** The intent of this review is to ensure that there is an effective QAPI system in place for reporting, investigating, and responding to errors/occurrences. **The error/occurrence log is not intended as a source for survey citations except as related to the QAPI process.** *Tell the responsible person that you will be reviewing the facility error/occurrence log with them.*

Review the facility error/occurrence log for the past 6 months: *Select one error/occurrence to “follow” along with the responsible person. You may randomly select the error or select one pertinent to concerns identified during the survey. Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI actions to prevent future similar occurrences.*

- Expect to see evidence that the facility thoroughly investigated the error/occurrence by looking at why it happened, including interviews with all applicable staff to understand what circumstances surrounded it, and involved those staff members in the development of the plan for resolution. There must be evidence that the facility implemented a meaningful action plan to mitigate factors that contributed to the error/occurrence, monitored the plan for effectiveness in preventing recurrence, and, if a similar error/occurrence happened, revised and implemented the revised plan (V634).

➤ **Data-driven focus areas and survey findings areas:** *Using your list of QAPI focus areas for the survey, Review those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask: How do you prioritize facility performance improvement activities? How did the facility-based QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did you take for improvement, and how were the actions and subsequent outcomes monitored to assure improvements were attained and sustained? If improvements were not attained, what actions did you take?

For each data-driven focus area and survey finding area you reviewed:

- Expect to see evidence that the facility:
 - Prioritized performance improvement activities to assure the areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner (V639)
 - Routinely monitored the focus area, recognized that a problem/opportunity for improvement existed, thoroughly investigated root/multiple causes of the issues, and developed and implemented performance improvement plans
 - Monitored the performance improvement plan to attain and sustain improvements, or, if goals were still not achieved, revised the actions until improvements were attained and sustained (V626, 628-637)

Segment III: Culture of Safety

In healthcare, lessons show that assurance of patient safety is only achieved through the implementation of a facility-wide “culture of safety.” The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated. A facility-wide culture of safety enables complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients. This segment includes reviews of the following 3 areas:

- **Risk Identification and Reporting:** To verify that there is an effective system in place for reporting all errors/occurrences, “near misses”/“close calls,” and potential risks to patients

Ask: How do you define medical errors/adverse occurrences/clinical variances? What occurrences are staff expected to report? **Compare:** *the answer (list of occurrences) with the list in the section “Medical error/adverse occurrences/clinical variances” from the table included on page 2 of the “ESRD Core Survey QAPI Review Worksheet” to ensure that these occurrences, at a minimum are recognized as potentially hazardous and are included in the facility reporting and investigation system.*

Ask: How do you ensure staff report “near misses” and “close calls” when an error/adverse occurrence/clinical variance did not actually occur, but was averted? How do you track and investigate near misses/close calls? **Note:** *The evaluation of near misses/close calls has been shown to be a rich source of error/adverse occurrence prevention and highly effective for improving patient safety.*

- Expect to see that the facility medical error/adverse occurrence/clinical variance reporting system includes all expected error/occurrences, and staff education for reporting defined occurrences and near misses/close calls (V634)

- **Staff Engagement Review:** To verify the presence of open communication between all levels of facility staff where all staff are engaged in the QAPI processes and encouraged to voice concerns without fear of retribution

Ask: How do you ensure open communication with all levels of staff? How are staff educated about and encouraged to freely report errors/occurrences/clinical variances, and near misses/close calls without fear of retribution? How are staff encouraged to voice concerns about or ideas for improvements in their work environment? How do you engage all levels of staff in QAPI activities? How are staff suggestions, concerns, and complaints recorded and responded to?

Review the Staff Suggestion/complaint log: *Look for evidence that the facility has an organized, facility-based system in place for staff to submit written or verbal suggestions for improvement, communication of concerns about their work environment, and complaints.*

- Expect to see evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment. There should be evidence that administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues (V627).

➤ Patient Engagement Review

Patient health outcomes, physical and mental functioning review: To verify that the facility QAPI Team is focused on patients' psychosocial status by regular monitoring through the administration and use of an age-appropriate standardized survey that assesses the patients' physical and mental functioning

Ask: How do you track and trend eligible patients' scores in an age-appropriate standardized physical and mental functioning survey (Health Related Quality of Life-HRQOL survey)? What is your facility's threshold for patients completing and refusing the survey annually? *Note:* Although it is expected that a few patients may refuse to participate in the assessment of their physical and mental functioning, high refusal rates, e.g., >20% would indicate a problem which should be recognized and addressed with performance improvement actions.

Review the QAPI documentation related to patient physical and mental functioning outcomes monitoring.

- Expect to see that the QAPI program tracks and trends the % of eligible patients who complete and refuse the physical and mental functioning survey, and track and trend the scores on a facility level.
- If the trends showed facility-level scores declined or an increase in the refusal rate, there should be evidence that the facility recognized a problem existed, investigated the possible causes, and took meaningful actions to address the issue(s) and attain improvements (V628).

Patient grievance/complaint/suggestion system: To verify that the facility is “listening” to the patients, and that a patient grievance/complaint submission system is in place that encourages patients to feel free to express concerns without fear of reprisal. *If the patient interviews indicated trends of concerns about reluctance to speak up, plan to spend more time reviewing this area with the responsible facility-based person. Tell the responsible facility-based person you will be reviewing the patient grievance/complaint suggestion log with them.*

Ask: How are staff taught to respond to patients' voiced concerns? What types of patient concerns do you educate and expect staff to report and record?

Ask: How are patients educated about and encouraged to freely speak up and voice suggestions and complaints/grievances without fear of retribution or retaliation? How are their concerns, verbal or written suggestions, and complaints/grievances recorded and responded to? What is your facility's system for communicating with the patient and reporting the resolution to him/her?

Review the patient suggestion/complaint/grievance log with the responsible facility-based person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient. You may wish to interview the involved patient about their experience using the facility patient suggestion/complaint/grievance system.

- Expect to see that the facility management and staff encourage patients to verbalize suggestions and concerns, in addition to written complaints/grievances. Staff should be educated how to respond professionally to patients' verbalized concerns and to report them to their supervisor for recording and follow up (V627).
- There must be evidence that the patient's concern you reviewed was recorded, the circumstances investigated, mutually acceptable resolution reached, and the result communicated to the patient (V636, 465, 765).

Patient Satisfaction Survey: To verify that the facility routinely assesses the patients' satisfaction with the facility and care received and acts upon the identified opportunities to improve care.

Ask: How do you assess patient satisfaction/perceptions of care at this facility?

Review summary information of the most recent patient satisfaction survey results. If trends of negative patient responses were identified, ask: How did you utilize that information to improve programs or care delivery (V636)?

Note: In the chronic dialysis setting where patients are encouraged to speak freely without fear of reprisal, patient voiced concerns, suggestions and complaints/grievances are expected and indicate the presence of a culture of safety. If the facility responsible person states there are no patient suggestions, verbalized or written concerns or complaints/grievances, this may be a cause for concern and indication of an absence of open communication and culture of safety (V627).

Triggers for citation in QAPI:

The QAPI program does not:

- Administer oversight of all facility operations including monitoring all areas and conducting practice audits as required by the CfC (V132, 260, 362-368, 403)
- Recognize and address risk areas where facility outcomes and/or survey findings indicate performance improvement is needed/indicated (V625-640)
- Follow up on performance improvement plans, resulting in improvements not attained or sustained or recurring similar adverse events (V634, 638)
- Make substantial efforts to establish and maintain a facility-wide culture of safety (V627)-
Consider the survey team's interviews with patients, staff and administrative personnel, along with the above reviews in the Culture of Safety QAPI Review Segment III, to determine if substantial efforts are being made to establish and maintain a facility-wide culture of safety.

Extending the QAPI review should be conducted if there are serious pervasive deficient practices identified during the survey which have not been recognized and/or adequately addressed by the QAPI program. Extending the QAPI review should include investigation into the facility's compliance with the Conditions for Coverage of Medical Director and Governance. This may include interviews with the facility administrator, medical director, and governing body members to determine what administrative failures have contributed to the pervasive problems, through lack of adequate staff and/or resources (V754, 756, 757); lack of staff training and education (V713, 715, 760, 761, 763); and/or lack of involvement or leadership of the medical director (V712, 714).

➡ Decision Making:

Purpose - To facilitate communication and collaboration among survey team members regarding potential survey findings and to prepare for the Exit Conference

- Meet with the survey team to discuss the survey findings
- Refer to reference documents on ESRD decision making
- Make copies of evidence as needed to document survey findings

➡ Exit Conference:

Purpose - To notify the facility of the concerns identified during the survey, and the preliminary findings of deficient practice

- Verbally present findings in order of severity; do not provide specific V-tags
- Follow relevant SOM & State procedures



ESRD Core Survey Field Manual

Tab 2: ESRD Core Survey Laminates

- Outline of ESRD Core Survey Process
- ESRD Core Survey Triggers
- ESRD Facilities V-Tags & Identifiers
- Measures Assessment Tool
- Infection Control/Requirements for Isolation Room/Area
- Critical Water and Dialysate Requirements/Water System Flow Diagram
- Personnel Requirements/National Commercial Dialysis Technician Certification Organizations

Outline of ESRD Core Survey Process

▲ Presurvey Preparation:

- *Review most current dialysis facility report following ESRD Core Survey Data Worksheet guidance; note how facility is ranked on the State Profile/Outcomes list*
- *Contact the ESRD Network about quality concerns*
- *Copy Entrance Conference Materials/Clinical Outcomes Tables from Data Worksheet*

Introductions: *Contact the person in charge; explain purpose of the survey; present them w/ Entrance Conference Materials/Clinical Outcomes Tables to complete & return w/in 3 hours*

Environmental "Flash" Tour: *Observe 4 patient-related areas listed; ASK staff about the facility "culture of safety" in all 4 areas:*

- **In-center dialysis patient treatment area:** *Observe 25% (min 3) occupied dialysis stations including the patients, their vascular accesses & surroundings of the stations; check availability & functionality of emergency equipment*

Triggers:

- Dummy drip chambers present in treatment area (V400, 403)
- Vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Evidence of poor staffing to meet patients' needs (V757)
- Blood spills not cleaned up; equip &/or surfaces spattered with blood (V122)
- HD machine transducer protectors wetted with blood not changed (V120)
- Insufficient space to prevent cross-contamination & use emergency equip (V404)
- No functional AED/defibrillator, oxygen, suction, emergency medications, Ambu bag (V413); insufficient or unavailable emergency evacuation supplies (V415)
- Hemodialysis machines in observed poor repair (V403)
- If dialyzer reuse, noticeable germicide odors (V318)
- Disrespectful communication or actions toward patients (V452, 627)
- Failure to offer patients privacy & confidentiality (V454)

➤ **Water treatment/dialysate preparation area:** *Observe carbon system, chlorine testing equip & reagents, current total chlorine test, RO & DI monitoring & dialysate proportioning ratios*

Triggers:

- Carbon system: absence of 2 or more carbon tanks w/sampling port between (V192)
 - Current total chlorine test not done, reagents not sensitive to 0.1mg/L, expired or don't match testing equip (V196)
- RO: absence of functioning H2O quality monitor & audible alarm in tx area (V200)
- If DI present: absence of functioning resistivity monitor & alarm visible & audible in tx area, absence of automatic divert-to-drain or stop valve, DI not monitored 2x/d (V202, 203)
- Water distribution equip in observable disrepair or contaminated state (V403)
- Acid & bicarb concentrates of different proportioning ratios present (V249)
- Acid or bicarb mixing & distribution equip in disrepair or contaminated state (V403)

➤ **Reuse room:** *Observe condition of equip, dialyzer storage & dialyzer refrigerator, if present*

Triggers:

- Stored dialyzers aesthetically unacceptable (V343); not protected from unauth access (V321)
- Dialyzers not stored w/n germicide manufacturer's temperature range (V345)
- Reprocessing room or equip in observable disrepair (V318, 403)
- Dirty dialyzers kept at room temp >2 hrs; dialyzer refrigerator temp not monitored (V331)

AVF=arteriovenous fistula; **AVG**=arteriovenous graft; **BFR**=blood flow rate; **CVC**=central venous catheter; **DFR**=dialysate flow rate; **DFU**=directions for use; **DI**=deionization; **EBCT**=empty bed contact time; **HD**=hemodialysis; **PCT**=patient care technician; **PD**=peritoneal dialysis; **PM**=preventative maintenance; **RO**=reverse osmosis; **TDS**=total dissolved solids ▲ Indicates a Core Survey worksheet for the task Centers for Medicare & Medicaid Services - ESRD Core Survey Version 1.3

➤ **Home dialysis training area:** *Observe the physical environment, infection control, availability of emergency equipment & method for summoning immediate assistance*

Triggers:

- Insufficient space to prevent cross-contamination between patients (V404)
- Insufficient patient privacy (V406)
- Blood /PD effluent spills not cleaned; equip or surfaces visibly spattered (V122)
- Absence of functional immediately available emergency resuscitation equipment (V413)
- No method for summoning immediate assistance (V402)

Triggers for extending the tour to other areas:

- Evidence of serious lack of environmental maintenance w/ potential to impact pt. safety, e.g., large areas of water damage, mold, uneven floor surfaces in pt.-related areas; (V401, 402)

▲ **Entrance Conference:** *with the facility administrative person*

- **Obtain & Review current facility information/outcomes on completed Entrance Conference Materials/Clinical Outcomes Tables**
- **Explain purpose & timeline of survey:** *Ask questions from "Entrance Conference Questions"*
- **Discuss the current/facility outcomes with the administrative person**
- **Compare the current/facility outcomes in "%Met Goal" column of Clinical Outcomes Tables with applicable "Threshold for % Met Goal" in Clinical Outcomes Threshold Table in current FY ESRD Core Survey Data Worksheet**
- **Determine the data-driven focus areas for survey clinical care reviews (areas where national thresholds not met & need for improvement is indicated)**

▲ **Observations of Hemodialysis Care & Infection Control Practices:**

➤ **Observe direct care staff delivering care to HD patients using observational checklists for:**

- Initiation of hemodialysis w/central venous catheter (CVC)
- CVC exit site care
- Discontinuation of hemodialysis & post-dialysis care of CVC
- Initiation of hemodialysis w/AVF or AVG
- Discontinuation of hemodialysis w/AVF or AVG
- Cleaning & disinfection of the dialysis station between patients
- Preparation of the dialysis machine & extracorporeal circuit
- Dialysis supply management
- Medication preparation & administration

Triggers:

- Observed trends of breaches in infection control patient care practices:
 - Poor hand hygiene & glove use practices (V113)
 - Supplies taken to station not disposed, disinfected or dedicated (V116)
 - Clean dialysis supplies not protected from potential contamination (V119)
 - Breaches in aseptic practices for CVC (V147) or AVF/AVG care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- Use of dummy drip chamber to set up HD machine for treatment (V400, 403)
- Not testing hemodialysis machine alarms (V403)
- Not testing dialysate pH/cond w/ independent method or staff unaware of parameters (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers per DFU (V352, 403)
- Not assessing patients or monitoring during tx per facility policy (V504, 543, 550, 551, 715)

Outline of ESRD Core Survey Process

- Medications not prepared in a clean area away from the dialysis stations (V117)
- Single dose vials punctured more than once or used for multiple patients (V118)
- Multidose vials punctured with previously used syringe or needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared/administered by unqualified personnel (V681)
- **Review Facility Isolation practices:** *If there is an HBV+ patient on in-center HD; Observe isolation room/area/equip/supplies; Observe care as above if possible; Review staff assignments for current week; Ask staff about assignments when HBV+ patient is dialyzing*
- HBV+ patient(s) not isolated (V110, 128, 129)
- Observed trends of breaches in infection control practices (V113, 116, 117, 119, 121)
- Staff assigned/delivering care to HBV+ patient & susceptible patients (V110, 131)-for exceptions, refer to Core Survey Process
- Isolation equip not dedicated for use on HBV+ patients (V130)
- Non-HBV+ patient(s) dialyzing in isolation room/area when HBV+ patient is on in-center HD census (V110, 128, 130)
- **Verify dialysis treatment prescription delivery:** *Compare the dialysis prescription/orders with delivered treatment for 4-5 patients (dialysate, dialyzer, BFR, DFR)*
- 1 or more patients not dialyzed on ordered prescription (V543, 544)
- **▲ Patient Sample Selection:**
 - **Review patient-specific info from Entrance Conference Materials/Clinical Outcome Tables**
 - **Select at least 10% of patients on census (min 4) w/ all modalities offered w/criteria below:**
 - Not meeting goals (“outliers”) in the data-driven-focus areas for the survey
 - “Unstable” patients
 - New admissions <90 days
 - LTC residents receiving home dialysis at the LTC facility
 - Observed w/concerns
 - Involved in a complaint to be investigated: limited to ≤25% of pt. sample
 - Involuntarily discharged in past 12 months, not previously investigated by SA
 - **Record the patient sample w/criteria used for selecting them**
- **▲ Water Treatment & Dialysate Review:** *Review critical water treatment components with on-site person(s) routinely responsible for the activity & daily monitoring:*
 - **Observe total chlorine test; interview about maximum allowable total chlorine; actions taken for breakthrough; amount of carbon (EBCT) present. See notes in Core Survey process re the use of block carbon and on-line chlorine monitors.**
- Triggers:
 - Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-verified by interview or record review (V195)
 - Total chlorine test result >0.1mg/L; done incorrectly or w/ incorrect reagents/equip (V196)
 - Staff unaware of max level of 0.1mg/L total chlorine & breakthrough procedures (V260)
 - **Observe reverse osmosis (RO) unit, water quality monitor & alarm; interview about monitoring RO function by % rejection & water quality by TDS or conductivity**
- Triggers:
 - Absence of RO % rejection & product water TDS or conductivity monitor & alarm audible in patient tx area; readings not recorded daily (V199, 200)
 - **Observe DI, if present: Interview about DI & if it is included in back-up plan; Ask about automatic divert-to-drain or stop valve, minimum resistivity, actions if resistivity <1 megohm (STOP dialysis), ultrafilter after DI**
- Triggers: (if DI is part of back-up plan, all items below must be included in plan)
 - Absence of functional resistivity monitor/alarm, visible & audible in patient tx area or not monitored 2x/day (V202, 203); No ultrafilter post DI (V204)
 - Absence of a functional automatic divert-to-drain or stop valve (V203)
 - Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion i.e., STOP dialysis (V260)
 - **Interview person(s) responsible for dialysate mixing/testing & microbiological monitoring about proper dialysate mixing, acid batch testing, timeframe for bicarbonate use, “spiking”, microbiological sample sites & techniques, timing, frequency of cultures on each HD machine**
- Triggers:
 - Water distribution system not disinfected monthly (V219); Water/dialysate samples not drawn before disinfection (V254); each HD machine not cultured at least annually (V253)
 - Staff unaware of correct dialysate mixing, acid batch testing procedures “spiking”, duration of bicarbonate usability, etc. (V233, 235, 236, 260)
 - **Review facility water/dialysate oversight logs:**
 - Total chlorine tests-2 months; Product water chemical analysis-12 months
 - RO monitoring % rejection & product water TDS or conductivity-2 months
 - DI, if present or used in past 12 months: resistivity readings 2x/day-2 months
 - Microbiological results of water (including reuse room) & dialysate-6 months
 - Practice audits of staff conducting water, dialysate testing & procedures-12 months
- Triggers:
 - Total chlorine >0.1mg/L & no documentation of appropriate actions taken (V197)
 - Chemical analysis of product water not done at least annually (V201)
 - Irregularities, trends of omitted tests (V178, 180, 196, 199, 200, 202, 203, 213, 252, 253)
 - Culture results exceeding action/max levels & no doc of appropriate actions taken (V178, 180)
 - Practice audits of staff not conducted at least annually (V260)
- **▲ Dialyzer Reprocessing/Reuse Review: Observe the high risk components of dialyzer reprocessing & interview the reuse technician:**
 - **Transportation of used/dirty dialyzers** to the reprocessing room/area
 - **Pre-cleaning procedures** rinsing, header removal/cleaning
 - **Ask about germicide mixing, storage & spill management; dialyzer labeling/similar names warning; pre-processing before use; water quality & water pressure at pre-rinse sink**
 - **Review 12 months of documentation of facility oversight of reuse program:**
 - **QA audits:** obs of staff reprocessing, setting up for patients’ dialysis & dialyzer labeling
 - **Reprocessing equip PM**
 - **Adverse events/dialyzer complaint log**
- Triggers:
 - Improperly performed pre-cleaning or header removal/cleaning (V334)
 - Water used for pre-cleaning not purified to AAMI standards (V333)
 - Absence of functional water pressure gauge at pre-cleaning sink (V332)

Outline of ESRD Core Survey Process

- Germicide not stored, mixed or handled per manufacturer's DFU (V321,339)
 - Reuse tech interview w/inadequate knowledge of key patient safety areas (V309, 319, 320, 328, 330, 345)
 - Dialyzers not transported in a sanitary manner (V331)
 - Dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
 - Reprocessed dialyzers stored for extended periods (V345)
 - QA audits listed not done or incomplete (V360-368)
 - Noticeable strong germicide odors or patient/staff complaints (V318)
 - Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)
- For centralized reprocessing, refer to the current CMS Survey & Certification guidance*

▲ Dialysis Equipment Maintenance:

- *Interview machine maintenance technician about HD machine manufacturer's DFU for PM i.e., prescribed intervals & operating hours for PM*
 - *Review 12 mos PM logs for 10% of HD machines (min. 3) for compliance with manufacturer's DFU –include home HD machines maintained by the facility in the 10% sample*
 - *Review 2 mos logs for calibration of equip used for machine PM & pH/conductivity testing*
- Triggers:**
- Trends of non-adherence to HD machine manufacturer's directions for PM (V403)
 - No calibration of pH & conductivity meters or equip calibration meters or not per DFU (V403)
 - Observations of serious lack of maintenance of ancillary equip that has the potential to impact patient safety (V403, 626)

Home Dialysis Training & Support Review:

- If the dialysis facility provides only home dialysis training and support, the survey must include all applicable survey tasks, e.g., Environmental Tour, Water/dialysate review, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review
- *Interview home training nurse(s) re patient candidacy evaluation, training, demo of comprehension, IDT support & QAPI oversight of home training & support programs*
 - *Observe the direct care of home dialysis patient(s) if the opportunity arises during the survey when a home dialysis patient is being treated or trained at the facility*
 - *Interview home dialysis patients during Patient Interviews*
 - *Review medical records of home dialysis patients during Medical Record Review*
- Triggers:**
- Home training nurse(s) lack knowledge of training patients/caregivers or monitoring patients
 - Patient/caregiver interviews identify concerns (V581, 585, 586, 592)
 - Medical record reviews of home dialysis patients identify concerns related to training or patient monitoring (V585, 586, 593-595)
 - Not evaluating home program outcomes separately in QAPI (V626, 628)
 - If care observed, refer to triggers for infection control in Observations of HD Care

▲ Patient Interviews: Interview sampled patients, minimum of 4 patients; If <4 sampled

patients can be interviewed, select additional alert patients to interview for total of at least 4. For phone interviews with home dialysis patients, ask nurse to alert patient about interview.

Triggers:

- Patients express concerns regarding:
- Patients' rights & responsibilities (V451)
- Education re transplant options & all dialysis modalities & settings (V451, 453, 458)

- Disrespectful treatment from staff (V452)
- How to prevent infections & protect their dialysis access (V562)
- The safety & comfort of physical environment of facility (V401, 402)
- Disaster preparedness & emergency evacuation procedures (V409, 412)
- Communication with IDT & involvement in planning their care (V501, 541)
- Proficiency of staff in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff (V757-759)
- Culture of Safety: freedom to report care concerns, make suggestions, ask questions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training & IDT support of home dialysis patients & caregivers (V585, 592)

▲ Medical Record Review: All medical record reviews are focused reviews focusing on the care provided related to the criteria used for sampling the patient

- *Review medical records of all sampled patients (10% census selected at Pt Sample Selection)*
- *For ALL sampled patients, review dialysis prescription & medication orders, & dialysis treatment records (2-3 wks HD tx records; 8-12 wks PD flowsheets)*
 - *For in-center HD: looking for machine safety checks, treatments delivered as ordered, BP/fluid management, patient monitoring per policy*
 - *For home HD: looking for staff monitoring patient's adherence to orders, BP/fluid management, machine safety checks; water/dialysate quality testing per equip in use*
 - *For PD: looking for staff monitoring patient's adherence to orders, BP/fluid management*
- *Patients w/poor outcomes ("outliers") in data-driven focus areas: review medical record related to THAT area: Looking for IDT actions in monitoring, recognizing the poor outcomes, & addressing it w/interventions to help patient reach outcome goals*
- *Unstable patients: review IDT documentation during 2 most recent assessment/plan of care periods: Looking at functionality of the IDT for addressing issues deeming patient unstable*
- *Newly admitted patients <90 days: review documentation in first weeks at facility: Looking for initial nursing evaluation & orders prior to 1st tx, surveillance for TB, HBV, offered vaccinations & medical, psychosocial & training (home dialysis) needs met*
- *Patients observed w/concerns: Follow the concern*
- *Patients involved in complaint being investigated: Follow applicable complaint process*
- *For Involuntarily discharged patients: Refer to guidance in ESRD Core Survey Process*
- *Home dialysis LTC residents: Follow CMS SCG guidance; Looking for safety of treatment delivery, caregiver training/competency, on-site supervision, ESRD facility oversight*

Triggers:

- Absence of a functional IDT process that monitors, recognizes & addresses barriers to attainment of identified outcome goals in clinical & psychosocial areas
- Patient/caregiver interviews indicate lack of functional patient education program & patients' rights concerns - Extend review to documentation of patient education & patients' rights
- Incomplete, inaccurate, inaccessible or insecure medical records (V726)
- Concerns identified in other survey tasks which can be investigated further through medical record review to support or dispel findings

▲ Personnel Interviews: Interview facility-based (not corporate-based) staff: med director, master's social worker, registered dietitian, 2-3 nursing staff (min. 1 RN & 1 PCT) & nurse manager. Water, reuse, equip main & home training staff interviewed during those survey tasks.

Triggers:

- Concerns identified from personnel or patient interviews or other survey tasks indicating need to expand questioning areas or interview more personnel to support or dispel findings

Outline of ESRD Core Survey Process

▲ **Personnel Record Review:**

- *Review the facility-completed "Personnel File Review" worksheet or equivalent*
- *Select a minimum of 3 personnel files to review/compare to facility documentation for accuracy and/or follow up on concerns from survey*

Triggers:

- Personnel lack required qualifications or competency verification (V410, 681)
- 1 or more personnel files validated indicates inaccurate facility-submitted documentation
- PCTs listed w/ no certification expiration date: check for hire date w/in 18 mos (V695)

▲ **Quality Assessment & Performance Improvement (QAPI) Review:**

- *Note on Facility-Based (not Corporate-Based) QAPI: The review of the facility QAPI program must be limited to the information for only the facility being surveyed, and conducted with facility-based (on-site) administrative personnel. The expectation of a facility QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care to and monitoring facility operations of their individual facility. The facility-based staff are expected to recognize when performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.*
- *Communicate with survey team about areas of concern. Determine focus areas for review during Segment II (i.e., data-driven focus areas & survey findings)*
- *Review QAPI documentation for 6 months; Interview the facility-based responsible person*

Segment I: Monitoring care & facility operations

- *Clinical & operational indicators: Review (briefly) facility QAPI summarizing info to verify all expected clinical & operational indicators are being monitored-per table/list of indicators in "QAPI Review Worksheet"*
- *Oversight of technical operations & practice audits: Review QAPI documentation of review/evaluation/audits and performance improvement actions, when indicated in:*
 - *Water/dialysate quality-monthly cultures, annual water chemical analysis, visual audits of staff conducting testing/operating equip*
 - *Dialysis equip-monthly review of HD machine PM/repairs*
 - *Dialyzer reuse/reprocessing-QA audits done at specified intervals*

Segment II: QAPI Activities in 3 critical priority areas & data-driven focus areas & survey findings (areas of risk) Review/interview re QAPI activities in:

- *Mortality review: Review documentation of QAPI analysis & discussion about mortality occurrences, causes, & trends. If mortality is ↑, performance improvement strategies for addressing contributory factors related to facility care.*
- *Infection prevention/control: Review & discuss 4 aspects of program:*
 - *Infection occurrence tracking/trending/surveillance: all positive cultures recorded w/sufficient info; trends recognized & addressed*
 - *Vaccination: high-risk disease management: Refer to vaccination info from Entrance Conference Materials: all patients tested for HBV & TB; all susceptible patients & staff offered HBV vaccination; patients offered pneumococcal & seasonal influenza vaccines.*
 - *Staff education & audit for infection control: Ask how staff are visually audited for infection control pt care practices; Review visual audits of staff while caring for patients; At least annual infection control education & visual practice audit for each staff member; applicable staff included in performance improvement plan development*

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- *Patient education for infection prevention: Ask about patient education & engagement for personal care & expectations of staff delivering care*
- *Medical error/adverse occurrence/clinical variance tracking & investigation system: Review log for past 6 mos. Note: Adverse event log review is NOT intended as a source for citations except as related to QAPI process. Select an event/occurrence to "follow" through the QAPI process with the facility-based responsible person.*
- *Data-driven focus areas & survey findings: Review QAPI activities for prioritizing, recognizing the problem existed, implementing performance improvement strategies, monitoring for improvements, & when goals still not met, revising & implementing revised plans to attain & sustain improvements.*

Segment III: Culture of Safety: Review/interview facility-based responsible person about the presence of a facility-wide culture that assures patient safety through open communication for all patients & staff, clear expectations communicated to staff, and an effective system for reporting & investigating adverse events/errors

- **Risk identification and reporting: Ask what events are reported at the facility & compare with list on table in QAPI Review Worksheet; how "near misses/close calls" are reported & investigated;**
- **Staff engagement review: Ask how administration supports open, non-judgmental communication with/among all levels of staff; how/what staff are educated about reporting concerns & suggestions for improvement; how staff are given clear expectation of their duties, & how all levels of staff are involved in the facility QAPI activities**
 - **Review staff suggestion/complaint log to ensure there is a functional & responsive system in place for staff to freely voice concerns without fear of retribution**
- **Patient engagement review:**
 - **Patient health outcomes, physical & mental functioning: Ask how scores from patient physical & mental functioning surveys (HRQOL) are tracked & trended in QAPI, what the threshold is for patient refusals.**
 - **Review QAPI Team analysis/discussion/action for patient HRQOL survey outcomes**
 - **Patient grievance/complaint/suggestion system: Ask how staff are educated on what patient voiced issues to report & how to respond professionally; how patients are encouraged to freely speak up, self-advocate, and voice concerns w/o fear of retribution;**
 - **Review patient grievance/complaint/suggestion log: "follow" a complaint; ask the facility-based responsible person to show how it was investigated, resolved & result reported to patient; You may wish to interview the patient, if indicated**
- **Patient satisfaction: Ask how patients' satisfaction/perceptions of care are assessed.**
- **Review summary of most recent patient satisfaction survey. If negative trends in patient responses were identified, ask how that information was used to improve care.**

Triggers: The QAPI program does not:

- Administer oversight of all facility operations: monitor all areas & conduct practices audits as required in the CFC (V132, 260, 362-368, 403)
- Recognize & address risk areas where performance improvement is indicated (V625-640)
- Follow up on performance improvement plans, resulting in improvements not attained or sustained (V638)
- Make substantial efforts to establish and maintain a facility-wide culture of safety (V627)

Decision Making: Meet with survey team to discuss survey findings; refer to ESRD decision-making tools, & make copies of facility documents as needed

Exit Conference: Verbally present findings in accordance with SOM and State procedures

AVF=arteriovenous fistula; AVG=arteriovenous graft; BFR=blood flow rate; CVC=central venous catheter; DFR=dialysate flow rate; DFU=directions for use; DI=deionization; EBCT=empty bed contact time; HD=hemodialysis; PCT=patient care technician; PD=peritoneal dialysis; PM=preventative maintenance; RO=reverse osmosis; TDS=total dissolved solids ▲ Indicates a Core Survey worksheet for the task

ESRD Core Survey Process Triggers

Environmental "Flash" Tour:

In-center dialysis patient treatment area

- Dummy drip chambers present (V400, 403)
- Vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Evidence of poor staffing to meet patients' needs (V757)
- Blood spills not cleaned up; equip &/or surfaces spattered with blood (V122)
- HD machine transducer protectors wetted with blood not changed (V120)
- Insufficient space to prevent cross-contamination & use emergency equip (V404)
- No functional AED/defibrillator, oxygen, suction, emergency medications, Ambu bag (V413); insufficient or unavailable emergency evacuation supplies (V415)
- Hemodialysis machines in observable poor repair (V403)
- If dialyzer reuse, noticeable germicide odors (V318)
- Disrespectful communication or actions toward patients (V452, 627)
- Failure to offer patients privacy & confidentiality (V454)

Water treatment/dialysate preparation area:

- Carbon system: absence of 2 or more carbon tanks w/sampling port between (V192)
 - Current total chlorine test not done, reagents not sensitive to 0.1mg/L, expired or don't match testing equip (V196)
- RO: absence of functioning H2O quality monitor & audible alarm in tx area (V200)
- If DI present: absence of functioning resistivity monitor & alarm visible & audible in tx area, absence of automatic divert-to-drain or stop valve, DI not monitored 2x/day (V202, 203)
- Water distribution equip in observable disrepair or contaminated state (V403)
- Acid & bicarb concentrates of different proportioning ratios present (V249)
- Acid or bicarb mixing & distribution equip in disrepair or contaminated state (V403)

Reuse room:

- Stored reprocessed dialyzers aesthetically unacceptable (V343); not protected from unauthorized access (V321); not stored w/n germicide temp range (V335)
- Reprocessing room or equipment in observable disrepair (V318, 403)
- Dirty dialyzers kept at room temperature >2 hrs. (V331)
- Dialyzer refrigerator temperature not monitored (V331)

Home dialysis training area:

- Insufficient space to prevent cross-contamination between patients (V404)
- Insufficient patient privacy (V406)
- Blood /PD effluent spills not cleaned; equip or surfaces visibly spattered (V122)
- Absence of functional immediately available emergency resuscitation equipment (V413)
- No method for summoning immediate assistance (V402)

Extending the tour to other areas:

- Evidence of serious lack of environmental maintenance w/potential to impact patient safety, e.g., large areas of water damage, mold, uneven floor surfaces in the patient-related areas (V401, 402)

Observations of Hemodialysis Care and Infection Control Practices:

Observations of direct staff delivering care

- Observed trends of breaches in infection control patient care practices:
 - Poor hand hygiene & glove use practices (V113)
 - Supplies taken to station not disposed, disinfected or dedicated (V116)
 - Clean dialysis supplies not protected from potential contamination (V119)
 - Breaches in aseptic practices for CVC (V147) or AVE/AVG care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- Use of dummy drip chamber to set up HD machine for treatment (V400, 403)
- Not testing hemodialysis machine alarms (V403)
- Not testing dialysate pH/conductivity w/ independent method or staff unaware of acceptable parameters (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers per DFU (V352, 403)
- Not assessing patients before & after tx or monitoring during tx per facility policy (V504, 543, 550, 551, 715)
- Medications not prepared in a clean area away from the dialysis stations (V117)
- Single dose vials punctured more than once or used for multiple patients (V118)
- Multidose vials punctured with previously used syringe or needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared/administered by unqualified personnel (V681)

Isolation practices:

- HBV+ patient(s) not isolated (V110, 128, 129)
- Observed trends of breaches in infection control practices (V113, 116, 117, 119, 121)
- Staff assigned/delivering care to HBV+ patient & susceptible patients (V110, 131)-*For exceptions, refer to Core Survey Process*
- Isolation equip not dedicated for use on HBV+ patients (V130)
- Non-HBV+ patient(s) dialyzing in isolation room/area when HBV+ patient is on in-center HD census (V110, 128, 130)

Verification of dialysis treatment prescription delivery:

- 1 or more patients not dialyzed on ordered prescription (V543, 544)

Water Treatment and Dialysate Review:

Chlorine removal/carbon system

- Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-*verified by interview or record review*(V195)
 - Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equip (V196)
 - Staff unaware of max level of 0.1mg/L total chlorine & breakthrough procedures (V260)
- #### **Reverse osmosis system**
- Absence of RO % rejection & product water TDS or conductivity monitor & alarm audible in patient tx area; Readings not recorded daily (V199, 200)

ESRD Core Survey Process Triggers

- DI, if present** (If part of back-up plan, items below must be included in plan)
- Absence of functional resistivity monitor/alarm, visible & audible in patient treatment area or not monitored 2x/day (V202, 203)
 - Absence of a functional automatic divert-to-drain or stop valve (V203)
 - Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion i.e., stop dialysis (V260)
 - No ultrafilter post DI (V204)
- Interviews**
- Water distribution system not disinfected monthly (V219) Water/dialysate samples not drawn b4 disinfection (V254); each HD machine not cultured at least annually (V253)
 - Staff unaware of correct dialysate mixing, acid batch testing, “spiking” (V260)
- Log reviews**
- Total chlorine >0.1mg/L & no documentation of appropriate actions taken (V197)
 - Chemical analysis of product water not done at least annually (V201)
 - Irregularities, trends of omitted tests (V178, 180, 196, 199, 200, 202, 203, 213, 252, 253)
 - Microbiological results exceeding action/maximum levels & no documentation of appropriate actions taken (V178, 180)
 - Practice audits of staff not conducted at least annually (V260)

Dialyzer Reprocessing/Reuse Review:

- Improperly performed pre-cleaning or header removal/cleaning (V334)
- Water used for pre-cleaning **not** purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V321,339)
- Dialyzers stored for extended periods (V345)
- Reuse tech interview w/inadequate knowledge of key patient safety areas (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
- QA audits listed not done or incomplete (V362-368)
- Noticeable strong germicide odors or patient/staff complaints (V318)
- Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)

Dialysis Equipment Maintenance:

- Trends of non-adherence to HD machine manufacturer's directions for PM (V403)
- No calibration of pH & conductivity meters or equip calibration meters or not per DFU (V403)
- Observations of serious lack of maintenance of ancillary equip that has the potential to impact patient safety (V403, 626)

Home Dialysis Training and Support Review:

- Home training nurse(s) lack knowledge of training or monitoring patients/caregivers
- Patient/caregiver interviews identify concerns (V581, 585, 586, 592)
- Medical record reviews of home dialysis patients identify concerns related to training or patient monitoring (V585, 586, 593-595)
- Not evaluating home program outcomes separately in QAPI (V626, 628)
- If care observed, refer to triggers for infection control in Observations of HD

Patient Interviews:

Patients express concerns regarding:

- Patients' rights & responsibilities (V451)
- Education re transplant options & all dialysis modalities & settings (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- How to prevent infections & protect their dialysis access (V562)
- The safety & comfort of physical environment of facility (V401, 402)
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- Problems due to inadequate numbers of qualified trained staff (V757-759)
- Culture of Safety: freedom to report care concerns, make suggestions, ask questions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training & IDT support of home dialysis patients & caregivers (V585, 592)

Medical Record Review:

- Absence of a functional IDT process that monitors, recognizes & addresses barriers to attainment of identified outcome goals in clinical & psychosocial areas
- Patient or caregiver interviews indicate lack of functional patient education program & patients' rights concerns
- Incomplete, inaccurate, inaccessible or insecure medical records (V726)
- Concerns identified in other survey tasks which can be investigated further through medical record review to support or dispel findings

Personnel Interviews:

- Concerns identified from personnel or patient interviews or other survey tasks that indicate the need to extend the questioning areas of personnel or interview more personnel to support or dispel findings

Personnel Record Review:

- Personnel lack required qualifications or competency verification (V410, 681)
- 1 or more personnel files validated indicates inaccurate facility-submitted documentation
- PCTs listed w/ no certification expiration date: *check for hire date w/in 18 mos* (V695)

Quality Assessment and Performance Improvement (QAPI) review:

The QAPI program does not:

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End Stage Renal Disease Facilities V-Tags & Identifiers

TAG	IDENTIFIER	TAG	IDENTIFIER	TAG	IDENTIFIER
V100	Cfc: 494.20 Compliance with Fed/State/Local Laws	V196	Carbon adsorp-monitor, test frequency	No tag	Info tag-monitor H2O & dialysate sys
V101	Compliance with Fed/State/Local laws	V197	Carbon adsorp-action if first test +	V252	Microb monitor-no H2O samples/method
		V198	Chemical injection systems	V253	Microb monitor-no dialysate sample/collect/freq
V110	Cfc: 494.30 Infection Control	V199	RO-Meets AAMI/monitored, recorded on log	V254	Microb monitor-sample before disinfect
V111	IC-Sanitary environment	V200	RO-Monitor/alarm/prevent use of unsafe H2O use	V255	Microb monitor-repeat cultures
V112	IC-CDC MMWR 2001	V201	RO-Chemical analysis-frequency	V256	Cultures-dip samplers require QC
V113	IC-Wear gloves/hand hygiene	V202	DI-Contain monitor/logged 2x/day	V257	Cultures-refrig over 2 hrs/no calib loop
V114	IC-Sinks available	V203	DI-Alarms/divert to drain	V258	Endotoxin testing in house-how to
V115	IC-Gowns, shields/masks-no staff eat/drink	V204	DI-Require carbon pre/UF post	V259	Personnel-P&P
V116	IC-If to station=disp/dedicate or disinfect	V205	DI-Polish or back up	V260	Personnel-training program/periodic audits
V117	IC-Clean/dirty, med prep area, no common med carts	V206	DI-Chemical analysis-frequency	No tag	Duplicative of requirements at V192, V197
V118	IC-Single use vials	V207	UF-Effective/opaque housing/monitor	V270	Ch/chl breakthrough-corrective action
V119	IC-Supply cart distant/no supplies in pockets	V208	H2O storage & distribution-design	V271	Ch/chl breakthrough-holding tank use
V120	IC-Transducer protectors-not wetted/changed	V209	H2O tank-shape/vent/disinfect/filtr p	V272	Ch/chl breakthrough-notif med dir
V121	IC-Handling infectious waste	V210	H2O storage-monitoring	V273	Ch/chl breakthrough: action=correction
V122	IC-Disinfect surfaces/equip/written protocols	V211	Dist sys-constant flow/no dead ends	V274	H2O test-deviations require response
No tag	IC-PT isolation procedures	V212	H2O dist systems-no added burden	V275	Adverse events-actions expected
V124	IC-HBV- Test all/rev results/status b4 admit	V213	Dist sys-culture/LAL/sites/freq(new)/log	V276	IC use of precontig HD-follow FDA label
V125	IC-HBV- Serococonversion=investigation	V214	Bact control devices-UV light	V277	In-center precontig HD-meets AAMI RD52
V126	IC-HBV-Vaccinate pts & staff	V215	UV lights-filters post	V278	In-center precontig HD cultures/LALs 4x/yr
V127	IC-HBV- Test pts/staff post last dose	V216	Ozone-sys requirements/monitoring		
V128	IC-HBV-Isolation (existing facility)	V217	Hot H2O disinf sys-temp/time/follow DFU/pipe	V300	Cfc: 494.50 Reuse of Hemodialyzers & Bloodlines
V129	IC-HBV-Isolation (new facility)	V218	Hot H2O disinfection sys-monitoring	V301	General requirements-no reuse for HBV+ pts
V130	IC-HBV0- Isolation machines/equip/supplies	V219	Bact control-disinfect 1X/mo/ dwell	No tag	Duplicative of requirement at V327
V131	IC-HBV-Isolation-staffing	V220	Bact control-supply line disinfected	V303	Dialyzer labeled for multiple reuse
V132	IC-Training & education	No tag	Info tag on bicarb & acid conc delivery	V304	Reprocessing-meets AAMI RD47 2001/2002
V142	IC-O sight: monitor activities & implement P&P	V222	Acid bulk storage tanks-safety controls	V305	Records-meet req for med records
V143	IC-Aseptic techniques for IV meds	V223	Conc prep-materials compatibility	V306	Dialyzer reprocessing manual
V144	IC-Staff report IC issues	V224	Mixing systems-H2O/drain/electric	V307	Personnel qualifications
V145	IC-Report communicable diseases	V225	Mixing systems-safe environment/PPE	V308	Training-curriculum
V146	IC-Catheters: general	V226	Mix sys-DFU/monitor/PMI/log/sanitize	V309	Training docu includes med dir cert
V147	IC-Staff education-catheters/catheter care	V227	Mixing systems-self designed	V310	Personnel health monitoring records
V148	IC-Monitor cath-related BSI rates/surv	V228	Mixing systems-labeling	V311	Pt considerations-medical issues
		V229	Mixing systems-perm record/verif/test	V312	Pts inform re dialyzer reuse process
V175	Cfc: 494.40 Water & Dialysate Quality	V230	Mixing systems-cleaning	V313	Equipment-design/construct/function
V176	Water purity: ANSI/AAMI RD52:2004	V231	Acid conc mix sys-empty all/prev corrosion	V314	H2O systems meet AAMI back/chem quality
V177	Max level chem contam in H2O/chem analysis	V232	Bicarb mix sys-empty/disinfect/prev corrosion	V315	Reprocessing systems-utility requirements
V178	Bact H2O-maximum & action levels	V233	Bicarb mix sys-stor/use time/min combine	V316	Maintenance per DFU or 2x/yr/record
V179	Bact H2O-medical director responsible	V234	Bicarb mix sys-not overmixed	V317	Repairs=qual personnel, test b4 ret to use
V180	Bact convent dialysate-max & act levels	V235	Additives-mixing spikes	V318	Reprocessing area & ventilation
V181	Bact of ultrapure dialysate	V236	Additives-label spiked jugs/label specific pt	V319	Environmental safety regarding chemicals
V182	Equipment-general/back up plan	V237	Conc distribute-materials compatible	V320	Personnel protective gear
No tag	Info tag on H2O components-general	V238	System configurations-elevated tanks	V321	Storage area/segregate dialyzers
V184	Environment-secure & restricted	V239	Bicarb conc distrib-wkly disinfect/dwell/conc	V322	Reprocess supplies-specs & testing
V185	Environment-access to ports/meters	V240	Bicarb distribution sys-use of UV	V323	Inventory control
V186	Environment-alarms in treatment area	V241	Bicarb distribution sys-ozone disinfect	V324	Process control test-methods established
V187	Environment-schematic diagrams/labels	V242	Conc distribute-bicarb monitor initially	V325	Process control test-conc of germicide
V188	Sediment filters-config & monitoring	V243	Bicarb jugs rinsed daily/stored dry	V326	Reprocess record complete/available to pt
V189	Cartridge filters-config & monitoring	V244	Bicarb jug maintenance/disinfection	V327	Hemodialyzer labeling-unique to pt
V190	Softeners-auto regenerate/timers/salt lvl	V245	Acid conc dist-conc labeled & color-coded red	V328	Time labeled b4 or 1 st use, updated each use
V191	Softeners-test hardness/log	V246	Bicarb conc dist-color coded blue & sealed	V329	Label composition & placement
V192	Carbon adsorption-two tanks/sample ports	V247	Conc outlets-separate/labeled/connect safety	V330	Information rec on label/similar name warn
V193	Carbon adsorption-banks of tanks	V248	Dialys proportion-match ratio-all conc/machine	V331	Reprocessing-transportation & handling
V194	Carbon adsorption-iodine #900/replacement	V249	Dialys proportion-match mach config w/ratio used	V332	Rinse/clean-preclean equip/pressures
V195	Carbon adsorption-10 minutes EBCT	V250	Dialys proportion-monitor pH/conductivity	V333	Rinsing/cleaning-use AAMI quality H2O

End Stage Renal Disease Facilities V-Tags & Identifiers

TAG	IDENTIFIER	TAG	IDENTIFIER	TAG	IDENTIFIER
V334	Dialyzer header cleaning & disinfection	V412	PE-ER prep-pts oriented/trained	V540	CfC: 494.90 Patient Plan of Care
V335	Rinse/clean-chem used/rinse after each	V413	PE-ER equip-on premises-O2, AED, suction	V541	POC-Goals= community-based standards
V336	TCV measured q use/orig vol known	V414	PE-Emergency plans: EMS contact	V542	POC-IDT develops plan of care
V337	Blood path integrity test after q use	V415	PE-Annual eval-emergency/disaster plans	V543	POC-Manage volume status
V338	Germicide: sufficient for point of use	V416	PE-Contact local EOC annually	V544	POC-Achieve adequate clearance
V339	Germ process-high-level disinfect	V417	PE-Fire safety-Life Safety Code 2000	V545	POC-Effective nutritional status
V340	Dialyzer germicide=90% conc/caps disinfect	V418	PE-LSC-sprinklers	V546	POC-Manage mineral metabolism
V341	Chemical germ conc-verification testing	V419	PE-LSC-Waiver if State req meet Fed req	V547	POC-Manage anemia/H/H measured q mo
V342	Dialyzer exterior-low-level disinfection	V420	PE-LSC-waiver	V548	POC-Home pt-eval safe ESA admin
V343	Dialyzer inspect p reprocess/all aspects			V549	POC-Monitor ESA response
V344	Disposition of rejected dialyzers	V450	CfC: 494.70 Patients' Rights	V550	POC-Vascular access-monitor/referrals
V345	Reprocessed dialyzer storage	V451	PR-Pts informed of rights when begin tx	V551	POC-VA monitor/ prevent failure/stenosis
V346	Prep 4 dialysis-written P&Ps for germ test	V452	PR-Respect & dignity	V552	POC-P/S counseling/referrals/HRQOL tool
V347	Prep 4 dialysis-visual inspect-all aspects	V453	PR-Receive understandable information	V553	POC-Home dialysis plan or why not
V348	Verify pt ID-2 people	V454	PR-Privacy & confidentiality-treatment	V554	POC-T transplantation status plan or why not
V349	Verify of germicidal contact	V455	PR-Privacy & confidentiality-records	V555	POC-Rehab status addressed
V350	Germicide presence test of each dialyzer	V456	PR-Participate in care: disc/refuse tx	V556	POC-Completed/signed by IDT & pt
V351	Germicide presence-process control/sampling	V457	PR-Can have advance dir, told fac AD P&P	V557	POC-Initial implemented-30 days/13 tx
V352	Dialyzer priming/rinsing the germicide	V458	PR-Informed-all modalities & settings	V558	POC-Implement updates-15 days p pt assess
V353	Test for resid germ/max time rinse to use	V459	PR-Informed of pt care policies	V559	POC-Outcome not achieved-adjust POC
V354	Monitor-dialysis/pt's clinical course	V460	PR-Informed of care & options	V560	POC-Pts seen by med staff 1x/mo
V355	Monitoring-fever/chills/other symptoms	V461	PR-Informed of own medical status	V561	POC-Track TP ref/status; contact TP ctr yrly
V356	Recording adv events/dialyzer c/o log	V462	PR-Informed of services & charges	V562	POC-PT/family education & training
V357	Dialyzer failures/blood leaks recorded	V463	PR-Receive services outlined in POC		
V358	Monitoring-pt clinical results/KtV	V464	PR-Informed of rules/expectations-conduct	V580	CfC: 494.100 Care at Home
V359	Ultrasaturation-monitoring pt's weight	V465	PR-Informed of internal grievance process	V581	H-IDT resp for services=in-center pts
V360	QA-General/records/trend analysis	V466	PR-Informed of external grievance processes	V582	H-IDT oversees home training
V361	Sch of QA acis-med dir responsible	V467	PR-Informed-may file grievance anon	V583	H-Training by certified home train facility
V362	QA audits-pt considerations annually	V468	PR-Informed-d/c/trans P&P inc IVD	V584	H-Training conducted by qualified RN
V363	QA audits-manuals/P&P annual & prin	V469	PR-Receive written notice 30 days pre IVD	V585	H-Training content includes ER prep home pts
V364	QA audits-phys plant/envirom safety 1x/yr	V470	PR-Rights posted; state/NW contact info	V586	H-PT/caregiver demo comprehend training
V365	QA audits-reprocessing supplies 2x/yr			V587	H-Fac get/review pt records q 2 mo
V366	QA audits-hemodialyzer labeling quarterly	V500	CfC: 494.80 Patient Assessment	V588	H-Support services must be provided
V367	QA audits-reprocess proced monthly/2x/yr	V501	PA-IDT members/responsibilities	V589	H-Monitor home adapt/home visits=POC
V368	QA audits-preparation for dialysis/4x/yr	V502	PA-Assess current health status/comorbid	V590	H-Coordination of care by member of IDT
V378	Reprocess dialyzers & bloodlines by DFU	V503	PA-Appropriateness of dialysis Rx	V591	H-Home pt plan of care dev/updated
V379	Dialyzers exposed to only one germicide	V504	PA-Assess B/P & fluid management needs	V592	H-PT consultation with IDT members pm
No tag	Duplicative of requirements at V354 & V355	V505	PA-Assess lab profile	V593	H-Monitor H2O/dialysate inc on site eval
V381	Blood/dialysate cultures for adv pt react	V506	PA-Immunization/medication history	V594	H-Preconfig HD sys -test H2O/dialy per DFU/FDA
V382	Cluster of adv pt reactions=suspend reuse	V507	PA-Assess anemia	V595	H-Meet RD 52:2004
V383	FDA reporting of adverse outcomes	V508	PA-Assess renal bone disease	V596	H-Fix H2O/dialysate probl/arrange back-up tx
		V509	PA-RD-nutritional status	V597	H-Provide ordered supplies/equipment
V400	CfC: 494.60 Physical Environment	V510	PA-MSW-psychosocial needs	V598	H-Plan for ER back-up dialysis
V401	PE-Safe/functional/comfortable environment	V511	PA-Dialysis access type & maintenance	V599	H-Recordkeeping system
V402	PE-Building-construct/maintain for safety	V512	PA-Eval for self care/modality/setting		
V403	PE-Equipment maintenance-manufacturer's DFU	V513	PA-Transplantation referral		
V404	PE-PT care environment-sufficient space	V514	PA-Eval family/support systems		
V405	PE-Comfortable temperature	V515	PA-Eval current phys act lvl/voc/phys rehab		
V406	PE-Accommodate pt privacy	V516	PA-Frequency-initial-30 days/13 tx		
V407	PE-HD pts in view during treatments	V517	PA-F/U reassessment-within 3 mo of initial		
V408	PE-Emergency preparedness-procedures	V518	PA-Assess HD adeq q mo;PD adeq q 4 mo		
V409	PE-ER prep staff-initial/annual/inform pts	V519	PA-Frequency reassess-able 1x/yr		
V410	PE-PT care staff-current CPR cert	V520	PA-Frequency reassess-unstable q mo		
V411	PE-Nurs staff trained in ER equip & meds				

End Stage Renal Disease Facilities V-Tags & Identifiers

TAG	IDENTIFIER	TAG	IDENTIFIER
V625	CfC: 494.110 Quality Assess & Performance Imp	V710	CfC: 494.150 Responsibilities of the Medical Director
V626	QAPI-Covers scope-serv/effective/IDT invol	V711	MD resp-Medical dir qualified/accountable to Gov Body
V627	QAPI-Facility-wide culture of safety	V712	MD resp-QAPI Program
V628	QAPI-Measure/track qual indicators	V713	MD resp-Staff ed, training & perform
V629	QAPI-Indicator-Adequacy of dialysis	V714	MD resp-Develop, review& approve P&P
V630	QAPI-Indicator-Nutritional status	V715	MD resp-Ensure all adhere to P&P
V631	QAPI-Indicator-CKD-MBD	V716	MD resp-Ensure IVD P&P followed
V632	QAPI-Indicator-Anemia management		
V633	QAPI-Indicator-Vascular access		CfC: 494.160 [Reserved]
V634	QAPI-Indicator-Medical injuries/errors		
V635	QAPI-Indicator-HD reuse program	V725	CfC:494.170 Medical Records
V636	QAPI-Indicator-Pl. satis & grievances	V726	MR-Complete, accurate, accessible
V637	QAPI-Indicator-Inf cont-trend/plan/act	V727	MR-Protect pt records fm loss/ confidential
V638	QAPI-Monitor/act/track/sustain improve	V728	MR-Obtain written permission for release
V639	QAPI-Prioritizing improvement activities	V729	MR-Complete records promptly
V640	QAPI-Immediately correct any IJ issues	V730	MR-Centralize all info; IDT has access
		V731	MR-Maintain home pt records
V660	CfC: 494.120 Special Purpose Renal Dialysis Facilities	V732	MR-Retain all records 6 years p dc/death
V661	SPDF-Special Purpose-two categories	V733	MR-Transfer req records in 1 working day
V662	SPDF-Approval period-8 months		
V663	SPDF-Service limitations	V750	CfC: 494.180 Governance
No tag	SPDF-Defines applicable V tags for camp SPDF	V751	GOV-ID Governing Body w/full authority/respons
No tag	SPDF-Defines applicable V tags for emer SPDF	V752	GOV-Appoint CEO/Administrator
V666	SPDF-Physician contact	V753	GOV-Adm resp for staff appointments
V667	SPDF-Records transferred within 30 days	V754	GOV-Adm resp for fiscal operations
		V755	GOV-Adm resp for relationship w/ESRD NW
V675	CfC: 494.130 Laboratory Services	V756	GOV-Adm resp for resources for QAPI
V676	LAB-CLIA labs/meet needs of pts	V757	GOV-Staff # & ratio meet pt needs
		V758	GOV-RN, MSW, & RD avail to meet pt needs
V680	CfC: 494.140 Personnel Qualifications	V759	GOV-RN present at all times
V681	PQ-Staff lic as req/qual/demo competency	V760	GOV-GB-resp for staff orientation
V682	PQ-Med Director-Bd cert+12 mo dialysis exp	V761	GOV-Staff have access to continuing ed
V683	PQ-Medical Dir exception (CMS approval)	V762	GOV-GB resp for medical staff credentialing
V684	PQ-Nurse manager: 12 mo RN+6 mo dialysis	V763	GOV-GB Informs med staff of P&P/QAPI prog
V685	PQ-Self home tlg RN-12 mo RN+3 mo modality	V764	GOV-Services furnished on the main premises
V686	PQ-Charge nurse-12 mo nursing+3 mo dialysis	V765	GOV-Internal grievance sys ID/implemented
V687	PQ-RN/LPN charge supervision	V766	GOV-GB&med dir resp staff flw dc/transfer P&P
V688	PQ-Staff nurse-meet State requirements	V767	GOV-Invol discharge process requirements
V689	PQ-Dietitian-RD	V768	GOV-GB: GB guide pts/staff re ER med care
V690	PQ-Dietitian-1 year experience after RD	V769	GOV-Physician roster available
V691	PQ-SW-MSW; grandfather if hired before 1976	V770	GOV-Transfer agreement whosp for inpt care
V692	PQ-PCT-State requirements & HS diploma	V771	GOV-Electronic data submission required
V693	PQ-PCT-complete training program	V772	GOV-Responds to NW request/works toward goals
V694	PQ-PCT training program content	V773	GOV- Disclosure of ownership
V695	PQ-PCT certified		
V696	PQ-H2O treatment system techs training		

End Stage Renal Disease Facilities V-Tags & Identifiers

§ 494.20 Condition: Compliance with Federal, State, and Local Laws and Regulations (V100-101): Emphasizes the Centers for Medicare & Medicaid Services' (CMS) role as a partner with State and local governments and with other Federal agencies. The purpose of this Condition is to affirm the principle that Medicare reimbursement should be distributed to ESRD facilities that comply with local, State and Federal laws and rules. This Condition is not intended to adjudicate laws and rules from other governmental agencies. Therefore, this Condition should only be cited when a specific "deficient" practice has been adjudicated with the appropriate entity, and a final decision of non-compliance with the other entity's requirement has been reached. Facilities are expected to comply fully with investigations conducted by public health, regulatory, or law enforcement authorities.

§ 494.30 Condition: Infection Control (V110-148): Incorporates as regulation two documents from the Centers for Disease Control and Prevention (CDC), along with CMS developed regulations. These infection control requirements apply to both the chronic dialysis facility's in-center dialysis and any home dialysis program(s).

§ 494.40 Condition: Water and Dialysate Quality (V175-278): Incorporates by reference the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standard for Dialysate for Hemodialysis," ANSI/AAMI RD52:2004 and has the authority of regulation. This AAMI document references portions of their "American National Standard for Water Treatment Equipment for Hemodialysis Applications, ANSI/AAMI RD62:2001 as the specifications for various water treatment components. The referenced portions of ANSI/AAMI RD62:2001 are also incorporated by reference, and have the authority of regulation.

§ 494.50 Condition: Reuse of Hemodialyzers and Bloodlines (V300-383): Applies only if the facility reuses hemodialyzers or bloodlines. The AAMI "Reuse of Hemodialyzers" Third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference as regulation as part of this Condition (V304-V368).

§ 494.60 Condition: Physical Environment (V400-420): Addresses the requirements related to the building and equipment of the facility and incorporates by reference the ambulatory health care occupancy provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. This Condition also includes requirements for emergency preparedness for medical and non-medical issues.

§ 494.70 Condition: Patients' Rights (V450-470): Requires the facility to provide respect, privacy, information, and appropriate services for their patients, as well as an internal grievance mechanism and information about external grievance mechanisms.

§ 494.80 Condition: Patient Assessment (V500-520): Addresses the requirements for an interdisciplinary assessment of patient needs; the requirements related to meeting those needs are contained in the Condition of Patient plan of care at 494.90.

§ 494.90 Condition: Patient Plan of Care (V540-562): Directly related to the Condition of Patient assessment, as the plan of care is built upon the patient assessment. The individual plan of care is revised after each patient assessment, and portions of the plan of care must be updated if the target goals for each area are not achieved or not sustained.

§ 494.100 Condition: Care at Home (V580-599): Applies to those facilities that provide training and support services for any type of home dialysis. This Condition focuses on items that are unique to the home dialysis modality. All of the ESRD Conditions must be met regardless of whether the setting is in-center or at home.

§ 494.110 Condition: Quality Assessment and Performance Improvement (V625-640): Looks at facility aggregate data and requires facility-based assessment and improvement of care, while the Plan of care Condition expects patient-based improvement of care.

§ 494.120 Condition: Special Purpose Renal Dialysis Facilities (V660-667): Outlines the requirements for dialysis facilities that provide care to patients who need dialysis on a short-term basis because of emergency conditions or because they are staying at remote vacation camps. These "special purpose renal dialysis facilities" (SPDF) require a special certification. This certification may not exceed 8 months in any 12-month period of time.

§ 494.130 Condition: Laboratory Services (V675-676): Describes the requirements for clinical laboratory services required to meet the needs of ESRD patients.

§ 494.140 Condition: Personnel Qualifications (V680-696): Defines the qualifications of dialysis facility staff and lists the minimum required content for patient care technician training programs.

§ 494.150 Condition: Responsibilities of the Medical Director (V710-716): Defines the role the facility medical director is expected to assume to ensure the delivery of quality patient care and clinical outcomes. Most deficient practices identified in the delivery of quality patient care and patient clinical outcomes are most appropriately cited under the Conditions pertinent to the practice (e.g., infection control practices, lack of patient assessment or plan of care implementation). Citation of these standards or this Condition should be considered when deficient practices are pervasive, the results of the deficient practices are egregious, or the deficient practice identified is not covered under other Conditions.

§ 494.160 [Reserved]

§ 494.170 Condition: Medical Records (V725-733): Requires the facility to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records.

§ 494.180 Condition: Governance (V750-773): Addresses the overall management of the facility. It requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. This Condition also holds the governing body accountable for establishing an internal grievance process and decreasing the potential for involuntary discharge of patients; for emergency coverage and backup; for electronic data submission; and the relationship of the facility to the ESRD Network.

MEASURES ASSESSMENT TOOL (MAT)

Tag	Condition/Standard	Measure	Values	Reference	Source
494.40 Water and dialysate quality:					
V196	Water quality: test for total chlorine	Max. total chlorine (includes chloramines)	≤0.1 mg/L daily/shift	AAMI RD52	Records
V178	Water & dialysate quality/test for microbiological contamination	Action /Max. bacteria – product water / dialysate	50 CFU/mL / <200 CFU/mL		
V180		Action /Max. endotoxin – product water / dialysate	1 EU/mL / <2 EU/mL (endotoxin units)		
494.50 Reuse of hemodialyzers and blood lines (only applies to facilities that reuse dialyzers &/or bloodlines)					
V336	Dialyzer effectiveness	Total cell volume (TCV) of (hollow fiber dialyzers	Measure original volume/TCV Discard if after reuse <80% of original TCV	KDOQI HD Adequacy 2006 AAMI RD47	Records Interview
494.80 Patient assessment:	The interdisciplinary team (IDT), patient/designer, RN, MSW, RD, physician must provide each patient with an individualized & comprehensive assessment of needs		Refer to Plan of care & QAPI sections (below) for values	Conditions for Coverage KDOQI Guidelines (see POC)	Chart Interview
V502	- Health status/comorbidities	- Medical/nursing history, physical exam findings			
V503	- Dialysis prescription	- Evaluate: HD every mo; PD first mo & q 4 mo			
V504	- BP & fluid management	- Interdialytic BP & wt gain, target wt, symptoms			
V505	- Lab profile	- Monitor labs monthly & as needed			
V506	- Immunization & meds history	- Pneumococcal, hepatitis, influenza, med allergies			
V507	- Anemia (Hgb, Hct, iron stores, ESA need)	- Volume, bleeding, infection, ESA hypo-response			
V508	- Renal bone disease	- Calcium, phosphorus, PTH & medications			
V509	- Nutritional status	- Multiple elements listed			
V510	- Psychosocial needs	- Multiple elements listed			
V511	- Dialysis access type & maintenance	- Access efficacy, fistula candidacy			
V512	- Abilities, interests, preferences, goals, desired participation in care, preferred modality & setting, expectations for outcomes	- Reason why patient does not participate in care, reason why patient is not a home dialysis candidate			
V513	- Suitability for transplant referral	- Reason why patient is not a transplant candidate			
V514	- Family & other support systems	- Composition, history, availability, level of support			
V515	- Current physical activity level & referral to vocational & physical rehabilitation	- Abilities & barriers to independent living; achieving physical activity, education & work goals			
494.90 Plan of care	The IDT must develop & implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs as identified by the comprehensive assessment & changes in the patient's condition, & must include measurable & expected outcomes & estimated timetables to achieve outcomes. Outcome goals must be consistent with current professionally accepted clinical practice standards.				
V543	(1) Dose of dialysis/volume status Monitor each treatment	Management of volume status	Euvolemic & pre-BP <140/90; post-BP <130/80 (adult); lower of 90% of normal for age/ht/wt or 130/80 (pediatric) ≥1.2 (or URR≥65); Min. 3 hours/tx if RKF <2ml/min	KDOQI HD Adequacy 2006 KDOQI Cardiovascular 2005	Chart Interview
V544	(1) Dose of dialysis (HD adequacy) Monitor adequacy monthly	Adult HD <5 hours 3x/week, minimum spKtV Adult HD 2x/week, RKF <2 mL/min. HD 2, 4-6x/week, minimum spKtV	≥2.0/week	NQF #0249 (adult) NQF #1423 (peds) KDOQI HD Adequacy 2006	Chart Interview
V544	(1) Dose of dialysis (PD adequacy – adult) Monitor 1 st month & every 4 months	Minimum delivered KtV _{urea}	≥1.7/week	NQF #0318 KDOQI PD Adequacy 2006	Chart Interview
V544	(1) Dose of dialysis (PD adequacy – pediatric) Monitor 1 st month & every 6 months	Minimum delivered KtV _{urea}	≥1.8/week	KDOQI PD Adequacy 2006	Chart Interview
V545	(2) Nutritional status - Monitor albumin & body wt monthly; monitor other parameters at V509 as needed	Albumin Body weight & other parameters listed at V509	≥4.0 g/dL BCG preferred; if BCP: lab normal % usual wt, % standard wt, BMI, est. % body fat	KDOQI Nutrition 2000 KDOQI CKD 2002	Chart Interview
V545	(2) Nutritional status (pediatric) monitor monthly	BMI-for-age % or SD, dry wt & wt-for-age % or SD, nPCR	nPCR normalized-HD teen (nPCR and albumin are not predictive of wt loss/nutritional status in younger children)	KDOQI Pediatric Nutrition 2008	Chart Interview
V546	(3) Mineral metabolism & renal bone disease Monitor calcium & phosphorus monthly Monitor intact PTH every 3 months	Calcium corrected for albumin (BCG) Phosphorus Intact PTH (consider with other MBD labs, not in isolation)	Normal for lab; preferred upper level <10.2 mg/dL ¹ Al: 3.5-5.5 mg/dL ² Under review	1NQF #1454 2KDIGO CKD-MBD 2009	Chart Interview
V547	(4) Anemia – Hgb non-ESA - monitor monthly	Hemoglobin (Adult & pediatric)	No upper level established ³ See Hgb on ESA (below) for management of anemia ³	3FDA 6/24/11 for more info re CKD 5D recommendation	Chart Interview
V547	(4) Anemia – Hgb on ESA – monitor weekly until stable;	Hemoglobin (Adult & pediatric)	Initiate ESAs <10 g/dL; interrupt or ↓ dose near or >11 g/dL ³ ;	3FDA 6/24/11 for more info re CKD 5D recommendation	Chart Interview
V548	then monitor monthly; evaluate other anemia causes; educate patients about risks/benefits	Blood transfusion	Give lowest dose of ESAs to avoid transfusion (especially in transplant candidates); consider patient preference		
V549	(4) Anemia - Monitor iron stores routinely	Adult & pediatric: transferrin saturation Adult & pediatric: serum ferritin	>20% (HD, PD), or CHR >29 pg/cell HD: >200 ng/mL; PD: >100 ng/mL HD/PD: <500 ng/mL or evaluate if indicated	KDOQI Anemia 2006	Chart Interview

Sources: DFR=Dialysis Facility Reports; CW=CROWNWeb; Chart=Patient Chart; Records=Facility Records; Interview=Patient/Staff Interview; BMI=Body mass index; CAHPS=Consumer Assessment of Healthcare Providers & Services; CFU=colony forming units; CHr=reticulocyte hemoglobin; CMS CPM=CMS Clinical Performance Measure; DOPPS=Dialysis Outcomes & Practice Patterns Study; ESA=erythropoiesis stimulating agent; KDIGO=Kidney Disease Improving Global Outcomes; KDOQI=Kidney Disease Outcomes Quality Initiative; nPCR=normalized protein catabolic rate; NQF=National Quality Forum; RKF=residual kidney function; SD=standard deviation; spKtV=single pool KtV Centers for Medicare & Medicaid Services - Version 2.3

MEASURES ASSESSMENT TOOL (MAT)

Tag	Condition/Standard	Measure	Values	Reference	Source
V550 V551	(5) Vascular access (HD)	Fistula Graft Central Venous Catheter	Preferred, if appropriate ^{4,5,7,8} Acceptable if fistula not possible or appropriate ^{5,6} Acceptable if evaluated for fistula/graft ⁶ , if transplant soon, or if AVF/AVG not possible in small adult or ped ⁵ Documentation of action in response to results	⁴ NQF #0257 ⁵ KDOQI Vascular Access 2006 ⁶ NQF #0251 ⁷ NQF #0256; ⁸ Fistula First	Chart Interview
V552	(6) Psychosocial status	Survey physical & mental functioning by standardized tool, e.g. KDQOL-36 survey or age appropriate survey	Documentation of action in response to results	Conditions for Coverage NQF #0260 (adult)	Chart Interview
V553 V554	(7) Modality	Home dialysis referral Transplantation referral	Candidacy or reason for non-referral	Conditions for Coverage	Chart Interview
V555	(8) Rehabilitation status	Productive activity desired by patient Pediatric: formal education needs met Vocational & physical rehab referrals as indicated	Achieve & sustain appropriate level, unspecified	Conditions for Coverage	Chart Interview
V562	(d) Patient education & training	Dialysis experience, treatment options, self-care, QOL, infection prevention, rehabilitation	Documentation of education in record	Conditions for Coverage	Chart Interview
<p>494.110 Quality assessment & performance improvement (QAPI): The dialysis facility must develop, implement, maintain, & evaluate an effective, data-driven QAPI program with participation by the professional members of the IDT. The program must reflect the complexity of the organization & services (including those under arrangement), & must focus on indicators related to improved health outcomes & the prevention & reduction of medical errors. The dialysis facility must maintain & demonstrate evidence of its QAPI program including continuous monitoring for CMS review. Refer to your ESRD Network's goals for targets for aggregate patient outcomes.</p>					
V628	Health outcomes: Physical & mental functioning	Survey adult/pediatric patients by standardized tool, e.g. KDQOL-36 survey or age appropriate survey	Achieve & sustain appropriate status ↑ % of eligible patients completing survey	Conditions for Coverage	Records
V628	Health outcomes: Patient hospitalization	Standardized hospitalization ratio (1.0 is average, >1.0 is worse than average, <1.0 is better than average)	↓ hospitalizations	Conditions for Coverage	DFR Records
V628	Health outcomes: Patient survival	Standardized mortality ratio (1.0 is average, >1.0 is worse than average, <1.0 is better than average)	↓ mortality	Conditions for Coverage	DFR Records
V629	(i) HD adequacy (monthly)	HD: Adult (patient with ESRD ≥3 mo)	↑ % with spKtV ≥1.2 or URR ≥65% if 3 times/week dialysis and stdKtV ≥2.0/week if 2 or 4-6 times/week dialysis	Conditions for Coverage NQF #0249 (adult) NQF #1423 (peds)	DFR Records
V629	(i) PD adequacy (rolling average, each patient tested ≤4 months)	PD: Adult	↑ % with weekly KtV _{urea} ≥1.7 (dialysis+RKF)	Conditions for Coverage NQF #0318	DFR Records
V630	(ii) Nutritional status	Facility set goals; refer to parameters listed in V509	↑ % of patients within lab target range on albumin and other nutritional parameters set by the facility	Conditions for Coverage; KDOQI Nutrition 2000 KDOQI CKD 2002	Records
V631	(iii) Mineral metabolism/renal bone disease	Calcium, phosphorus, & PTH	↑ % in target range on all measures monthly	Conditions for Coverage	Records
V632	(iv) Anemia management Monitor patients on ESAs &/or patients not taking ESAs	Anemia symptoms Blood transfusion Serum ferritin & transferrin saturation or CHR Patient education on ESAs	↓ % of patients with anemia symptoms ↓ % of patients (esp. transplant candidates) transfused Evaluate if indicated ↑ % of patients educated about potential risks/benefits	FDA 6/24/11 for more info re CKD 5D recommendation	DFR Records Interview
V633	(v) Vascular access (VA) Evaluation of VA problems, causes, solutions	Cuffed catheters > 90 days AV fistulas for dialysis using 2 needles, if appropriate Thrombosis episodes Infections per use-life of access VA patency	↓ to <10% ⁶ ↑ to ≥65% ⁶ or ≥66% ⁷ ↓ to <0.25/pt-yr at risk for fistulas; 0.50/pt-yr at risk for (grafts) ↓ to <1% (fistula); <10% (graft) ↑ % with fistula >3 yrs & graft >2 yrs	⁶ KDOQI Vascular Access 2006 ⁷ Fistula First	DFR Records
V634	(vi) Medical injuries & medical errors identification	Medical injuries & medical errors reporting	↑ frequency through prevention, early identification & root cause analysis	Conditions for Coverage	Records
V635	(vii) Reuse	Evaluation of reuse program including evaluation & reporting of adverse outcomes	↓ adverse outcomes	Conditions for Coverage	Records
V636	(viii) Patient satisfaction & grievances	Report & analyze grievances for trends CAHPS In-Center Hemodialysis Survey or other survey	Prompt resolution of patient grievances ↑ % of patients satisfied with care	Conditions for Coverage	Records Interview
V637	(ix) Infection control	Analyze & document incidence for baselines & trends	Minimize infections & transmission of same Promote immunizations	Conditions for Coverage	DFR Records
V637	Vaccinations	Hepatitis B, influenza, & pneumococcal vaccines Influenza vaccination by facility or other provider	Documentation of education in record ↑ % of patients vaccinated on schedule ↑ % of patients receiving flu shots 10/1-3/31	Conditions for Coverage NQF #0226	Records DFR

Sources: DFR=Dialysis Facility Reports; CW=CROWNWeb; Chart=Patient Chart; Records=Facility Records; Interview=Patient/Staff Interview; BMI=Body mass index; CAHPS=Consumer Assessment of Healthcare Providers & Services; CFU=colony forming units; CHr=reticulocyte hemoglobin; CMS CPM=CMS Clinical Performance Measure; DOPPS=Dialysis Outcomes & Practice Patterns Study; ESA=erythropoiesis stimulating agent; KDIGO=Kidney Disease Improving Global Outcomes; KDOQI=Kidney Disease Outcomes Quality Initiative; nPCR=normalized protein catabolic rate; NQF=National Quality Forum; RKF=residual kidney function; SD=standard deviation; spKtV=single pool KtV Centers for Medicare & Medicaid Services - Version 2.3

INFECTION CONTROL

Guidance: Surveillance of practices, activities, infections & adverse events is required to monitor effectiveness of infection control practices to ensure appropriate infection control behaviors & techniques are carried out.

Patient Status	On Admission	Monthly	Semi-annual	Annual
All patients	HBsAg* Anti-HBc* (total) Anti-HBs* ALT			
HBV-susceptible, including non-responders to vaccine		HBsAg		
Anti-HBs positive (≥10 mIU/mL), anti-HBc negative				Anti-HBs
Anti-HBs and anti-HBc positive		No additional HBV testing needed		
Anti-HCV negative		ALT		

* Results of HBV testing should be known before the patient begins dialysis.

† HBsAg=hepatitis B surface antigen; Anti-HBc=antibody to hepatitis B core antigen; Anti-HBs=antibody to hepatitis B surface antigen

- **V637-Review QAPI:** monitoring, analyzing trends, planning & acting.
- **V132-Staff** must have initial and ongoing **infection control education & training** to ensure appropriate infection control.
- **V142-Oversight:** monitor & implement **infection control policies and activities;** facility must review practices and update policies/procedures to ensure infection control practices are followed.
- **V113-Wear disposable gloves** when caring for the patient or touching the patient's equipment at the dialysis station; remove gloves & perform **hand hygiene** between each patient or station.
- **V115-Wear personal protective equipment (PPE)** as appropriate.
- **V116-Items** taken into the dialysis station: disposed of, dedicated for use on a single patient, or cleaned & disinfected before taken to a common clean area or used on another patient. **Nondisposable items** that cannot be cleaned & disinfected (e.g., adhesive tape, cloth-covered B/P cuffs) should be dedicated for use on a single patient. **Unused medications** (including multiple dose vials containing diluents) or supplies (e.g., syringes, alcohol swabs) taken to the patient's stations used only for that patient & not returned to a common clean area or used on other patients.
- **V117-Designate clean areas** for preparation, handling & storage of medications, unused supplies & equipment. **Separate clean areas from contaminated areas** where used supplies & equipment are handled. Do not handle & store medications or clean supplies in the same or an adjacent area where used equipment or blood samples are handled.
- **V117-Prepare multiple dose vials** (including vials containing diluents) in a clean (centralized) area away from dialysis stations & **deliver separately** to each patient. Do not carry multiple dose medication vials from station to station. Do not use common **medication carts** to deliver medications to patients. If using **trays** to deliver medications, clean trays between patients.

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Hepatitis B Vaccination

- **V126-Offer** to vaccinate all hepatitis B (HBV)-susceptible patients & staff against hepatitis B; advise HBV+ patient's care partner to ask own physician for HBV vaccination.
- **V127-Test** for anti-HBs 1-2 months after last dose.
- **V127-If** anti-HBs is <10 mIU/mL, consider patient susceptible, revaccinate with an additional three doses, & retest for anti-HBs.
- **V127-If** anti-HBs is ≥10 mIU/mL, consider patient immune, & retest annually.
- **V127-Give** booster dose of vaccine if anti-HBs declines to <10 mIU/mL & continue to retest annually.

Management of HBV+ Patients

- Follow infection control practices for hemodialysis units for all patients.
- **V128-V130-Dialyze** HBV+ patients in an isolation room/area using dedicated machines, equipment, instruments, supplies, & medications.
- **V131-Staff** members caring for HBV+ patients should not care for HBV-susceptible patients at the same time (e.g., including during the period when dialysis is terminated on one patient & initiated on another).
- **V118-Intravenous medication vials** labeled for single use=single use; not punctured more than once. Do not pool residual medication from ≥2 vials into a single vial.
- **V119-Common supply cart** used to store clean supplies must remain in a designated area to avoid contamination & not be moved between patient stations to deliver supplies. Medications vials, syringes, alcohol swabs or supplies not carried in staff pockets.
- **V120-Change & do not reuse** external venous & arterial pressure **transducer filters/protectors** used for each patient treatment between treatments. If the external transducer protector becomes wet, change immediately & inspect for breakthrough. If internal transducer contaminated, take machine out of service & disinfect. (Does not apply to bloodlines without external transducer protectors.)
- **V122-Clean & disinfect the dialysis station** (e.g., chairs, beds, tables, machines), contaminated surfaces, medical devices & equipment between patients.
 - Pay special attention to cleaning control panels on the dialysis machines & other surfaces frequently touched & potentially contaminated with patients' blood.
 - Discard all fluid & clean & disinfect all surfaces & containers associated with the prime waste, including prime containers attached to the dialysis machines.
- **V147-For catheter & catheter-site care,** refer to the catheter checklists.
- **V585-Home patient training** on PPE & waste disposal

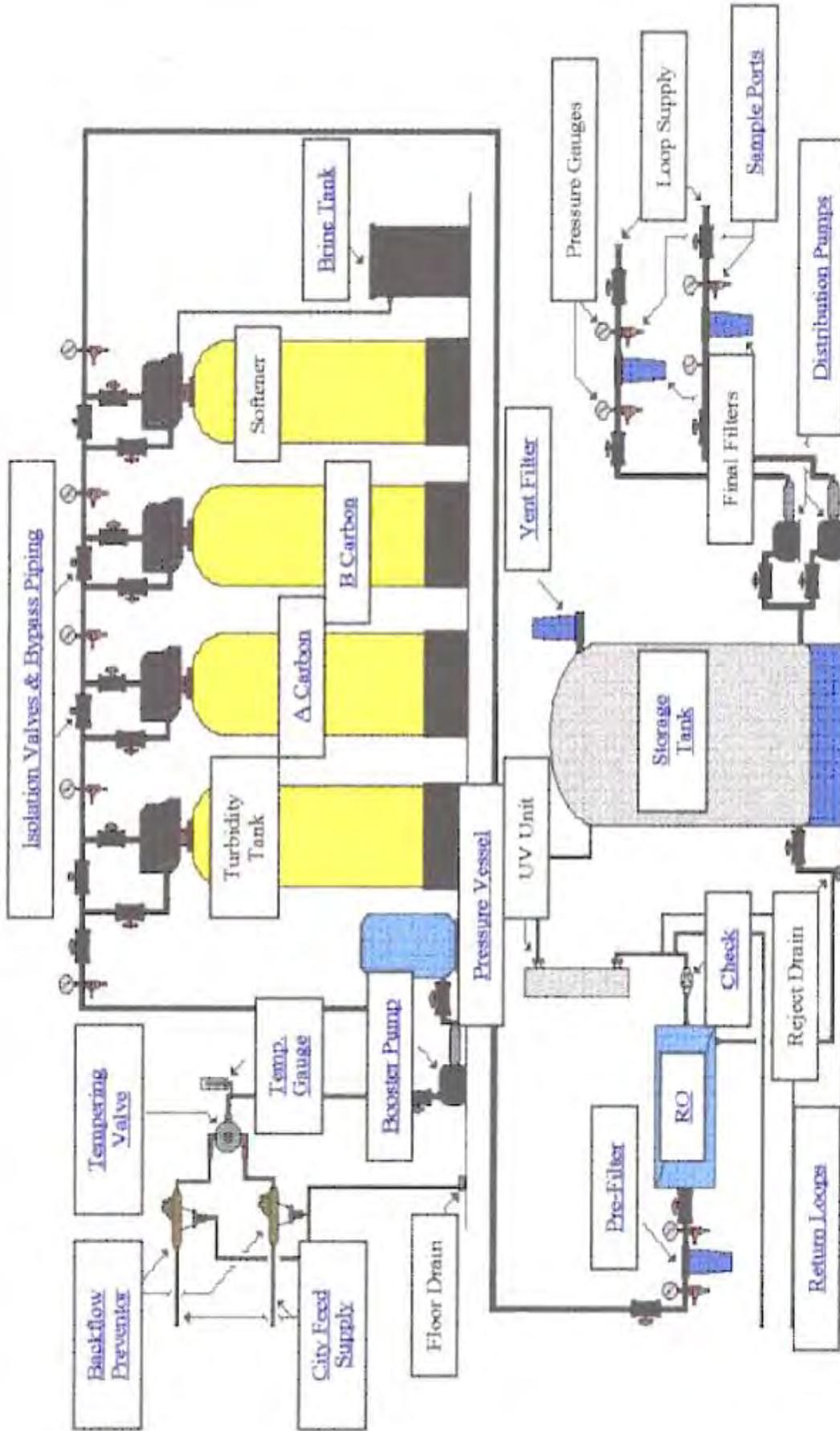
Requirements for Isolation Room/Area

Who Must Comply	How To Comply	Definitions
All Facilities (V130)		
Any facility treating a HBV+ patient	Must dedicate machine(s), equipment, instruments, supplies & medications	“Dedicate” means to use only for HBV+ patient(s), all days/shifts.
If HBV+ patient is no longer treated in-center or in home training	Must terminally clean & disinfect machine and room/area to use for any other patient(s) Training options:	“Terminally clean & disinfect” includes all external surfaces and machine internal pathways if applicable.
Certified for home training and support and currently has or admits a home patient or home training patient who is HBV+	<ul style="list-style-type: none"> • Train in isolation room/area • Dedicate training room for HBV+ patient • Train at HBV+ patient’s home Must terminally clean & disinfect the room/area & equipment when training is completed Must follow standard infection control protocol for clinic visits & supply disposal	An “isolation room” is a separate room with door that is closed at dialysis initiation/ termination, with walls that touch floor but may not reach ceiling; walls and door must allow visual monitoring of the patient at all times when a staff member is not in the room; see definition for “terminally clean & disinfect.”
Existing Facility (V128)		“Existing” is defined as a facility that as of 10/14/08 was certified or had a building permit or completed plan reviews (whichever applies in the specific location).
A. Has an HBV+ patient in-center		
Has an isolation room	Must maintain isolation room	See definitions of “isolation room” and “terminally clean & disinfect.”
Has an isolation area	Must maintain isolation area & meet space requirements	“Space requirements” is defined as separated from other stations by a space equivalent to the width of a hemodialysis station.
Physically expand or relocate after 10/14/08?	Must add an isolation room	“Physically expand” is defined as physically expanding the treatment area.
B. Admits an in-center HBV+ patient or has an in-center patient convert to HBV+	Must “make provision” for HBV+ patients	Definitions for “make provision” include having an isolation room or area or having a transfer agreement with a facility with isolation capacity in the same geographic area. If no local facility is available to accept such transfers, the original facility must establish an isolation room/area for use with the HBV+ patient
C. Has no HBV+ patients		
Has an isolation room	Must maintain isolation room	See definition of “isolation room.”
Has an isolation area	Must maintain isolation area & meet space requirements	See definition of isolation area “space requirements.”
Has no isolation room/area	Must make provision	See definition of “make provision.”
D. Physically expands or relocates	Must add an isolation room or obtain a waiver from CMS	See definition of “physically expand.”
New Facility (V129)	Must have an isolation room on or after 2/9/09 or obtain a waiver from CMS	“New” is defined as a facility that as of 10/14/08 was not certified and did not have a building permit or completed plan reviews (whichever applies in the specific location).

CRITICAL WATER AND DIALYSATE REQUIREMENTS

- ❖ **Water (product) chemical quality**
 - Within maximum allowable levels per AAMI:RD 52 Table 1 (V177)
 - Tested at least annually and as indicated (V201)
- ❖ **Reverse Osmosis unit function and monitoring**
 - Function monitored and recorded daily by % rejection & conductivity or TDS; audible & visible alarms (V199, 200)
- ❖ **Water (product) microbiological quality**
 - Maximum 200CFU/2EU; Action levels 50CFU/1EU (V178)
 - Distribution system disinfected monthly (V219)
 - Tested at least monthly from sites; actions taken if >action levels (V213)
- ❖ **Dialysate microbiological quality**
 - Maximum 200CFU/2EU; Action levels 50CFU/1EU (V180)
 - Tested monthly from at least 2 HD machines; each HD machine tested at least annually; sampling methods; actions taken if >action levels (V253)
- ❖ **Dialysate pH & conductivity testing at HD machine prior to treatment**
 - 2 carbon tanks (or banks of tanks) with sample port between (V192)
 - Sufficient carbon to remove chlorine/chloramines; total EBCT 10 min-verified by interview and/or record review (V195)
- ❖ **Dialysate pH & conductivity testing at HD machine prior to treatment**
 - Dialysate pH & conductivity tested at the HD machine with an independent method prior to each treatment per machine manufac. DFU (V250)
- ❖ **Dialysate proportioning ratios match**
 - Only matching dialysate proportioning ratios used on HD machine set at same ratio (V249)
- ❖ **Dialysate pH & conductivity testing at HD machine prior to treatment**
 - Automatic divert-to-drain or automatic cut-off valve to prevent water flow to the HD machines (V203)
 - DI followed by ultrafilter (V204)
- ❖ **Deionization system monitoring (if present or part of back-up plan)**
 - Resistivity continuously monitored; audible & visible alarms in patient treatment areas; resistivity maintained >1.0 megohm/cm (V202, 203)
 - Automatic divert-to-drain or automatic cut-off valve to prevent water flow to the HD machines (V203)
 - DI followed by ultrafilter (V204)
- ❖ **Staff training and monitoring**
 - All staff who conduct water, dialysate testing and technical operations sufficiently trained; practices audited at least annually (V260)
- ❖ **Chlorine testing**
 - Water after first carbon tank(s) tested for total chlorine prior to each ICHD shift or approx. q 4 hours during the treatment day (V196)
 - If total chlorine test >0.1mg/L, "breakthrough", immediate actions taken (V197)

Water System Flow Diagram



PERSONNEL REQUIREMENTS

V Tag	Position	Minimum Education	Minimum Experience	Minimum Competence
V501	Interdisciplinary Team Member	RN; physician treating the patient for ESRD; MSW & RD as qualified below	Experience specified for that discipline	Competence specified for that discipline
V681	ALL	As specified for each IDT member (below)	Scope of practice board & licensure required in State where practicing	Demonstrate & sustain skills to perform specific duties of their position
V682	Medical director	Medical degree; successful completion of board-approved training program in nephrology	12 months providing care to dialysis patients	Board certified internal medicine, nephrology, pediatrics, or pediatric nephrology
V683				
V684	Nurse manager (Full-time employee)	Nursing degree (RN)	12 months experience as an RN plus 6 additional mo in dialysis	Registration by State
V685	Self-care & home dialysis training nurse	Nursing degree (RN)	12 months as an RN plus 3 additional mo in each specific modality	Registration by State
V686	Charge nurse	Nursing degree (RN, LPN/ LVN)	9 mo nursing experience plus 3 additional months in dialysis	Registration or licensure by State
V687				
V688	Staff nurse	Nursing degree (RN, LPN/ LVN)	Experience not specified	Registration or licensure by State
V689	Dietitian	Baccalaureate degree	1 year clinical experience post-registration	Registration by Commission on Dietetic Registration
V690				
V691	Social worker	Masters degree in social work or Complies with "grandfather clause"	- Experience not specified if masters degree is in social work; - To comply with "grandfather clause" must have worked as a social worker since 9/1/75 and have ≥2 years of social work experience in dialysis or transplant facilities prior to 9/1/76.	- Licensure or certification by State if required by State. and - To comply with "grandfather clause," must have consultative relationship (written agreement of supervision) with masters prepared social worker
V692	Patient care dialysis technician (PCT)	- High school diploma or equivalency - If a PCT employed on 10/14/08 lacks evidence of high school diploma or GED, >4 years of dialysis work experience can be used in lieu of high school diploma or GED	Experience not specified if PCT meets educational requirement	- Successful completion of RN-directed training program approved by medical director and governing body - Certified by CMS-approved State or national certifying program by the latter of 4/15/2010 or 18 months post hire - Continuing certification required
V693				
V694				
V695				
V696	Water treatment technician	Complete training program approved by medical director and governing body	Experience not specified	- Successful completion of training - Monitoring by audits of compliance with procedures at least annually or more often if problems are identified; retraining if needed. -Ongoing training required
V260				
V307	Reprocessing technician	Complete training program with specified curriculum	Sufficient to ensure patient safety, and a safe and effective reprocessing/reuse program	- Successful completion of a training course certified by medical director or designee and demonstrated competence - Annual competence review - Retraining as needed
V308				
V309				
V752	CEO/administrator	Education not specified	Experience not specified	Facility defined with sufficient education and experience to fulfill responsibilities
V753	Staff appointments - physicians, non-physician practitioners	Education as appropriate for position	Experience not specified	Registration or licensure by state

NATIONAL COMMERCIAL DIALYSIS TECHNICIAN CERTIFICATION ORGANIZATIONS* (AS OF SEPTEMBER 2009)

National Organization	Board of Nephrology Examiners Nursing and Technology (BONENT)	Nephrology Nursing Certifying Commission (NNCC)	National Nephrology Certification Organization (NNCO)
Certification provided	Certified Hemodialysis Technologist/Technician (CHT) Every 4 years	Certified Clinical Hemodialysis Technician (CCHT) Every 2 years prior to 11/1/2009; every 3 years effective 11/1/2009	Certified Clinical Nephrology Technology (CCNT) Every 4 years
Certification period	Every 4 years	Every 2 years prior to 11/1/2009; every 3 years effective 11/1/2009	Every 4 years
Recertification offered	Re-exam or 40 contact hours of in-person continuing education, of which 15 contact hours can be earned from other education specified on BONENT Web site	Re-exam or effective 11/1/2009 , 30 contact hours of continuing education plus 3,000 work hours every 3 years; effective 11/1/2011 , 10 contact hours of continuing education plus 1,000 work hours/year with recertification every 3 years	Re-exam or 30 contact hours of continuing education, of which 15 contact hours can be earned from work in nephrology (3.75 contact hours/year)
Educational requirement(s) to apply for examination	High school diploma or equivalency; if no evidence of high school diploma, > 4yrs of dialysis work experience can substitute	Government approved high school diploma or GED with current name or proof of name change	High school diploma or equivalency OR four years of full time experience in the field of nephrology technology
Training/experience requirement(s) to apply for examination	12 months of experience in nephrology patient care and current active work in an ESRD facility or successful completion of an accredited dialysis course approved by the BONENT Board.	Successful completion of PCT training program (classroom & supervised experience); signed verification by educator or certificate of completion; current or employment as HD PCT within last 18 months verified by supervisor; recommend >6 months (1000 hours) of clinical experience	1 year training program in nephrology technology with clinical experience and/or training program and clinical experience equivalent to 1 year. OH requires 12 months specified dialysis care experience
Testing sites	Providers may be test sites for paper & pencil tests. Independent test sites are used for computer-based tests. BONENT accommodates people with ADA disabilities.	ANNA chapters & dialysis clinics may host paper & pencil tests at on or off-site locations; NNCC partners with the Center for Nursing Education Testing to offer computer-based tests at CBT centers. NNCC accommodates disabilities & religious convictions against Saturday tests	Computer-based tests are offered at hundreds of PSI/LaserGrade Computer Testing sites in the U.S. and Canada. NNCO accommodates ADA disabilities & religious convictions against Saturday tests.
Proctored Test	Yes	Yes	Yes
Website	http://www.bonent.org	http://www.nncc-exam.org	http://nnco.nbccc.net



ESRD Core Survey Field Manual

Tab 3: Presurvey Preparation & Introductions

- FY2015 ESRD Core Survey Data Worksheet
- CMS 3427 End Stage Renal Disease Survey and Certification Report (05/13)
- ESRD Core Survey Facility Worksheet: Personnel File
- Task: Presurvey Preparation

Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET

Facility: _____ **Date:** _____

CCN: _____ **Surveyor:** _____

Use of this worksheet: The data elements that must be reviewed for a survey will change over time due to the dynamic nature of data pertaining to the care and clinical outcomes of dialysis patients. **This worksheet will be revised each fiscal year (FY)** to reflect clinical indicators, outcome goals, and outcome thresholds based on current national data.

Contents: There are 3 sections of this worksheet:

- I. Presurvey Preparation and Dialysis Facility Report (DFR) Review** (pages 1-2): To review and evaluate the facility outcomes data from the 2014 DFR (used in FY 2015), as well as ESRD Network contact, and facility survey history review
- II. Entrance Conference Materials List with Clinical Outcomes Tables** (pages 3-6): To be copied and given to the facility to enter the facility current clinical outcomes
- III. Clinical Outcomes Thresholds Table** (page 7): To compare the current facility clinical outcomes against current national benchmarks, and determine the **data-driven focus areas** for the survey

I. PRESURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW:

Download and Review the 2014 DFR (used in FY 2015) for the facility. The DFR and the partially pre-populated "FY 2015 Pre-survey DFR Extract" for each facility, as well as the Region and State Profiles may be accessed at www.DialysisData.org. Enter your Username and Password then click "Log in" to log onto the Secure DialysisData.org web site. The *DFR* tab (at the top of the page) is where you may obtain the current DFR for all facilities in your State or Region. The *Profiles* tab (at the top of the page) contains the partially pre-populated FY 2015 Pre-survey DFR Extract for each facility, as well as the Region and State profiles, which contain the Outcomes list.

Note how the facility is ranked on the State Profile/Outcomes List. Review the information about the facility on pages 1-4 of the DFR. To guide your review of the DFR data tables, you may use STAR or download the FY 2015 Pre-survey DFR Extract for the facility.

STAR Users: You do not need to download the pre-populated FY 2015 Pre-survey DFR Extract for the facility. STAR 3.7 and later versions display the key DFR data elements for each facility, automatically uploaded from ASPEN with the survey shell. Follow the guidance on STAR screen [3] in the Presurvey Preparation task.

Non STAR users: Review the FY 2015 Pre-survey DFR Extract in conjunction with the facility DFR. Review each pre-populated data element on the DFR Extract, which are key aspects of facility performance. Note trends in outcomes over the 4 year period. For standardized mortality (SMR) and transplant ratios (STR), the 4-year average is a more consistent measure of facility performance. For standardized hospitalization ratio (SHR), the most recent 1-year statistic is most meaningful.

Record in the "Outcome and Trend Conclusions" column of the FY 2015 Pre-survey DFR Extract how the facility compares with U.S. Averages. Note declining or improving trends and flag which elements are worse than the U.S. Average. Consider those clinical areas for **preliminary data-driven focus areas** for the survey. Attach the completed FY 2015 Pre-survey DFR Extract document to this worksheet.

Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET

Preliminary data-driven focus areas based on DFR review:

- | | |
|----------|----------|
| 1. _____ | 4. _____ |
| 2. _____ | 5. _____ |
| 3. _____ | 6. _____ |

Contact the ESRD Network: *Prior to the survey or upon arrival at the facility, call the Network to ask about concerns related to involuntary discharges, complaints, and other survey issues related to the ESRD Core Survey process.*

Network person contacted _____ **Position:** _____

Is the facility under any special Network quality monitoring? If yes, describe. _____

Have there been any involuntary discharges or patterns of involuntary transfers from the facility? If yes, how many, and describe any pattern(s) identified: _____

Have there been patterns of patient complaints about the facility? If yes, describe any pattern(s) identified: _____

Are there any other concerns you have about the facility that the survey team should be aware of? If yes, describe your concerns: _____

Review Facility Survey and Complaint History (12-18 months): *This information may be located in facility files maintained by the State Agency office, in ASPEN, and in Table 15 of the facility DFR.*

Does your review of the facility survey and complaint history indicate areas of concerns that should be included as a survey focus? If yes, describe: _____

Record additional areas of concern for review, based on your contact with the ESRD Network and review of facility survey and complaint history:

- | | |
|----------|----------|
| 1. _____ | 3. _____ |
| 2. _____ | 4. _____ |

Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET

II. ENTRANCE CONFERENCE MATERIALS LIST /CLINICAL OUTCOMES TABLES

Guidance to surveyors: *Make a copy of the Entrance Conference Materials List/Clinical Outcomes Tables (pages 3-6) to give to the facility person in charge during "Introductions." You will be reviewing the patient-specific outcomes, and facility information submitted during "Entrance Conference." Attach the completed facility-submitted copy to this worksheet.*

Facility: _____

Date: _____

Documents/items needed for the survey: Please return this form to the survey team leader after completion of facility current information requested.

Needed within 3 hours:

1. List of current patients by name, separated into modalities
2. List of facility key personnel: medical director, administrator, nurse manager, social worker, dietitian, chief technician, and home training nurse(s)
3. Current in-center hemodialysis patient listing by days & shifts with any isolation patients identified (seating chart or assignment sheet)
4. Patients admitted to this facility within the past 90 days and currently on census (do not include visiting patients)
5. Patients who have been designated as "unstable" for any month in the past 3 months
6. All patients involuntarily discharged (not transferred to another outpatient dialysis facility) from the facility in the past 12 months
7. All patients transferred or discharged from the facility categorized as "lost to follow up" (i.e., no outpatient dialysis facility identified as patient's destination) for the past 12 months
8. Home dialysis (HD or PD) patients scheduled to be seen at the facility during the survey.
9. Residents of long term care facilities receiving dialysis at the LTC facility and the name of the LTC where they are receiving dialysis
10. Hospitalization logs with admitting diagnoses listed for 6 months
11. Infection logs for past 6 months
12. Patient individual laboratory results for hemoglobin, Kt/V, corrected calcium, phosphorus and albumin for the current 3 months; separated by modality

Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET

Materials needed by the end of Day 1 of survey:

13. Vaccination information:
- # of patients who received a complete series of hepatitis B vaccine _____
 - # of patients who received the influenza vaccine between August 1 and March 31 _____
 - # of patients who received the pneumococcal vaccine _____
14. Patient care staff schedule for the current time period (last two weeks)
15. Policy and procedure manuals for patient care, water treatment, dialysate preparation and delivery, and dialyzer reprocessing/reuse, if applicable
- Anemia management protocol
16. Patient suggestion/complaint/grievance log for past 6 months
17. Adverse occurrence (e.g., clinical variances, medical errors, unusual events) documentation for the past 6 months
18. QAPI team meeting minutes for past 6 months and any supporting materials
19. Copy of CMS-approved waivers for medical director and/or isolation room
20. Facility Life Safety Code attestation or waiver (required if the in-center or home training treatment area does not provide exit to grade level or if the facility is adjacent an industrial high hazard occupancy)
21. For Water and Dialysate Review: logs for:
- Daily water system monitoring-3 months
 - Total Chlorine testing-3 months
 - Bacterial cultures and endotoxin results-water and dialysate-12 months
 - Chemical analysis of product water-12 months
 - Staff practice audits for water testing, dialysate mixing & testing and microbiological sampling-12 months
22. For Equipment Maintenance Review: 12 months documentation of preventative maintenance and repair of hemodialysis machines
23. For Dialyzer Reprocessing Review, if applicable, logs for:
- Bacterial cultures and endotoxin results from reuse room sites-12 months
 - Preventative maintenance and repair of reprocessing equipment-12 months
 - Reuse QA audits-12 months

Materials needed by noon on Day 2 of survey

24. Completed "Personnel File Review" Worksheet (or same information generated electronically)
25. Completed "CMS 3427-End Stage Renal Disease Application and Survey and Certification Report"

Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET

Signature of person completing this form _____ **Date:** _____

Needed within 3 hours. Please fill in the tables below with your facility data based on your most current QAPI information. Provide the average for the number of months listed next to each indicator. List additional patient names on a separate sheet of paper if needed.

Clinical Outcomes Table for Hemodialysis (Designate if patient is on Home Hemodialysis)

Indicator	MAT Goal Unless Other Specified	% Met Goal or Other Specified	Current Patients Who Did Not Meet Goal (or as listed) in Time Specified
Adequacy (3 months) Single pool Kt/V Standardized Kt/V	≥1.2 for 3 tx/week ≥2.0 weekly for ≥4 tx/week	_____ % _____ %	HD patients not meeting goal ≥2 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Anemia (3 months) Hemoglobin-patients' last value of month	Refer to MAT	<10 g/dL _____ %	HD Patients with Hgb <10 in ≥2 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Mineral & bone (3 mo) Calcium corrected for albumin Phosphorus	Normal for lab; preferred <10.2mg/dL 3.5-5.5 mg/dL	_____ % _____ %	Patients w/either goal not met in ≥2 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Nutrition Albumin (3 mo)	≥4 g/dL for BCG; lab normal for BCP	_____ %	Patients w/ Alb <3.5 in ≥2 mos.(if none, list patients w/Alb 3.6-3.9 in ≥2 mo) 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Fluid mgmt (3 mo) Average intradialytic weight loss in treatment ≤ 4 hours duration calculated from target weight (TW)	Average intradialytic weight loss ≤5% of target weight	_____ %	HD Pts w/av wt loss >5% of TW in ≥2 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Vascular access (VA) (12 mo) CVCs >90 days VA infection rate/100 patient months	↓ CVC rates ↓ VA infection rate	CVCs >90 days _____ % VA infection rate _____	HD Patients with CVC >90 days 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Hospital Readmissions (12 mo) % of total patients admitted to hospital readmitted within 30 days of discharge	Minimize hospital readmissions	Hospital Readmission rate _____	Current HD patients readmitted to hospital w/in 30 days of discharge in past 3 mo 1. _____ 2. _____ 3. _____ 4. _____
Transplant waitlist (12 mo) % of all patients age <70 on waitlist any time during period	Interested patients are referred for transplant unless excluded by evaluation or listed exclusion criteria	Transplant waitlist rate % _____	Provide a copy of the transplant waitlist, transplant program(s) exclusion criteria, and procedure for candidacy evaluation and referral of patients.

Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET

Signature of person completing this form _____ Date: _____

Peritoneal Dialysis Clinical Outcomes Table

Indicator	MAT Goal Unless Other Specified	% Met Goal or Other Specified	Current Patients Who Did Not Meet Goal (or as listed) in Time Specified
Adequacy (6 mo) Kt/V	≥1.7 weekly	_____ %	PD patients not meeting goal in last 6 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Anemia (3 mo) Hemoglobin – patients' last value of month	Refer to MAT	<10 g/dL _____ %	PD Patients w/Hgb <10g/dL for ≥2 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Mineral/bone (3 mo) Calcium corrected for albumin Phosphorus	WNL for lab; <10.2 mg/dL 3.5-5.5 mg/dL	_____ % _____ %	Patients with either goal not met for ≥2 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Nutrition (3 mo) Albumin	≥4g/dL BCG; lab normal for BCP	_____ %	Patients w/ Alb.<3.5 in ≥2mos. (if none, list patients w/Alb. 3.6-3.9 in ≥2 mo) 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
PD infections (12 mo) Peritonitis infection rate/100 patient months	Minimize peritonitis episodes	Peritonitis infection rate _____	Current PD patients with peritonitis in past 6 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Hospital Readmissions (12 mo) % of total patients admitted to hospital readmitted within 30 days of discharge	Minimize hospital readmissions	Readmissions _____ %	Current PD patients readmitted to hospital within 30 days of discharge in past 3 mo 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Transplant waitlist (12 mo) % of all patients age <70 on waitlist any time during period	Interested patients are referred for transplant unless excluded by evaluation or listed exclusion criteria	Transplant waitlist rate % _____	Provide a copy of the transplant waitlist, transplant program(s) exclusion criteria, and procedure for candidacy evaluation and referral of patients

**Fiscal Year 2015 (10/01/14-9/30/15)
ESRD CORE SURVEY DATA WORKSHEET**

III. CLINICAL OUTCOMES THRESHOLDS TABLE

During the Entrance Conference review and discuss with the administrative person the current patient outcomes data submitted. *Compare the current facility outcomes listed in the “% Met Goal” columns of the Clinical Outcomes Tables to the applicable “Threshold for % Met Goal” from the Clinical Outcomes Thresholds Table below.*

Clinical Outcomes Thresholds Table for FY 2015

HD Indicator	Threshold for % Met Goal	PD Indicator	Threshold % Met Goal
Adequacy: Single pool Kt/V ≥1.2 Standardized Kt/V ≥2.0 for ≥4x/week or nocturnal	≥97.6% Kt/V* Not reported*	Adequacy: Kt/V≥1.7	≥92.1%*
Anemia: Hemoglobin <10 g/dL	≤12%*	Anemia: Hemoglobin <10 g/dL	≤23.6%*
Mineral & bone disorder: Calcium corrected for albumin (BCG) <10.2	≥94.8%**	Mineral & bone disorder: Calcium corrected for albumin (BCG) <10.2	≥94.8%
Phosphorus 3.5-5.5 mg/dL	≥61.2%**	Phosphorus 3.5-5.5 mg/dL	≥61.2%
Nutrition: Albumin ≥4.0	≥42.1%**	Nutrition: Albumin ≥4.0	≥42.4%
Fluid management: Intradialytic wt loss ≤5% from target wt	≥92.5%**	N/A	N/A
Vascular access: CVCs >90 days	≤8.1%*	PD Infection Peritonitis rate/100 pt mo	≤3.00***
HD vascular access infection rate/100 HD patient months	≤1.77*		
Hospital readmission within 30 days	≤30.7%*	Hospital readmission within 30days	≤30.7%*
Transplant waitlist <age70	≥24.5%*	Transplant waitlist <age 70	≥24.5%*

*2014 DFR National Average, **NOTE:** average of monthly facility lab results will likely show more variation and a higher percentage of patients above the threshold for any given month

**2014 DOPPS Practice Monitor: patient-level 3 month average as of April, 2014

***2012 ISPD Position Statement on Reducing the Risks of Peritoneal Dialysis-Related Infections

Calculating infection rates per 100 Pt Mo = [# of infections / sum of mo pts on that modality during last 12 mo] x 100

“Lost to Follow Up”: *If the facility lists >3 patients as “lost to follow up” (#7 on Entrance Conference Materials List), ask facility to explain the circumstances of those patients’ discharges without transfers to other dialysis facilities. If you identify concerns that patients’ rights may have been violated, you may wish to review those patients’ closed medical records pertinent to their discharges.*

Transplant Waitlist: *If the facility DFR and current transplant waitlist % is lower than the national average, review requested information to assure patients are being educated and referred as required.(V458, 513, 554, 561)*

Determine the data-driven focus areas for the survey (clinical areas for review): *Discuss the selection of the data-driven focus areas for the survey with the administrative person, to engage them in the process. If the facility has attained improvements and is currently meeting the thresholds in an area where the DFR review indicated problems, this indicates that performance improvement has taken place, and you may chose not to include that as a data-driven focus area for review.*

Record the data-driven focus areas for this survey:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

PART 1 – APPLICATION – TO BE COMPLETED BY FACILITY

1. Type of Application/Notification (check all that apply; if "Other," specify in "Remarks" section [Item 33]): (v1)

1. Initial 2. Recertification 3. Relocation 4. Expansion/change of services 5. Change of ownership
 6. Other, specify:

2. Name of Facility

3. CCN

4. Street Address

5. NPI

6. City

7. County

8. Fiscal Year End Date

9. State

10. Zip Code:

11. Administrator's Email Address

12. Telephone No.

13. Facsimile No.

14. Medicare Enrollment (CMS 855A) completed? Yes No NA

15. Facility Administrator Name:

Address:

City:

State:

Zip Code:

Telephone No:

16. Ownership (v2)

1. For Profit

2. Not for Profit

3. Public

17. Is this facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? (v3)

1. Yes 2. No

Is this facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? (v4)

1. Yes 2. No

Is this facility not owned or managed by a hospital (i.e., independent)? (v5)

1. Yes 2. No

If owned and managed by a hospital: hospital name: (v6)

CCN: (v7)

18. Is this facility located in a SNF/NF (check one): (v8)

1. Yes 2. No

If Yes, SNF/NF name: (v9)

CCN: (v10)

19. Is this facility owned &/or managed by a multi-facility organization? (v11)

1. No 2. Yes, Owned 3. Yes, Managed

If Yes, name of multi-facility organization: (v12)

Multi-facility organization's address:

20. Current Services (check all that apply): (v13)

1. In-center Hemodialysis (HD)

2. In-center Peritoneal Dialysis (PD)

3. In-center Nocturnal HD

4. Reuse

5. Home HD Training & Support

6. Home PD Training & Support

7. Home Training & Support **only**

21. New services being requested (check all that apply): (v14)

1. N/A

2. In-center HD

3. In-center PD

4. In-center Nocturnal HD

5. Reuse

6. Home HD Training & Support

7. Home PD Training & Support

8. Home Training & Support **only**

22. Does the facility have any home dialysis (PD/HD) patients receiving dialysis in long-term care (LTC) facilities?

(v15) 1. Yes 2. No

LTC (SNF/NF) facility name: (v16)

CCN: (v17)

Staffing for home dialysis in LTC provided by: (v18)

1. This dialysis facility

2. LTC staff

3. Other, specify

Type of home dialysis provided in this LTC facility: (v19)

1. HD

2. PD

For additional LTC facilities, record this information and attach to the "Remarks" (item 33) section.

23. Number of dialysis patients currently on census:

In-Center HD: (v20) _____

In-Center Nocturnal HD: (v21) _____

In-Center PD: (v22) _____

Home PD: (v23) _____

Home HD <= 3x/week: (v24) _____

Home HD >3x/week: (v25) _____

24. Number of approved in-center dialysis stations: (v26) _____

Onsite home training room(s) provided? (v27) 1. Yes 2. N/A

25. Additional stations being requested: (v28) None

In-center HD: (v29) _____

In-center nocturnal HD: (v30) _____

In-center PD: (v31) _____

26. How is isolation provided? (V32)

1. Room 2. Area (established facilities only) 3. CMS Waiver/Agreement (Attach copy)

27. If applicable, number of hemodialysis stations designated for isolation: (V33)

28. Days & time for in-center patient shifts (check all days that apply and complete time field in military time): (V34)

1 st shift starts:	M	T	W	Th	F	Sat	Sun
Last shift ends:	M	T	W	Th	F	Sat	Sun

29. Dialyzer reprocessing system: (V35) 1. Onsite 2. Centralized/Offsite 3. N/A

30. Staff (List full-time equivalents):

Registered Nurse: (V36)	Certified Patient Care Technician: (V37)
LPN/LVN: (V38)	Technical Staff (water, machine): (V39)
Registered Dietitian: (V40)	Masters Social Worker: (V41)
Others: (V42)	

31. State license number (if applicable): (V43)	32. Certificate of Need required? (V44) <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No <input type="checkbox"/> 3. NA
---	---

33. Remarks (copy if more and attach additional pages if needed):

34. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my knowledge. I understand that incorrect or erroneous statements may cause the request for approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 494.1 and 488.604 respectively.

I have reviewed this form and it is accurate:

Signature of Administrator/Medical Director	Title	Date
---	-------	------

PART II TO BE COMPLETED BY STATE AGENCY

35. Medicare Enrollment (CMS 855A approved by the MAC/FI)? (V45) 1. Yes 2. No

(Note: approved CMS 855A required prior to certification)

36. Type of Survey: (V46) 1. Initial 2. Recertification 3. Relocation 4. Expansion/change of services

5. Change of ownership 6. Complaint 7. Revisit 8. Other, specify

37. State Region: (V47)	38. State County Code: (V48)
-------------------------	------------------------------

39. Network Number: (V49)

My signature below indicates that I have reviewed this form and it is complete.

40. Surveyor Team Leader (sign)	41. Name/Number (print)	42. Professional Discipline (Print)	43. Survey Exit Date:
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INSTRUCTIONS FOR FORM CMS-3427

PART 1 – DOCUMENTATION NEEDED TO PROCESS FACILITY APPLICATION/NOTIFICATION TO BE COMPLETED BY APPLICANT

A completed request for approval as a supplier of End Stage Renal Disease (ESRD) services in the Medicare program (Part I – Form CMS-3427) must include:

- A narrative statement describing the need for the service(s) to be provided, and
- A copy of the Certificate of Need approval, if such approval is required by the state.

TYPE OF APPLICATION (ITEM 1)

Check appropriate category. A “change of service” refers to an addition or deletion of services. “Expansion” refers to addition of stations. If you relocate one of your services to a different physical location, you may be required to obtain a separate CCN for that service at the new location.

IDENTIFYING INFORMATION (ITEMS 2-24)

Enter the name and address (*actual physical location*) of the ESRD facility where the services are performed. If the mailing address is different, show the mailing address in Remarks (*Item 33*). Check the applicable blocks (*Item 17* and *Item 18*) to indicate the facility’s hospital and/or SNF/NF affiliation, if any. If so, enter the CCN of the hospital and/or SNF/NF. Check whether the facility is owned and/or managed by a “multi-facility” organization (*Item 19*) and provide the name and address of the parent organization. A “multi-facility organization” is defined as a corporation or a LLC that owns more than one facility.

TYPES OF SERVICE, DIALYSIS STATIONS, AND DAYS/HOURS OF OPERATION (ITEMS 20-28)

Provide information on current services offered (*Item 20*). Check N/A or each **New** service for which you are requesting approval (*Item 21*). Note that facilities providing home therapies must provide both training and support. If you are requesting to offer home training and support **only** (*Item 21*), you must have a functional plan/arrangement to provide backup dialysis as needed. A new “home training and support only” service applies to initial applications. If you request **any** home training and support program (*Item 21*), you must also indicate “Yes” for a training room (*Item 24*). If you provide or support dialysis within one or more a LTC facilities (SNF/NF), list all LTCs (name, CCN, and address) participating in this service under Remarks (*Item 33*), and complete Item 22. Enter the number of stations for which you are asking approval (*Item 25*). Provide information on isolation (*Items 26-27*). Facilities not existing prior to October 14, 2008 which do not have an isolation room must attach evidence of CMS waiver and written agreement with geographically proximal facility with isolation room. Provide all days and start time for the first shift of patients and end time for the last shift of patients (in military time) for each day of operation (*Item 28*). Provide information on dialyzer reprocessing (*Item 29*).

STAFFING (ITEM 30)

“Other” includes non-certified patient care technicians, administrative personnel, etc. To calculate the number of full-time equivalents of any discipline (*Item 30*), add the total number of hours that all members of that discipline work at this facility and enter that number in the numerator. Enter into the denominator the number of hours that facility policy defines as full-time work for that discipline. Report FTEs in 0.25 increments only. Example: An RD works 20 hours a week at Facility A. Facility A defines full time work as 40 hours/week. To calculate FTEs for the RD, divide 20 by 40. The RD works 0.50 FTE at Facility A.

REMARKS (ITEM 33)

You may use this block for explanatory statements related to Items 1-32.

LICENSING AND CERTIFICATE OF NEED

If your state requires licensing for ESRD facilities, include your current license number in Item 31. If your state requires a Certificate of Need (CON) for an initial ESRD or for the change you are requesting, mark the applicable box in Item 32 and include a copy of the documentation of the CON approval.

Upon completion, forward a copy of form CMS-3427 (Part I) to the State agency.

PART II - SURVEY AND CERTIFICATION REPORT TO BE COMPLETED BY STATE AGENCY

The surveyor should review and verify the information in Part I with administrator or medical director and complete Part II of this form.

Recognize that CMS cannot issue a CCN for an initial survey until all required steps are complete, including CMS-855A approved by the applicable MAC. Complete the Statement of Deficiencies (CMS Form 2567) in ASPEN. Complete the CMS-1539 in ASPEN entering recommended action(s). All required information must be entered in ASPEN and uploaded in order for the survey to be counted in the state workload.

➡ **TASK: Presurvey Preparation** ▲

Purpose - To determine the preliminary data-driven focus area(s) for the survey

Review the most current Dialysis Facility Report (DFR): *Note how the facility is ranked on the State Profile/Outcomes List. Follow the guidance in the Presurvey Preparation section of the current fiscal year “ESRD Core Survey Data Worksheet” for review of the DFR, and comparison of the facility outcomes and trends with national averages. If the facility outcomes in an area are worse than the national average, plan to include that area as a **preliminary data-driven focus area**.*

Contact the ESRD Network: *Ask about any quality concerns at the facility, information regarding involuntary discharges and transfers, and patient complaints.*

Review the facility complaint and survey history for the current 12-18 months. *Look for trends in patient and/or staff complaint allegations, and survey citations.*

Copy the Entrance Conference Materials List/Clinical Outcomes Tables section of the “ESRD Core Survey Data Worksheet” for the current fiscal year to present to the facility person in charge during “Introductions.” *Gather other documents needed to conduct the survey (e.g., 3427, survey worksheets).*

➡ **TASK: Introductions**

Purpose – To announce the survey, introduce the survey team, and give the facility person in charge notification of the materials needed from the facility to conduct the Entrance Conference.

Contact the person in charge: *Introduce the survey team; give that person the copy of the Entrance Conference Materials List/Clinical Outcomes Tables from the ESRD Core Survey Data Worksheet for the current fiscal year. Explain that the document lists the items the survey team will need to conduct the survey and that the facility should provide much of the information within 3 hours (e.g. current facility and patient-specific outcomes) for discussion during the Entrance Conference.*

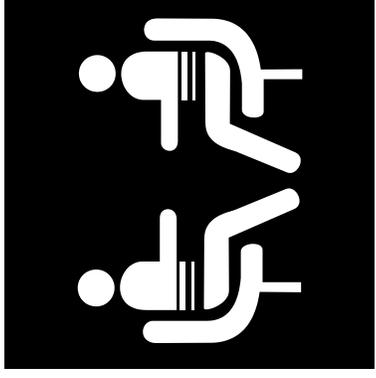


ESRD Core Survey Field Manual

Tab 4: Environmental "Flash" Tour

- Signage: Routine Federal Survey in Progress
- Task: Environmental "Flash" Tour

Routine Federal Survey in Progress



**Surveyors will be happy to talk
with patients or staff onsite or
call:**

➔ **TASK: Environmental “Flash” Tour**

Purpose - To observe the patient care-related areas for conditions which may have immediate impact on patient safety in infection control, physical environment hazards, serious lapses in equipment and building maintenance, and availability of emergency equipment.

Observe four patient-related areas of the facility as listed: *This is a “flash” look at the patient-related areas listed below, looking for observable indicators of patient safety concerns. This “flash tour” begins immediately after the Introductions task.*

Ask staff about the facility “culture of safety” *in the patient-related areas listed below. Early in the survey is a key time to begin to look for evidence of a culture of safety in the facility. Begin to determine if the facility culture supports open communication, clarity for staff on the expectations of their roles, and if all levels of staff are engaged in identifying and addressing risks and errors. These determinations are important in evaluating the strength of the QAPI program and how well patients are protected from recurring medical errors. Begin to understand the role the direct care and technical staff play in this process. Ask technicians and nurses about actions taken when errors or “near misses” occur. These conversations can demonstrate if the facility “culture of safety” program is active and effective.*

Examples of questions for staff:

- What is the system of communication like here? How does administration ask for your input?
- Are you comfortable bringing issues and concerns to administration’s attention? Does the administration listen?
- How are you involved in the QAPI program? How are QAPI plans for improvement communicated to you?
- What can someone in your position do to prevent or reduce treatment errors?
- What errors or near misses are you expected to report? Do you feel comfortable reporting errors?
- How and to whom would you report an error or near miss that you observed or were involved in?
- How would you expect the error or near miss to be addressed? What is your role in follow up?

In-center dialysis patient treatment area - Observe the general environment and atmosphere of the treatment area. *Observe a sample of 25% (minimum of 3) dialysis stations with patients undergoing treatments. Observe the patient, their vascular access, and the surroundings of the dialysis station. This is a “flash” look, and not a verification of their dialysis prescription delivery, which is done during “Observations of Hemodialysis Care and Infection Control Practices.” Observe the availability and functionality of emergency resuscitation and evacuation equipment.*

Triggers for citation or more investigation of concerns:

- Dummy drip chambers present in the patient treatment area (V400, 403)
- Patients' vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Evidence of poor staffing, e.g., machine alarms not answered, patients not regularly monitored, no dietitian or social worker currently on staff (V757)
- Blood spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood (V122)
- HD machine transducer protectors wetted with blood not changed - *observe/interview staff regarding the practice of inspecting the internal transducer for blood prior to machine use for another patient* (V120)
- Insufficient space to prevent cross-contamination and use emergency equipment (V404)

- Absence of functional emergency resuscitation equipment (i.e., AED/defibrillator, oxygen, suction, emergency medications, Ambu bag) (V413); emergency evacuation equipment insufficient or unavailable (V415)
- Hemodialysis machines in observable poor repair (e.g., alarms not functional, missing components) (V403)
- If dialyzer reuse, germicide odors noticeable in patient treatment area (V318)
- Disrespectful communication, e.g., rude, demeaning, harassing, name calling, loudly calling out weight; disrespectful or punitive actions toward patients, e. g., physical or chemical restraints, involuntary seclusion (V452, 627)
- Failure to offer patients confidentiality when discussing their condition/treatment; failure to protect the patients' confidentiality by allowing exposure of patients' sensitive body parts during procedures (V454)

Water treatment/dialysate preparation area - *Observe the carbon system, the chlorine testing equipment and reagents, and current day/shift total chlorine test results. Look at the alarm/monitoring systems for the reverse osmosis (RO) and/or deionization (DI) components, and the dialysate concentrate proportioning ratios listed on the packaging.*

Triggers for citation or more investigation of concerns:

- Carbon system: absence of 2 or more carbon tanks, with sampling port between (V192), current shift total chlorine test not done, testing reagents not sensitive to 0.1mg/L total chlorine, expired or don't match testing equipment (V196)
- RO: absence of functioning water quality monitor; no audible alarm in patient treatment area (V200)
- If DI is present: absence of functioning resistivity monitor, no audible AND visible alarm in patient treatment area, absence of automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis stations if resistivity falls <1 megohm, DI not monitored twice/day (V202, 203)
- Water distribution equipment in observable disrepair or contaminated state, e.g., the presence of algae or discoloration of water (V403)
- Acid and bicarbonate dialysate concentrates of different proportioning ratios present - *interview staff regarding the use of the different concentrates and verify only matching ratios are used with machines programmed to that ratio* (V249)
- Acid or bicarbonate dialysate concentrate mixing and distribution equipment in observable disrepair or contaminated state, e.g., algae (V403)

Reuse room - *Observe the condition of the reprocessing equipment, dialyzer storage, and dialyzer refrigerator, if present.*

Triggers for citation or more investigation of concerns:

- Stored reprocessed dialyzers aesthetically unacceptable, e.g., header caps with blood, leaking, port caps off (V343)
- Stored dialyzers not protected from unauthorized access (V321) Not within germicide manufacturer's temperature range (V345)
- Reprocessing room or equipment in observable disrepair (V318, 403)
- Dirty dialyzers kept at room temperature >2 hrs. before reprocessing (V331)
- Dialyzer refrigerator temperature not monitored (V331)

Home dialysis training area - *Observe the physical environment, infection control, availability of emergency equipment and method for summoning immediate assistance.*

Triggers for citation or more investigation of concerns:

- Insufficient space in patient training area to prevent cross-contamination and provide emergency care if >1 patient trained at a time (V404)
- Insufficient methods to provide patient privacy (V406)
- Blood or PD effluent spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood or PD effluent (V122)
- Absence of functional, immediately available emergency resuscitation equipment (V413)
- Absence of method for summoning immediate assistance for patient or solitary staff (V402)

Extending the “flash” tour to other areas of the facility : Consider looking at other patient-related areas of the facility, e.g., waiting room, patient bathrooms, supply storage room, hazardous waste storage, laboratory area if you observe:

- Evidence of serious lack of environmental maintenance that has the potential to impact patient safety, e.g., large areas of water damage, presence of mold in the patient-related areas, uneven/broken floor surfaces creating multiple trip hazards where patients ambulate (V401, 402)



ESRD Core Survey Field Manual

Tab 5: Entrance Conference

- ESRD Core Survey—Entrance Conference Questions
- Task: Entrance Conference

**ESRD Core Survey
Entrance Conference Questions**

Facility: _____ Date: _____

Gather the following information from the facility representative:

Current HD in-center census: _____

Number of currently used in-center HD treatment stations: _____

What are the facility's days & hours of operation? _____

How many patient shifts are there? MWF _____ TThS _____

What hours is the facility open? _____

What time do patient shifts start? _____

What time do staff arrive? _____

When are water tests done? _____

Does the facility have an isolation room or area? Yes No

If yes: how many isolation stations are available? _____

How many HBV+ patients are on census? _____

If no: does the facility have a written agreement with a local facility which accepts HBV+ patients? Yes No

If opened or expanded on or after 10/14/2008, does the facility have a waiver from CMS for the requirement of an isolation room? Yes No

Does the facility reprocess/reuse dialyzers? Yes No

If yes, what type of germicide is used? _____

Is the reprocessing off-site/centralized? Yes No

Does the facility have any home dialysis programs? Yes No

If yes: Number of PD patients _____ Number of HHD patients _____

Does the facility provide home staff-assisted hemodialysis? Yes No

If the facility does not provide home peritoneal and/or hemodialysis training and support, how is access to these modalities provided? _____

Does the facility dialyze or support the dialysis of nursing home patients at their nursing homes? No Yes

Are any staff members currently in orientation? Yes No

Do agency nursing staff provide care in the facility? Yes No

Has the facility ever had any TB conversions (patients or staff)? Yes No

If yes, did the facility report TB positive patients to the state health department?

Yes No

What action is taken if a patient is identified with active TB? _____

Are there any current patients with MRSA or VRE? Yes No

What are the names of those patients? _____

What system for patient medical records is used? Is part or all of the medical record computerized? _____

➔ **TASK: Entrance Conference** ▲

Purpose- To communicate with and engage facility administrative personnel in the survey process. To review current facility outcomes and determine the data-driven focus areas of the survey for patient sample selection, clinical care reviews, and QAPI review

Obtain and Review documentation of current facility and patient-specific clinical outcomes data submitted from/on the Entrance Conference Materials List/Clinical Outcomes Tables. *You may wish to review this information prior to the Entrance Conference, to be prepared to ask for clarifications, and discuss possible areas of concern.*

Explain purpose and timeline for the survey

Ask the administrative person the facility-specific questions from the “Entrance Conference Questions” worksheet.

Discuss with the administrative person the current facility and patient outcomes data submitted. *Compare the current facility outcomes listed in the “% Met Goal” column of the Clinical Outcomes Tables to the applicable “Threshold for % Met Goal” on the Clinical Outcomes Thresholds Table in the “ESRD Core Survey Data Worksheet” for the current fiscal year. Ask (briefly) about actions being taken for improvement in the areas where national thresholds are not currently achieved.*

Determine the data-driven focus areas for the survey (clinical areas for review): The data-driven focus areas for the survey are the clinical areas where improvement is currently needed at that facility. *Discuss the selection of the data-driven focus areas for the survey with the administrative person, to engage them in the process. Note if the survey team selected an area as a preliminary data-driven focus, based on the DFR information, but the facility has attained improvements and are currently meeting the national thresholds listed for that area, you may chose not to include that as a data-driven focus area for review.*



ESRD Core Survey Field Manual

Tab 6: Observations of Hemodialysis Care & Infection Control Practices

- Observations of Hemodialysis Care & Infection Control Practices
- Task: Observations of Hemodialysis Care & Infection Control Practices

ESRD CORE SURVEY OBSERVATIONS OF HEMODIALYSIS CARE AND INFECTION CONTROL PRACTICES

Facility _____ CCN# _____ Surveyor _____

The contents of this worksheet are intended to guide the surveyor through the Observations of Hemodialysis Care and Infection Control Practices in the ESRD Core Survey Process. There are 3 parts to this survey task:

1. Observe the direct care staff delivering care: *Observe the following activities using the applicable observational checklists in this worksheet:*

Hemodialysis patient care and dialysis station & equipment preparation: *Attempt to capture at least 2 separate observations of each of the procedures listed below. Try to conduct observations on different days and of different staff. It may be possible to observe several of the procedures at one dialysis station during the changeover between patient shifts. Observe each procedure listed below one at a time, to assure focus on that activity.*

- Initiation of hemodialysis for a patient with a central venous catheter (CVC) (**Checklist 1**)
- CVC Exit site care (**Checklist 2**)
- Discontinuation of hemodialysis with a CVC (**Checklist 3**)
- Initiation of hemodialysis for a patient with an arteriovenous fistula (AVF) or arteriovenous graft (AVG) (**Checklist 4**)
- Discontinuation of hemodialysis with an AVF or AVG (**Checklist 5**)
- Cleaning and disinfection of the dialysis station between patients (**Checklist 6**)
- Preparation of the dialysis machine and extracorporeal circuit (**Checklist 7**)
- Dialysis supply management and contamination prevention: *This checklist is intended for completion after the surveyor has conducted the other activity observations, to document assessment of the facility practices in supply management and contamination prevention. (Checklist 9)*

Medication preparation and administration: *Use observational Checklist 8 to attempt to capture 2 observations of different licensed nursing staff preparing and administering medications to 1-2 patients.*

Note: Observational Checklists 1-9 are intended to focus your observations on the elements/steps of the procedures that would be expected to prevent the transmission of infections and assure safe operation of dialysis equipment. **Individual steps omitted or conducted out of sequence should not be used as a sole basis for citation. Citation decision-making must be based on consideration of trends in observed practices, the potential an individual practice has for patient harm, and the *triggers* listed in the ESRD Core Survey Process, which have applicable V-tags listed.**

2. Review Facility Isolation practices: *If there is a hepatitis B positive (HBV+) patient on in-center hemodialysis at the facility on any day or time, complete this section. If there are no HBV+ patients being dialyzed in-center, check here*

3. Verify dialysis treatment prescription delivery: *Complete this section to record your findings from comparing the dialysis treatments being delivered for 4-5 patients to their ordered dialysis prescriptions.*



Initiation of Dialysis with Central Venous Catheter

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: Patient should wear a mask whenever CVC is accessed
Staff PPE must be gown, mask, eye protection, and gloves (V115,113)

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Y/N	Y/N
Hand hygiene, don clean gloves (V113)	Y/N	Y/N
Place clean field under CVC ports (V147)	Y/N	Y/N
Close the catheter clamps; Disinfect CVC hubs, using an appropriate antiseptic. May perform either (or both): <ul style="list-style-type: none"> • External disinfection by wiping exterior caps before removing; or • Open hub disinfection by wiping the threads and top of uncapped hub with antiseptic, removing any residue/blood • Closed connector devices which have penetrable caps not removed, wipe outside connecting surfaces of device (V147) 	Y/N	Y/N
Connect sterile syringes aseptically to each port to remove indwelling solutions and/or flush with sterile saline; initiate treatment	Y/N	Y/N
Remove gloves, hand hygiene (V113)	Y/N	Y/N

Additional Notes: _____

Central Venous Catheter Exit Site Care

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: Patient should wear a mask whenever CVC is accessed (V147)
 Staff PPE must be gown, mask, and gloves (V115, 113)

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Y/N	Y/N
Hand hygiene, don clean gloves (V113)	Y/N	Y/N
Remove old dressing and discard	Y/N	Y/N
Remove gloves, hand hygiene, don clean gloves (V113)	Y/N	Y/N
Cleanse area around CVC exit site with antiseptic ; allow to dry before applying dressing (V147)	Y/N	Y/N
Sterile dressing applied to CVC exit site; may apply antimicrobial ointment if not contraindicated or chlorhexidine-impregnated dressing if no sensitivity (V147)	Y/N	Y/N
Remove gloves, hand hygiene (V113)	Y/N	Y/N

Additional Notes: _____

Discontinuation of Dialysis with Central Venous Catheter

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: Patient should wear mask whenever the CVC is accessed (V147)

Staff PPE must be gown, mask, eye protection, and gloves (V115, 113)

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station; supplies for only that patient brought to station (V116)	Y/N	Y/N
Hand hygiene, don clean gloves (V113)	Y/N	Y/N
Place clean field under CVC ports (V147)	Y/N	Y/N
Reinfuse extracorporeal circuit	Y/N	Y/N
Remove gloves, hand hygiene, don clean gloves (V113)	Y/N	Y/N
Close CVC clamps; Disinfect CVC connections with appropriate antiseptic. May perform one or both: <ul style="list-style-type: none"> • External disinfection wiping exterior of connections b/4 disconnecting blood lines; or • Open hub disinfection wiping threads and top of open CVC hubs, removing any residue/blood after disconnecting blood lines • Closed connector devices: wiping exterior of connections before disconnecting blood lines (V147) 	Y/N	Y/N
Disconnect blood lines aseptically (V147)	Y/N	Y/N
Apply sterile port caps aseptically after post treatment protocol (applicable to closed connector devices when changed) (V147)	Y/N	Y/N
Discard unused supplies or dedicate to that patient; no disposable supplies returned to common supplies (V116)	Y/N	Y/N
Remove gloves, hand hygiene (V113)	Y/N	Y/N

Additional Notes: _____

Access of AV Fistula or Graft for Initiation of Dialysis

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes:

Staff PPE must be gown, face shield or mask/eye protection, and gloves (V115,113)

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Y/N	Y/N
Wash skin over access with soap and water or antibacterial scrub (patient or staff may do this-patients should be instructed to wash their access upon entering facility & staff verbally confirm with patient that it was done; for dependent patients, staff must do this before proceeding with skin antisepsis) (V550)	Y/N	Y/N
Evaluate access; Locate/palpate cannulation sites	Y/N	Y/N
Hand hygiene (remove gloves, if worn); don clean gloves (V113)	Y/N	Y/N
Apply antiseptic to skin over cannulation sites and allow to dry; sites not touched again after skin antisepsis, without repeating skin antisepsis (V550)	Y/N	Y/N
Insert cannulation needles; tape in place; initiate treatment	Y/N	Y/N
Remove gloves, hand hygiene (V113)	Y/N	Y/N

Note: This checklist is not intended for use with buttonhole cannulation technique

Discontinuation of Dialysis and Post Dialysis Access Care for AV Fistula or Graft

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: Staff PPE must be gown, face shield or mask/eye protection, and gloves (V115, 113)

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Y/N	Y/N
Hand hygiene, don clean gloves (V113)	Y/N	Y/N
Reinfuse extracorporeal circuit; disconnect bloodlines aseptically	Y/N	Y/N
Remove gloves, hand hygiene, don clean gloves (V113)	Y/N	Y/N
Remove needles aseptically; discard needles in Sharps container at point of use; Needle sites held with clean gauze or bandage using clean gloved hands (patient, staff or visitor) or disinfected clamps (V550, 113)	Y/N	Y/N
Remove gloves, hand hygiene (V113)	Y/N	Y/N
When hemostasis is achieved: Hand hygiene, don clean gloves; replace blood-soiled bandage/ gauze on needle sites; Bandage/gauze on each needle site is clean & dry prior to discharge (V550, 113)	Y/N	Y/N
Discard unused supplies or dedicate to that patient (no supplies returned to common supplies) (V116)	Y/N	Y/N
Remove gloves, hand hygiene (patient or visitor who held sites, remove gloves, hand hygiene) (V113)	Y/N	Y/N

Additional Notes: _____

Cleaning and Disinfection of the Dialysis Station

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: All items listed in this checklist must be disinfected using an EPA-registered hospital disinfectant prepared and used in accordance with manufacturer's instructions (V122)

Staff PPE must be gown, face shield or mask/eye protection, and gloves (V115, 113)

ACTION	OBSERVATION 1	OBSERVATION 2
Remove all bloodlines and disposable equipment; discard in biohazardous waste; dialyzer for reprocessing: all ports capped, dialyzer and bloodlines transported in a manner to prevent contamination of other surfaces (V122,)	Y/N	Y/N
Empty prime waste receptacle, if present on machine	Y/N	Y/N
Remove gloves, hand hygiene, don clean gloves (V113)	Y/N	Y/N
Use disinfectant-soaked cloth/wipe to visibly wet all machine top, front and side surfaces, dialysate hoses, Hansen connectors, and outside surfaces of dialysate concentrate containers (V122)	Y/N	Y/N
Wipe wet all internal and external surfaces of prime waste container and allow to dry if present; prime waste container must be disinfected before used to prepare for another patient's treatment (V122)	Y/N	Y/N
When chair vacated: discard unused disposable supplies (or dedicate to that patient); chair fully reclined, fresh disinfectant cloth/wipe used to visibly wet all external front-facing and side chair surfaces, including down sides of seat cushion and tops of side tables (V116, 122)	Y/N	Y/N
Non-disposable items: BP cuff & tubing, TV controls, call button, data entry station and counters around dialysis station wiped wet with disinfectant (V122)	Y/N	Y/N
If clamps are used, cleaned of visible blood and disinfected (V116)	Y/N	Y/N
Discard cloths/wipes; remove gloves, hand hygiene (V113)	Y/N	Y/N

Attention: It is not a regulatory requirement that the dialysis station is vacated before surface cleaning and disinfection and set up of the dialysis machine is done. The patient should only be removed from the station once they have completed treatment and it is clinically safe to do so. If the previous patient remains in the chair while the machine is cleaned/disinfected and prepared for the next patient, pay close attention to staff adherence to separation (changing gloves, hand hygiene) when moving between the patient and the disinfected and/or prepared machine.

Preparation of the Hemodialysis Machine/Extracorporeal Circuit

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: Hemodialysis machines must be operated in accordance with the manufacturer's directions for use for internal function verification and dialysate testing. Artificial dialyzers must be rinsed and tested in accordance with the germicide (if reprocessed) and dialyzer manufacturer's directions for use. Dummy drip chambers must never be used to prepare a machine for patient treatment (V400,V403)!

Staff PPE must be gloves; if reprocessed dialyzer, gown, face shield or mask/eye protection (V115, 113, 320)

ACTION	OBSERVATION 1	OBSERVATION 2
Reprocessed dialyzer germicide tests done (i.e., presence test before rinsing/priming, absence of residual test prior to treatment initiation) (V350, 353)	Y/N	Y/N
Dialyzer rinsed/primed with sufficient saline (note that single use dialyzers not chemically sterilized may require less saline for rinsing than reprocessed dialyzers and chemically sterilized single use dialyzers) (V352)	Y/N	Y/N
Dialysate pH and conductivity tested with an independent method; Staff aware of allowable pH range and variation from machine conductivity reading (V250)	Y/N	Y/N
Machine alarms and internal functions (e.g., pressure holding test) tested (V403)	Y/N	Y/N
Reprocessed dialyzer: patient and dialyzer matched and identified by 2 people while patient is at dialysis station (V348)	Y/N	Y/N

Additional Notes: _____

Parenteral Medication Preparation and Administration

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Notes: Medications must be prepared in a clean area on a clean surface away from dialysis stations (V117). The exception to this is drawing saline syringes from patient's saline bag in an emergency situation at the station, following aseptic technique after wiping port with disinfectant prior to aspirating.

ACTION	OBSERVATION 1	OBSERVATION 2
Hand hygiene (V113)	Y/N	Y/N
Single dose vials used for one patient only and discarded (V118)	Y/N	Y/N
Multiple dose vials are only entered with a new, sterile syringe and needle, labeling with date opened and discarded within 28 days or by manufacturer's instructions (V143)	Y/N	Y/N
Wipe stopper with alcohol or other antiseptic (V143)	Y/N	Y/N
Withdraw medication into sterile syringe; Label syringe if medication not immediately administered; Medications may be prepared for multiple patients at one time, but administration must be to one patient at a time, leaving remainder of medications in the clean preparation area (V117)	Y/N	Y/N
Only individual patient's medications taken to their dialysis station (V117)	Y/N	Y/N
Hand hygiene, don clean gloves and other PPE as indicated by potential exposure (e.g., gown and mouth/nose/eye protection if injecting into blood lines) (V113, 115)	Y/N	Y/N
Wipe injection port with antiseptic; inject medication (V143)	Y/N	Y/N
Discard syringe into Sharps container Exception: If using a needleless system with no attached needle, disposal in Sharps container not necessary (V121)	Y/N	Y/N
Remove gloves, hand hygiene (V113)	Y/N	Y/N

Additional Notes: _____

Dialysis Supply Management and Contamination Prevention

Facility _____ Surveyor _____

Obs. #1: Patient ID: _____ Date/time _____ Station# _____ Staff _____

Obs. #2: Patient ID: _____ Date/time _____ Station# _____ Staff _____

NOTE: This checklist is intended to be completed after observations of care using checklists 1-8 have been completed, to record your observations related to the facility supply management in general throughout that observation period.

ACTION	OBSERVATION 1	OBSERVATION 2
Supplies are stored and kept in designated clean areas, sufficient distance from dialysis stations to prevent contamination from potentially infectious materials/substances (V119)	Y/N	Y/N
Supplies for next patient are not brought to the station before the prior patient's treatment is terminated and applicable piece of equipment (machine, chair) is cleaned/disinfected (i.e., supplies are not placed on or near the machine until it has been “stripped” and surface disinfected) (V119)	Y/N	Y/N
Carts or trays containing supplies are not taken to or moved between dialysis stations (V119)	Y/N	Y/N
Staff do not keep patient care supplies in pockets or on their person (V119)	Y/N	Y/N
Non-disposable equipment (e.g., thermometer, pH/conductivity meter, access flow device, O ₂ saturation meter, blood glucose meter, stethoscope diaphragm/bell end) brought to the dialysis station is disinfected before being returned to a common area or taken to another dialysis station Disinfection=all surfaces wiped visibly wet with EPA-registered hospital disinfectant and allowed to dry (V116)	Y/N	Y/N
Medication vials are not taken to the dialysis station (V117)	Y/N	Y/N
Disposable supplies taken to the dialysis station not used on the patient are discarded or dedicated to that patient and not returned to common supplies (V116)	Y/N	Y/N

Additional Notes: _____

2. Review facility isolation practices: Complete this section if there are HBV+ patient(s) receiving in-center hemodialysis at the facility.

Determine if there are any HBV+ patients who will be receiving hemodialysis at the facility during the survey.

Observe the isolation room or area, and the equipment and supplies contained within it.

- Is the isolation room or area (area separated from the other dialysis stations by the width of one station), equipped with dedicated equipment and supplies for use by only HBV+ patients?

Yes No-explain (V110, 128, 130) _____

Observe (if possible) the care delivery for an HBV+ patient in the isolation room/area, using the observational checklists in this worksheet.

- Did you observe the care of an HBV+ patient Yes No
 - **If Yes:** were the staff members caring for the HBV+ patient **NOT** concurrently assigned to and caring for HBV susceptible patients? (**Note:** Exceptions to this should be rare. If this is occurring, the facility's efforts to avoid this situation should be explained and clarified for the surveyor. Examples of such efforts are to schedule patients in a manner to avoid overlap between HBV+ and HBV-susceptible patients or scheduling HBV+ patients on shifts when there are 2 Registered Nurses (RN) on duty so that one RN may access the HBV+ patient's CVC and administer their medications, while the other RN does so for the other patients. Emergency medical situations may be a justifiable exception.) Yes No-explain (V110, 131) _____

 - Did you observe appropriate isolation practices, such as staff and others removing all PPE and performing hand hygiene when leaving the isolation room/area? Yes No-explain (V113, 130) _____

Review the staff assignments for the current week, looking for which patients are concurrently assigned to the staff member assigned to the HBV+ patient(s).

Ask: Staff on duty how the patient care assignments are routinely made when an HBV+ patient is being treated.

- Are staff assigned to care for HBV+ patients **NOT** concurrently assigned to care for HBV susceptible patients? Yes No-explain (V110, 131) _____

Additional notes: _____

➡ **TASK: Observations of Hemodialysis Care and Infection Control Practices** ▲

Purpose - To identify routine patient care practices which may impact patient safety in the areas of infection control, equipment operation, reprocessed dialyzer use, and patient assessment

1. **Observe the direct care staff delivering care** – *Observe the following activities using the applicable observational checklists from the “Observations of Hemodialysis Care and Infection Control Practices” worksheet:*

Hemodialysis patient care and dialysis station & equipment preparation: *Attempt to capture at least 2 separate observations of each of the procedures listed below. Try to conduct observations on different days and of different staff. It may be possible to observe several of the procedures at one dialysis station during the changeover between patient shifts.*

Observe each procedure listed below one at a time, to assure focus on that activity.

- Initiation of hemodialysis for a patient with a Central Venous Catheter (CVC)
- CVC Exit site care
- Discontinuation of hemodialysis and post-dialysis vascular access care for a CVC
- Initiation of hemodialysis for a patient with an arteriovenous fistula (AVF) or arteriovenous graft (AVG)
- Discontinuation of hemodialysis and post-dialysis access care for an AVF or AVG
- Cleaning and disinfection of the hemodialysis station between patients
- Preparation of the hemodialysis machine and extracorporeal circuit
- Dialysis Supply Management: *Observation checklist 9 is intended for completion after the surveyor has conducted the other activity observations, to document assessment of the facility practices in supply management and contamination prevention.*

Triggers for citation or more investigation of concerns:

- Observed trends of breaches in infection control patient care practices:
 - Poor hand hygiene and glove use practices (V113)
 - Supplies taken to station not disposed, disinfected or dedicated to that patient (V116)
 - Clean dialysis supplies not protected from potential contamination (V119)
 - Breaches in aseptic practices for CVC (V147) or AVF/AVG care (V550)
- Not adequately disinfecting the HD station & equipment between patients (V122)
- Using dummy drip chamber to set up HD machine for patient treatment (V400, 403)-*This practice has been determined to be a serious risk to patient safety, and should be considered as an IJ*
- Not testing hemodialysis machine alarms (V403)
- Not testing dialysate pH/conductivity with independent method or lack of staff knowledge of acceptable parameters for pH/conductivity (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers according to manufacturer’s DFU (V352, 403)
- Not assessing patients before and after treatment or monitoring during treatment according to facility policy (V504, 543, 550, 551, 715)

Medication preparation and administration: *Observe this process using the applicable observational checklist. Attempt to capture 2 observations of different staff preparing and administering medications for 1-2 patients.*

Triggers for citation or more investigation of concerns:

- Medications not prepared in a clean area away from the dialysis stations (V117)
- Single dose medication vials punctured more than once or used for multiple patients (V118)
- Multidose medication vials punctured with previously used syringe or needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared and/or administered by unqualified personnel (V681)

Extending any of the above direct care and medication preparation/administration observations should not be necessary if poor practices were identified during either or both of the 2 observations of each procedure. If the surveyor determines that more observations are indicated, 2 additional observations of the applicable procedure(s) should be sufficient to determine the presence of deficient practice.

2. Review Facility Isolation practices: If there is a hepatitis B positive (HBV+) patient on in-center hemodialysis at the facility:

- **Observe** the isolation room/area, and the equipment and supplies contained within it. If possible, **observe** the care delivery for an HBV+ patient for the observations of direct care procedures in the section above. Observe for separation of care practices from the HBV susceptible patients.
- **Review** staff/patient assignments for the current week, looking at which patients are concurrently assigned to the staff caring for HBV positive patient.
- **Ask** staff on duty how staff assignments are made when an HBV+ patient is dialyzing.

Triggers for citation or more investigation of concerns:

- HBV+ patient(s) not isolated (V110, 128, 129)
- Observed trends of breaches in infection control practices when caring for HBV+ patients (V113, 116, 117, 119, 121)
- Staff assigned/delivering care to HBV+ patient and HBV susceptible patients on same shift- *Investigate the extent of the practice* (V110, 131). (**Note:** Exceptions to this should be rare. If this is occurring, the facility's efforts to avoid this situation should be explained and clarified for the surveyor. Examples of such efforts are to schedule patients in a manner to avoid overlap between HBV+ and HBV-susceptible patients or scheduling HBV+ patients on shifts when there are 2 Registered Nurses (RN) on duty so that one RN may access the HBV+ patient's CVC and administer their medications, while the other RN does so for the other patients. Emergency medical situations may be a justifiable exception.)
- Isolation equipment not dedicated for use on HBV+ patients (V130)
- Non-HBV+ patient(s) dialyzing in the isolation room/area when an HBV+ patient is on in-center HD census (V110, 128, 130)

3. Verify dialysis treatment prescription delivery: *Review and compare the dialysis prescription delivery (dialysate, dialyzer, blood flow rate, dialysate flow rate) to patients' dialysis orders for 4-5 patients during their treatments.*

Trigger for citation or more investigation of concerns:

- 1 or more patients not dialyzed on ordered prescription, e.g., wrong dialysate, dialyzer type, blood flow rate, dialysate flow rate (V543, 544)



ESRD Core Survey Field Manual

Tab 7: Patient Sample Selection

- ESRD Core Survey Worksheet: Patient Roster
- Task: Patient Sample Selection

ESRD Core Survey Worksheet: Patient Roster

(Make Additional Copies As Needed)

Instructions: Check ONLY the criteria/data-driven or other focus area(s) for why the patient was sampled

Facility:

CCN:

Census:

Date:

Survey Information ICHD = In-center HD ICPD = In-center PD HHD = Home HD PD = Home PD I = Interview O = Observation R = Record Review	Reason Sampled	Unstable	New Admit <90 days	Involuntary Discharge	Home Dialysis in LTC	Infection	Hospitalized/ Readmitted	Anemia Management	Adequacy	Calcium/Phosphorus CKD MBD	Albumin/Nutrition	Fluid Management	CVC >90 days	Observation	Random Sampled for Observation/Interview (circle one)	Complaint
Name _____ ID _____ Admit Date _____ <input type="checkbox"/> ICHD <input type="checkbox"/> HHD <input type="checkbox"/> ICPD <input type="checkbox"/> PD <input type="checkbox"/> I <input type="checkbox"/> O <input type="checkbox"/> R Surveyor _____																
Name _____ ID _____ Admit Date _____ <input type="checkbox"/> ICHD <input type="checkbox"/> HHD <input type="checkbox"/> ICPD <input type="checkbox"/> PD <input type="checkbox"/> I <input type="checkbox"/> O <input type="checkbox"/> R Surveyor _____																
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ESRD Core Survey Worksheet: Patient Roster

(Make Additional Copies As Needed)

Instructions: Check ONLY the criteria/data-driven or other focus area(s) for why the patient was sampled

Survey Information ICHD = In-center HD ICPD = In-center PD HHD = Home HD PD = Home PD I = Interview O = Observation R = Record Review	Reason Sampled	Unstable	New Admit <90 days	Involuntary Discharge	Home Dialysis in LTC	Infection	Hospitalized Readmitted	Anemia Management	Adequacy	Calcium/Phosphorus CKD MBD	Albumin/Nutrition	Fluid Management	CVC >90 days	Observation	Random Sampled for Observation/Interview (circle one)	Complaint
Name _____ ID _____ Admit Date _____ <input type="checkbox"/> ICHD <input type="checkbox"/> HHD <input type="checkbox"/> ICPD <input type="checkbox"/> PD <input type="checkbox"/> I <input type="checkbox"/> O <input type="checkbox"/> R Surveyor _____																
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➔ **TASK: Patient Sample Selection:**

Purpose - To select a core patient sample for clinical care review that represents clinical areas where facility data indicates improvements are needed (i.e., data-driven focus areas) as well as areas pertinent to quality patient care/management and patients' rights that are not represented by available data

Review the patient-specific information submitted by facility from the Entrance Conference Materials List/Clinical Outcomes Tables.

Select at least 10% of the total number of patients on census (minimum 4) representing all dialysis modalities provided at the facility. Attempt to include in-center hemodialysis patients from different days/shifts. Select patients using the criteria below:

Criteria for patient selection:

- **Not meeting outcome goals (“outliers”) in the data-driven focus areas** for the survey. *Refer to the patient-specific information submitted from the Entrance Conference Materials List/Clinical Outcomes Tables, i.e., the lists of patients, hospitalization logs, infection logs. Select patients with trends of not meeting outcome goals in the data-driven focus areas for the survey.*
- **Unstable** - *To look at interdisciplinary team (IDT) activation and functionality for assessing and planning care for the most fragile patients*
- **New admission <90 days** - *To look at facility processes for assuring timely evaluation and appropriate care of patients new to the facility prior to and during their first treatment and first weeks at the facility.*
- **Long Term Care (LTC) residents receiving home hemodialysis (HHD) or peritoneal dialysis (PD) at the LTC facility** - *If the dialysis facility supports long term care (LTC) residents who receive home dialysis at their LTC facility, select at least one patient to sample and follow the process as outlined in the current CMS Survey and Certification guidance for review of the care of the home dialysis LTC resident.*
- **Observed patients:** *You may also sample patients you have observed with possible concerns during the survey.*
- **Complaints:** *Patients involved with a complaint being investigated during the survey may also be included in the patient sample. This should be limited to no more than 25% of the patient sample.*
- **Involuntarily discharged (IVD) in the past 12 months, if applicable** - *To review facility actions taken in attempt to avert the IVD prior to the patient's discharge. **An IVD of a dialysis patient is a grave situation, because the patient has no reliable means for obtaining their dialysis treatments, and may expire as a result. Note:** Do not include patients who voluntarily or involuntarily transferred to other dialysis facilities.*

Minimum patient sample: If there are fewer than 10% of patients on census who fit into any of the criteria listed above, the survey team should select at least 10% of the total number of patients on census (minimum of 4) representing every dialysis modality provided at the facility, for Patient Interviews and Medical Record Reviews.

Record the patient sample - *Record the criteria used for selecting each patient. **Note** that when patients fit more than one criterion above, they may only be counted once in the core patient sample of 4-10 patients.*



ESRD Core Survey Field Manual

Tab 8: Water Treatment & Dialysate Review

- Water Treatment and Dialysate Preparation Review Worksheet
- Task: Water Treatment & Dialysate Review

**ESRD CORE SURVEY WORKSHEET
WATER & DIALYSATE REVIEW: OBSERVATION & INTERVIEW**

Facility: _____ CCN: _____ Surveyor _____

Technician(s): _____ ID #: _____ Date/time: _____

Conduct this review with on-site staff routinely responsible for the activity and daily monitoring of the component(s). You may need to interview more than one technician.

Carbon System and Chlorine Removal	Trigger Identified?	
OBSERVE: Are there 2 carbon tanks or banks of tanks with a sample port between? <i>Note the alternate form of carbon, block carbon, may only be used in the outpatient setting with a single portable reverse osmosis unit supplying a single hemodialysis machine. The block carbon system must include 2 carbon "blocks" with a sample port between.</i>	<input type="checkbox"/> V192	<input type="checkbox"/> No
ASK: What is the empty bed contact time (EBCT) of the carbon system? <i>Note: surveyors are not expected to calculate EBCT. If the technical staff are unable to verbalize, ask for documentation of the EBCT; If block carbon is being used as outlined above, the manufacturer of the block carbon must demonstrate equivalency to the required EBCT of 10 minutes.</i>	<input type="checkbox"/> V195	<input type="checkbox"/> No
ASK: What test is done for chlorine in the water system? When is the test done? What is the maximum allowable result? <i>If the facility is using a continuous on-line chlorine monitor, ask about periodic (usually daily) validation testing with an alternate method.</i>	<input type="checkbox"/> V196 <input type="checkbox"/> V260	<input type="checkbox"/> No
ASK: If the maximum level of 0.1 mg/L total chlorine is exceeded, what actions are taken?	<input type="checkbox"/> V197 <input type="checkbox"/> V260	<input type="checkbox"/> No
Water Testing for Total Chlorine	Trigger Identified?	
OBSERVE: Total Chlorine test: <i>If you are unfamiliar with the testing equipment, review written instructions for the test prior to observation of staff. The sample must come from the sample port after the primary carbon tank.</i> Is the test performed correctly? Are the correct reagents used for the correct sample size? Are they within the expiration dates? Are they sufficiently sensitive to detect 0.1 mg/L total chlorine? If a digital meter is used, is it zeroed prior to testing? If strips are used, is the quantitative method of testing used?	<input type="checkbox"/> V196	<input type="checkbox"/> No
Reverse Osmosis (RO) & Continuous Water Quality Monitor	Trigger Identified?	
OBSERVE: The RO unit and the water quality monitoring system. Is there a continuous water quality monitor and an audible alarm to notify staff in the patient treatment area of poor water quality? <i>(do not require an alarm test)</i>	<input type="checkbox"/> V200	<input type="checkbox"/> No
ASK: How is the water quality monitored? What is the set point for the water quality alarm? What actions are taken if the percent rejection falls below 90% or the water quality exceeds the set point?	<input type="checkbox"/> V199 <input type="checkbox"/> V200	<input type="checkbox"/> No

ESRD CORE SURVEY WORKSHEET
WATER & DIALYSATE REVIEW: OBSERVATION & INTERVIEW

Deionization (DI)	Trigger Identified?	
<p>OBSERVE: Is a DI system present in the water treatment system? <i>(Note: DI should not be used as the primary water purification component in a central water system, except on a temporary basis due to RO failure (V205))</i></p> <p>ASK: Does the facility back-up plan for water system failure include the use of DI? <i>(If DI is part of the back-up plan, verify that the items in the next 2 fields below are included in the back-up plan)</i></p>	N/A	N/A
<p>OBSERVE: Is there a functional, continuous resistivity monitor after the DI system, with an audible and visual alarm in the patient treatment area? Is there an automatic divert-to-drain component or stop valve to prevent water with resistivity <1 megohm from reaching the dialysis stations?</p> <p>Is there an ultrafilter after the DI system?</p>	<input type="checkbox"/> V202 <input type="checkbox"/> V203 <input type="checkbox"/> V204	<input type="checkbox"/> No
<p>ASK: How often is the DI system monitored? What resistivity level would cause the alarm to sound? What actions are taken if a DI tank exhausts and water resistivity drops <1 megohm?</p>	<input type="checkbox"/> V202 <input type="checkbox"/> V203 <input type="checkbox"/> V260	<input type="checkbox"/> No
Disinfection and Water and Dialysate Microbiological Monitoring		
<p>ASK: How often is the water distribution system disinfected?</p>	<input type="checkbox"/> V219	<input type="checkbox"/> No
<p>ASK: When are water cultures and endotoxin/LALs obtained in relation to disinfection and from which sample sites?</p>	<input type="checkbox"/> V213 <input type="checkbox"/> V254	<input type="checkbox"/> No
<p>ASK: How often are dialysate cultures taken from each hemodialysis machine? How many machines are cultured each month?</p>	<input type="checkbox"/> V253	<input type="checkbox"/> No
<p>ASK: How are samples of water and dialysate collected and how are cultures and LALs performed?</p>	<input type="checkbox"/> V252 <input type="checkbox"/> V253 <input type="checkbox"/> V255 <input type="checkbox"/> V258	<input type="checkbox"/> No
<p>ASK: What are the action and maximum allowable microbiological levels for product water and dialysate? What actions are taken when those levels are exceeded?</p>	<input type="checkbox"/> V178 <input type="checkbox"/> V180	<input type="checkbox"/> No

**ESRD CORE SURVEY WORKSHEET
WATER & DIALYSATE REVIEW: OBSERVATION & INTERVIEW**

Dialysate Preparation and Delivery	Trigger Identified?	
OBSERVE: Do the dialysate mixing systems appear maintained?	<input type="checkbox"/> V403	<input type="checkbox"/> No
ASK: Are batches of bicarbonate and/or acid dialysate concentrates mixed on-site? What verification testing is done for batches of acid concentrate?	<input type="checkbox"/> V229	<input type="checkbox"/> No
ASK: How long is mixed bicarbonate concentrate kept?	<input type="checkbox"/> V233	<input type="checkbox"/> No
ASK: Are acid concentrates ever spiked with additional electrolytes? Who is responsible for doing this? Are there any spiked jugs of concentrate available for use now? If so, OBSERVE: are they clearly labeled?	<input type="checkbox"/> V235 <input type="checkbox"/> V236	<input type="checkbox"/> No
Review of Facility Water/dialysate Oversight Logs	Trigger Identified?	
REVIEW: <u>2 months of total chlorine testing logs</u> <ul style="list-style-type: none"> • Are there trends of omitted tests? • Did the level exceed 0.1mg/L total chlorine? Were appropriate actions taken? 	<input type="checkbox"/> V196 <input type="checkbox"/> V197	<input type="checkbox"/> No
REVIEW: <u>2 months of RO function monitoring (NOT all gauge readings in the water system)</u> <ul style="list-style-type: none"> • Was the water quality recorded daily (TDS or conductivity)? • Was the % rejection monitored? 	<input type="checkbox"/> V199 <input type="checkbox"/> V200	<input type="checkbox"/> No
REVIEW: <u>12 months or most recent product water chemical analysis</u> <ul style="list-style-type: none"> • Was a chemical analysis done at least annually? 	<input type="checkbox"/> V201	<input type="checkbox"/> No
REVIEW: <u>6 months of microbiological testing of water and dialysate</u> <ul style="list-style-type: none"> • Were monthly cultures and endotoxin levels tested from identified sites in the water treatment and distribution system, and dialyzer reprocessing room (if applicable)? • Were dialysate cultures and endotoxins tested from at least 2 hemodialysis machines per month, and each machine cultured at least annually? • If culture or endotoxin results exceeded action levels (50 CFU/1 EU) or maximum allowable levels (200 CFU/2EU), were appropriate actions taken? 	<input type="checkbox"/> V213 <input type="checkbox"/> V253 <input type="checkbox"/> V178 <input type="checkbox"/> V180	<input type="checkbox"/> No

**ESRD CORE SURVEY WORKSHEET
WATER & DIALYSATE REVIEW: OBSERVATION & INTERVIEW**

Review of Facility Water/dialysate Oversight Logs (continued)	Trigger Identified?	
REVIEW: <u>If DI present or used in past 12 months, DI monitoring logs for 2 months</u> <ul style="list-style-type: none"> • Were resistivity readings recorded at least 2 times a day? • If resistivity fell below 1 megohm, was dialysis stopped and appropriate actions taken to resolve the problem? 	<input type="checkbox"/> V202 <input type="checkbox"/> V203	<input type="checkbox"/> No
Review of Technical Practice Audits	Trigger Identified?	
REVIEW: <u>12 months of audits of staff</u> conducting water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use (HD machines) <ul style="list-style-type: none"> • Were periodic audits (not less than annually) of staff conducting technical procedures done? 	<input type="checkbox"/> V260	<input type="checkbox"/> No

➔ TASK: Water Treatment and Dialysate Review ▲

Purpose - To verify that systems in use and facility oversight of water and dialysate quality are able to protect patients from harm

Review critical water treatment components with on-site staff routinely responsible for the activity and daily monitoring of the component:

- **Observe total chlorine test and interview** about maximum allowable level of 0.1mg/L total chlorine, chlorine “breakthrough” procedure, and the amount of carbon in the system (empty bed contact time-EBCT). Note the alternate form of carbon, block carbon, may only be used in the outpatient setting with a single portable reverse osmosis unit supplying a single hemodialysis machine. The block carbon system must include 2 carbon “blocks” with a sample port between. The manufacturer of the block carbon must demonstrate equivalency to the required EBCT of 10 minutes. If the facility is using a continuous on-line chlorine monitor, **ask** about periodic (usually daily) validation testing with an alternate method.

Triggers for citation or more investigation of concerns:

- Absence of 2 or more carbon tanks with sample port between (V192)
- Insufficient carbon empty bed contact time (<10 minutes total EBCT) or equivalency documentation for block carbon used with portable RO-verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)
- Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equipment (V196)
- Staff assigned total chlorine testing has inadequate knowledge of maximum allowable level of 0.1mg/L total chlorine and/or breakthrough procedures (V260)

Extending may include an additional observation of another staff member conducting the chlorine test, or additional staff interviews. **Note** that the absence of 2 carbon tanks with a sample port between in an outpatient water treatment system is citable on identification and should be considered an immediate jeopardy situation.

- **Observe reverse osmosis (RO) unit, water quality monitor and alarm and interview** about monitoring RO function by % rejection, and product water quality by total dissolved solids (TDS) or conductivity.

Trigger for citation or more investigation of concerns:

- RO % rejection and product water conductivity or TDS not monitored and recorded daily, water quality alarm non-functional, not audible in patient treatment area (V199, 200)

Extending should include an interview with technical administrative staff. **Note** that the absence of accepted methods for monitoring RO function and warning staff of problems is citable on identification. If the water treatment components appear in observable disrepair, consider reviewing the pre-treatment and water distribution components for compliance with the applicable V-tags (V188-191, V198-215).

- **Observe deionization (DI) and resistivity monitor and alarm**, if present. **Interview** about the DI system, and determine if there is a plan to use DI as back-up. If DI is present or included in a back-up plan, **ask** about the presence of an automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis stations, ultrafilter (UF) post DI, how monitoring is conducted, what the minimum allowable resistivity level is, and what actions are taken when resistivity falls <1 megohm (i.e., STOP dialysis). **Note:** DI should not be used as the primary water purification component in a centralized water treatment system except on a temporary basis due to RO failure (V205).

Triggers for citation (Note if DI is part of a backup plan, all of the items below must be included):

- Absence of functional resistivity monitor or alarm; alarm not audible **and** visible in patient treatment area; resistivity not monitored/recorded at least twice per treatment day (V202, 203)
- Absence of functional automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis machines (V203)
- Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion (i.e., stop dialysis) (V260)
- No ultrafilter in-line post DI (V204)

All of the above DI triggers are citable on identification, due to the serious safety hazard poorly managed and monitored DI systems present to patients.

Interview the person responsible for microbiological sampling and monitoring of water and dialysate regarding system disinfection, sample sites, collection methodology, sample timing (before disinfection) and how often dialysate cultures are done for each HD machine.

Interview the person responsible for bicarbonate and acid dialysate concentrate mixing regarding verification of proper mixing, testing of acid concentrate, bicarbonate concentrate time frame for use (24 hours or per manufacturer's DFU) and "spiking" (inserting additives) into individual dialysate containers.

Triggers for citation or more investigation of concerns:

- Water/dialysate samples not drawn before disinfection (V254)
- Water distribution system not disinfected at least monthly (V219)
- Each HD machine not cultured at least annually (V253)
- Staff unaware of correct dialysate concentrate mixing, acid concentrate batch testing, "spiking", duration of bicarbonate usability, etc. (V233, 235, 236, 260)

Extending may include additional interviews with staff responsible for applicable water & dialysate activities, observations of dialysate mixing and acid concentrate batch testing (V229, V232), and review of dialysate mixing and bicarbonate system disinfection logs (V230,239).

Review facility documentation of oversight of water & dialysate systems in the following areas:

- **Chemical and microbiological monitoring**
 - Total chlorine testing-2 months
 - RO monitoring by % rejection and product water quality by TDS or conductivity, **NOT** all gauge and component readings-2 months
 - If DI present or has been used in past 12 months: 2 months of resistivity readings at least twice per treatment day
 - Product water chemical analysis-12 months
 - Microbiological monitoring of water, including in the reuse room, and dialysate; both colony forming units (CFU) and endotoxin units (EU)-6 months
- **Practice audits of the operators' compliance with technical procedures** - Look at 12 months of facility documentation of observations of staff conducting water testing, dialysate mixing, pH/conductivity testing, etc. (V260)

Triggers for citation or more investigation of concerns:

- Total chlorine results exceeding 0.1mg/L without documentation of appropriate actions taken (V197)
- Chemical analysis of product water not done at least annually (V201)
- Irregularities, trends of omitted tests (V178, 180, 196, 199, 200, 202, 203, 213, 252, 253)

- Microbiological results of water or dialysate exceeding action or maximum levels without documentation of appropriate actions taken (V178, 180)
- Practice audits of staff conducted less than annually (V260)

***Extending** should include technical administrative staff interview and may include review of an equal number of additional logs, e.g., 2 more months of total chlorine logs or RO logs, 12 more months of chemical analysis.*



ESRD Core Survey Field Manual

Tab 9: Dialyzer Reprocessing/Reuse Review

- Dialyzer Reprocessing/Reuse Review Worksheet
- Task: Dialyzer Reprocessing/Reuse Review

**ESRD CORE SURVEY WORKSHEET
REUSE: OBSERVATION/INTERVIEW/REVIEW**

Facility: _____ CCN: _____

Surveyor: _____ ID#: _____

Note: Conduct the Dialyzer Reprocessing/reuse Review with the personnel routinely assigned to reprocess the dialyzers (Reuse Technician)

Reuse Tech: _____ Date/time: _____

Reprocessing Equipment: _____ Germicide: _____

Observations of Reprocessing Area <i>(Also occur during Initial "Flash" Tour)</i>	Triggers Identified?	
OBSERVE: Does the reprocessing area and equipment appear clean, sanitary, and maintained?	<input type="checkbox"/> V318	<input type="checkbox"/> No
OBSERVE: Are there noticeable odors of germicide? If so, ASK: When/how are air levels of germicide tested?	<input type="checkbox"/> V318	<input type="checkbox"/> No
OBSERVE: Is the room temperature appropriate for storage of the germicide in use and the storage of reprocessed dialyzers?	<input type="checkbox"/> V321 <input type="checkbox"/> V345	<input type="checkbox"/> No
OBSERVE: Are used/dirty dialyzers reprocessed within 2 hours or refrigerated? Is the refrigerator temperature monitored?	<input type="checkbox"/> V331	<input type="checkbox"/> No
OBSERVE: Are reprocessed dialyzers protected from unauthorized access, damage, and contamination?	<input type="checkbox"/> V321	<input type="checkbox"/> No
Observation and Interview with Reprocessing Personnel	Triggers Identified?	
PPE: OBSERVE: Are staff using PPE appropriate to the tasks performed and the germicide (durable gloves, face shield/mask/goggles, gown)?	<input type="checkbox"/> V320	<input type="checkbox"/> No
Germicide: ASK: What are the germicide manufacturer's instructions for proper germicide storage? How long must dialyzers be filled with germicide before they can be used for dialysis? How long may a reprocessed dialyzer stay on the shelf (when a patient is absent) before it must be refilled with fresh germicide? What are the procedures for germicide/chemical spills? Are there readily available equipment & supplies in the case of splashes (i.e., eyewash station, spill kit) or spills of chemicals and/or germicide?	<input type="checkbox"/> V319 <input type="checkbox"/> V320 <input type="checkbox"/> V345	<input type="checkbox"/> No
Dialyzer labeling: ASK: When are patients' dialyzers labeled? How to you label dialyzers for patients with same or similar names?	<input type="checkbox"/> V328 <input type="checkbox"/> V330	<input type="checkbox"/> No

**ESRD CORE SURVEY WORKSHEET
REUSE: OBSERVATION/INTERVIEW/REVIEW**

Observation and Interview with Reprocessing Personnel (continued)	Triggers Identified?	
<p>Transportation of dirty dialyzers: OBSERVE: Are used/dirty dialyzers transported in a clean/sanitary manner (all ports capped, not cross-contaminating other dialyzers)? If dialyzers are refrigerated, ASK: How soon after dialysis must a dialyzer be reprocessed or refrigerated? What is the maximum time a dialyzer may be refrigerated prior to reprocessing?</p>	<input type="checkbox"/> V331	<input type="checkbox"/> No
<p>Pre-cleaning procedures: OBSERVE for 1-2 dialyzers: If header caps are removed, are the dialyzer headers, caps and o-rings cleaned and disinfected appropriately? Are water pressures at the pre-rinse sink monitored and maintained within dialyzer parameters? Is cross-contamination avoided by disinfecting equipment connections between dialyzers or the use of barrier adaptors? ASK: What quality of water is used for pre-cleaning the internal compartments of the dialyzers?</p>	<input type="checkbox"/> V334 <input type="checkbox"/> V332 <input type="checkbox"/> V331 <input type="checkbox"/> V333	<input type="checkbox"/> No
Review of Reuse QA Oversight	Triggers Identified?	
<p>REVIEW: 12 months of the following Reuse QA Audit results to verify they are routinely conducted:</p> <p>Quarterly: Dialyzer labeling including verification of similar names warnings and appropriate labeling practices</p> <p>Preparation for dialysis including observations of staff preparing reprocessed dialyzers for use in patients' treatments</p> <p>Semi-annual: Reprocessing procedures including observations of reprocessing personnel performing dialyzer reprocessing procedures</p>	<input type="checkbox"/> V366 <input type="checkbox"/> V368 <input type="checkbox"/> V367	<input type="checkbox"/> No
Reprocessing Equipment Preventive Maintenance (PM) and Repair	Triggers ID'd?	
<p>REVIEW: 12 months of reprocessing equipment PM and repair logs: Are PM procedures and repairs performed by qualified personnel, in accordance with manufacturer's directions and recorded? Are the automated reprocessing systems calibrated per manufacturer DFU (<i>this may be found in daily "start up logs"</i>)? Is equipment tested after repairs and before being placed back in service?</p>	<input type="checkbox"/> V316 <input type="checkbox"/> V317	<input type="checkbox"/> No
Reuse Adverse Occurrences	Triggers Identified?	
<p>REVIEW: 12 months of dialyzer "complaint" logs-recording of problems, events related to reprocessed dialyzers Were appropriate actions taken in response to serious events related to reprocessed dialyzers?</p>	<input type="checkbox"/> V355 <input type="checkbox"/> V356 <input type="checkbox"/> V357 <input type="checkbox"/> V635	<input type="checkbox"/> No

➔ TASK: Dialyzer Reprocessing/Reuse Review ▲

Purpose - To validate that dialyzer reprocessing and the clinical use of reprocessed dialyzers are conducted safely, and facility QA oversight of the reuse program assures ongoing patient protection

Observe the following high risk components of dialyzer reprocessing, and interview the reuse technician:

- **Transportation of used/dirty dialyzers to the reprocessing area** – *how promptly reprocessing occurs; if refrigerated, ask about procedures for refrigeration and maximum refrigeration time.*
- **Pre-cleaning procedures** - *if manual pre-cleaning, header removal/cleaning and/or reverse ultrafiltration are conducted, observe these processes for 1-2 dialyzers and interview about the procedures, the water source for pre-cleaning, and the maximum allowable water pressures at the pre-rinse sink.*

Interview the reuse technician about germicide mixing, storage and spill management; dialyzer labeling/similar names warnings; reprocessing procedures; and dialyzer refrigeration and storage.

Review the documentation of facility oversight of dialyzer reprocessing/reuse program in the following areas:

- **Quality Assurance (QA) audits** - *Review 12 months of facility documentation of the following reuse observational audits. For clarification about the audits, you may need to interview a technical administrative person, instead of the reuse technician:*
 - Observations of reprocessing procedures -each reuse technician observed at least semi-annually
 - Observations of preparation of dialysis machines with reprocessed dialyzers for patients' treatments, i.e., germicide tests, priming, 2 persons identification of patient/dialyzer quarterly
 - Dialyzer labeling, including similar names labeling quarterly
- **Reprocessing equipment preventative maintenance** - *Briefly look at 12 months of documentation, to verify adherence to manufacturer's directions for daily calibration of automated equipment (this may be located on a daily "start-up" log) and routine maintenance procedures.*
- **Reuse adverse events/dialyzer "complaint" log** - *Look at 12 months for actions taken in response to occurrences possibly related to reprocessing.*

Triggers for citation or more investigation of concerns:

- Improperly performed dialyzer pre-cleaning, header removal/cleaning (V334)
- Water used for pre-cleaning dialyzers not purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V319, 321,339)
- Reuse tech unaware of requirements in key patient safety areas per interview guide (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)
- Reprocessed dialyzers stored for extended periods (V345)
- QA audits listed above not done or incomplete - **Extend** to review all of the required QA audits for reuse (V360-368)
- Noticeable strong germicide odors and/or patient or staff complaints regarding germicide odors- review the last 12 months of ambient air vapor testing for the germicide (V318)

- Serious adverse events possibly related to dialyzer reprocessing/reuse, e.g., **dialyzing patient on another patient's dialyzer**, without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)-**Extend** to include reuse as a focus area for QAPI Review.

Extending the facility-based reprocessing/reuse review may include: Observing the complete dialyzer reprocessing procedures, i.e., pre-rinse, automated cleaning, testing, germicide instillation, and labeling for at least 2-3 dialyzers (V327-345); and additional interviews with reuse technicians and/or technical supervisory personnel.

Note: If centralized dialyzer reprocessing is conducted with the dialyzers transported to an off-site location for reprocessing, refer to the current CMS Survey and Certification guidance in the State Operations Manual.



ESRD Core Survey Field Manual

Tab 10: Dialysis Equipment Maintenance

- ESRD Core Survey Interview/Review Worksheet: Machine/Equipment Maintenance Technician
- Task: Dialysis Equipment Maintenance

**ESRD CORE SURVEY INTERVIEW/REVIEW WORKSHEET
MACHINE/EQUIPMENT/MAINTENANCE TECHNICIAN**

Facility: _____ CCN: _____ Surveyor _____

Technician(s): _____ ID #: _____ Date/time: _____

Conduct this review with the on-site personnel routinely assigned to maintain the dialysis equipment.

Interview with machine/equipment maintenance technician				Trigger Identified	
ASK: What types of patient and staff concerns, suggestions/complaints, errors and near misses are staff taught to respond to, report, and record? How comfortable would you feel to report? What is your facility's system for reporting resolution?				<input type="checkbox"/> V627	<input type="checkbox"/> No
ASK: What hemodialysis (HD) machines does the facility maintain? Are there machines from different manufacturers? Does the facility maintain the HD machines for home patients? What is the total number of HD machines maintained by the facility?					
ASK: What are the manufacturer's PM directions for use (DFU) for each type of machine (i.e., at what prescribed intervals—by calendar months or operating hours, or both)? Machine type _____ PM DFU _____ Machine type _____ PM DFU _____ Machine type _____ PM DFU _____					
Review 10% of PM logs for the hemodialysis machines maintained by the facility (minimum 3)					
REVIEW: 12 months of PM logs for 10% (minimum of 3) of the HD machines maintained by the facility. Include machines of home HD patients, and of the different types (manufacturers) of machines used at the facility. Record the dates, operating hours, and type of PM procedures conducted (e.g. quarterly, semi-annual, annual, etc.) in the table below.					
Machine # or ID & Type	Dates of PMs for Past 12 Months	Operating Hours Recorded	PM Procedure (quarterly, semi-annual, annual, etc.)	Trigger Identified	

**ESRD CORE SURVEY INTERVIEW/REVIEW WORKSHEET
MACHINE/EQUIPMENT/MAINTENANCE TECHNICIAN**

Machine # or ID & Type	Dates of PMs for Past 12 Months	Operating Hours Recorded	PM Procedure (quarterly, semi-annual, annual, etc.)	Trigger Identified	
Were the HD machines you reviewed maintained according to the manufacturer's DFU for PM procedures and intervals between PMs?				<input type="checkbox"/> V403	<input type="checkbox"/> No
Review documentation of calibration of maintenance/testing equipment				Trigger Identified	
ASK: What is the manufacturer's DFU <ul style="list-style-type: none"> • For calibrating the dialysate pH and conductivity meters? • For the equipment/meter used to conduct HD machine PM and repair? 					
REVIEW: 2 months of calibration logs for the dialysate pH and conductivity meters used at the dialysis machines prior to patients' treatments. Were the pH/conductivity meters calibrated according to manufacturer's DFU (e.g., daily, correct calibration solutions used, etc.)				<input type="checkbox"/> V403	<input type="checkbox"/> No
REVIEW: The most recent calibration documentation for the equipment/meter used to conduct the HD machine PMs and repairs. Was the equipment/meter used to conduct HD machine PM and repairs calibrated according to the manufacturer's DFU?				<input type="checkbox"/> V403	<input type="checkbox"/> No

Additional notes: _____

➔ **TASK: Dialysis Equipment Maintenance Review:** ▲

Purpose - To verify that facility programs for dialysis-related equipment preventative maintenance (PM) protect patients from harm due to avoidable equipment malfunction

Interview machine/equipment maintenance technician – *Ask: about the hemodialysis machine manufacturer's directions for PM and repair and the prescribed intervals for PM, i.e., per operating hours or calendar.*

Review PM documentation for 10% of hemodialysis machines (minimum 3) *for 12 months: include 10% of the home hemodialysis machines maintained by the facility in the total 10% sample. If there are multiple types of machines, i.e., from different manufacturers, include a sampling of each type. Review for adherence to manufacturer's directions for PM. You may wish to verify what the manufacturer's directions include, which may be obtained in the machine operator's manual.*

Review documentation of calibration of equipment used for dialysis machine maintenance and dialysate pH and conductivity testing: *Briefly look at 2 months of logs for pH and conductivity meters and at the most recent documentation of calibration of the equipment/ meters used to conduct the hemodialysis machine maintenance and repairs.*

Triggers for citation or more investigation of concerns:

- Trends of non-adherence to hemodialysis machine manufacturer's directions for PM (V403)
- No calibration of pH and conductivity meters or equipment calibration meters or not per manufacturer's directions (V403)
- Observations of serious lack of maintenance of ancillary equipment, e.g., scales, chairs, infusion pumps, oxygen concentrators, that has the potential to impact patient safety (V403)

Extending *review of dialysis equipment maintenance may include review of the PM logs for an additional 10% of HD machines; review of 2-3 additional months of calibration meter logs, or review of maintenance documentation of equipment that is in observable disrepair (V403).*



ESRD Core Survey Field Manual

Tab 11: Home Dialysis Training & Support Review

- ESRD Core Survey Interview Worksheet:
PD Training Nurse
- ESRD Core Survey Interview Worksheet:
Home HD Training Nurse
- Task: Home Dialysis Training & Support
Review

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PD TRAINING NURSE**

Facility: _____ **Date/Time:** _____

PD Training Nurse: _____ **Surveyor:** _____

Ask the theme-based **core questions** (required). If you have identified additional issues during the survey, ask the appropriate **extended questions** (optional).

Core Questions	Concern Identified?
[Staff voice/culture of safety] What do you do to prevent or reduce treatment errors or near misses? How comfortable would you feel to report an issue or make a suggestion? How does this facility address an error/near miss involving you or others?	<input type="checkbox"/> V627 <input type="checkbox"/> V634 <input type="checkbox"/> No
[Patient voice/culture of safety] What types of patients' concerns do you respond to, report, and record? How are patients encouraged to voice suggestions and complaints? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V627 <input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636 <input type="checkbox"/> V765 <input type="checkbox"/> No
[Staffing] Are there enough qualified and trained staff in this facility to meet PD patients' medical, nutritional, and psychosocial needs? How and how often do IDT members see and provide services to PD patients? How does this facility ensure that each PD patient has a care coordinator?	<input type="checkbox"/> V685 <input type="checkbox"/> V757 <input type="checkbox"/> V681 <input type="checkbox"/> V592 <input type="checkbox"/> V590 <input type="checkbox"/> No
[Patient education/knowledge] What information do you give/present to patients about their options for treatment modalities and settings? How do you evaluate patients' abilities, interests, preferences, and goals? How do you educate patients who have mental illness, cognitive impairment, cultural or language differences?	<input type="checkbox"/> V458 <input type="checkbox"/> V512 <input type="checkbox"/> V513 <input type="checkbox"/> V453 <input type="checkbox"/> No
[Home dialysis candidacy, training & competency] How do you evaluate patients for PD and their need for a care partner? How do you ensure that the patient (or care partner) is well trained and competent to perform dialysis at home, including training on infection prevention, supply disposal, storing/administering ESAs, 24/7 coverage, symptoms to report, and what to do in an emergency?	<input type="checkbox"/> V586 <input type="checkbox"/> V132 <input type="checkbox"/> V585 <input type="checkbox"/> No
[Monitoring Patients] How do you monitor the PD patients after they are trained? When do you visit the patient's home? How often do you collect their PD flow sheets/treatment records, and who reviews them?	<input type="checkbox"/> V592 <input type="checkbox"/> V589 <input type="checkbox"/> V587 <input type="checkbox"/> No
[Staff & patient partnership/care planning] How do PD patients participate in their plan of care? How do you monitor, recognize, and address PD patients' barriers to meeting goals (targets), including learning barriers?	<input type="checkbox"/> V542 <input type="checkbox"/> V559 <input type="checkbox"/> No
[QAPI] How do you participate in QAPI? How do you track and trend PD program data, e.g., catheter infections, peritonitis, etc.?	<input type="checkbox"/> V756 <input type="checkbox"/> V628 <input type="checkbox"/> V637 <input type="checkbox"/> No
[Emergency preparedness] What is the procedure for patient emergencies in the PD area? What is the procedure for a fire or disaster emergency at the facility?	<input type="checkbox"/> V408 <input type="checkbox"/> V409 <input type="checkbox"/> V411 <input type="checkbox"/> V413 <input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V____ <input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PD TRAINING NURSE**

Extended Questions

PD Training & Support	Concern Identified?	
What is the plan for patients' emergency back up dialysis, if needed?	<input type="checkbox"/> V598	<input type="checkbox"/> No
Does your facility support PD performed in LTC settings? How do you monitor the care of those patients? Does your facility offer staff-assisted PD?	<input type="checkbox"/> V581 <input type="checkbox"/> V681	<input type="checkbox"/> No
What is your system for ordering supplies and tracking patients' supply usage?	<input type="checkbox"/> V597 <input type="checkbox"/> V599	<input type="checkbox"/> No
Interdisciplinary Clinical Care	Concern Identified?	
How often do you measure residual kidney function? How do you know that the PD modality used by the patient is optimal for dialysis adequacy.	<input type="checkbox"/> V544	<input type="checkbox"/> No
How often do you review patients' immunizations and medication history with them (e.g., allergies, home medications, over-the-counter medications, supplements, etc.)?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Infection Control	Concern Identified?	
Did the facility offer you and your PD patients the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
How and where do you train patients who are HBV+?	<input type="checkbox"/> V130 <input type="checkbox"/> V585	<input type="checkbox"/> No
What training have you had in infection prevention and control?	<input type="checkbox"/> V132	<input type="checkbox"/> No
QAPI	Concern Identified?	
How do you and the QAPI team evaluate the PD training and support program as part of the facility's QAPI program?	<input type="checkbox"/> V626	<input type="checkbox"/> No
How do you assess PD patients' satisfaction? What do you do to prevent PD patients' involuntary transfers and involuntary discharges?	<input type="checkbox"/> V636 <input type="checkbox"/> V766 <input type="checkbox"/> V767	<input type="checkbox"/> No
How do you address in QAPI problems that threaten the health and safety of PD patients and that require immediate correction?	<input type="checkbox"/> V640	<input type="checkbox"/> No
Recordkeeping	Concern Identified?	
How do you assure PD patients' medical records are maintained and complete, even when they see their physicians in their offices?	<input type="checkbox"/> V731 <input type="checkbox"/> V592	<input type="checkbox"/> No
What is your system for documenting exchange of PD cyclers and other home equipment?	<input type="checkbox"/> V597	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
HOME HEMODIALYSIS TRAINING NURSE**

Facility: _____ **Date/Time:** _____

Home HD Training Nurse: _____ **Surveyor:** _____

Ask the theme-based **core questions** (required). If you have identified additional issues during the survey, ask the appropriate **extended questions** (optional).

Core Questions	Concern Identified?	
[Staff voice/culture of safety] What do you do to prevent or reduce treatment errors or near misses? How comfortable would you feel to report an issue or make a suggestion? How does this facility address an error/near miss involving you or others?	<input type="checkbox"/> V627 <input type="checkbox"/> V634	<input type="checkbox"/> No
[Patient voice/culture of safety] What types of patients' concerns do you respond to, report, and record? How are patients encouraged to voice suggestions and complaints? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V627 <input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636 <input type="checkbox"/> V765	<input type="checkbox"/> No
[Staffing] Are there enough qualified and trained staff in this facility to meet home HD patients' medical, nutritional, and psychosocial needs? How and how often do IDT members see and provide services to home HD patients? How does this facility ensure that each home HD patient has a care coordinator?	<input type="checkbox"/> V685 <input type="checkbox"/> V757 <input type="checkbox"/> V681 <input type="checkbox"/> V592 <input type="checkbox"/> V590	<input type="checkbox"/> No
[Patient education/knowledge] What information do you give/present to patients about their options for treatment modalities and settings? How do you evaluate patients' abilities, interests, preferences, and goals? How do you educate patients who have mental illness, cognitive impairment, cultural or language differences?	<input type="checkbox"/> V458 <input type="checkbox"/> V512 <input type="checkbox"/> V513 <input type="checkbox"/> V453	<input type="checkbox"/> No
[Home dialysis candidacy, training & competency] How do you evaluate patients for home HD and their need for a care partner? How do you ensure that the patient (or care partner) is well trained and competent to perform dialysis at home, including training on infection prevention, supply disposal, ESA use and storage, 24/7 coverage, symptoms to report, and what to do in an emergency?	<input type="checkbox"/> V586 <input type="checkbox"/> V132 <input type="checkbox"/> V585	<input type="checkbox"/> No
[Monitoring patients] How do you monitor the home HD patients after they are trained? When do you visit the patient's home? How is the home HD patient's home hemodialysis equipment monitored/maintained? How often do you collect their flow sheets/treatment records, and who reviews them?	<input type="checkbox"/> V589 <input type="checkbox"/> V587 <input type="checkbox"/> V593 <input type="checkbox"/> V597	<input type="checkbox"/> No
[Staff & patient partnership/care planning] How do home HD patients participate in their plan of care? How do you monitor, recognize, and address home HD patients' barriers to meeting goals (targets), including learning barriers?	<input type="checkbox"/> V542 <input type="checkbox"/> V559	<input type="checkbox"/> No
[QAPI] How do you participate in QAPI? What and how do you track and trend home HD program data, e.g., vascular access, blood stream infections, etc.?	<input type="checkbox"/> V756 <input type="checkbox"/> V628 <input type="checkbox"/> V637	<input type="checkbox"/> No
[Emergency preparedness] What is the procedure for patient emergencies in the home HD area? What is the procedure for a fire or disaster emergency at the facility?	<input type="checkbox"/> V408 <input type="checkbox"/> V409 <input type="checkbox"/> V411 <input type="checkbox"/> V413	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V_____	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
HOME HEMODIALYSIS TRAINING NURSE**

Extended Questions

Home HD Training & Support	Concern Identified?	
What is the plan for patients' emergency back up dialysis, if needed?	<input type="checkbox"/> V598	<input type="checkbox"/> No
Does your facility support home HD performed in LTC settings and how do you monitor the care of those patients? Does your facility offer staff-assisted home HD?	<input type="checkbox"/> V581 <input type="checkbox"/> V681	<input type="checkbox"/> No
What is your system for ordering supplies and tracking patients' supply usage?	<input type="checkbox"/> V597 <input type="checkbox"/> V599	<input type="checkbox"/> No
Interdisciplinary Clinical Care	Concern Identified?	
How do you know that the home HD prescription used by the patient is optimal for dialysis adequacy?	<input type="checkbox"/> V544	<input type="checkbox"/> No
How often do you review patients' immunizations and medication history with them (e.g., allergies, home medications, over-the-counter medications, supplements, etc.)?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Infection Control	Concern Identified?	
Did the facility offer you and your home HD patients the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
How and where do you train patients who are HBV+?	<input type="checkbox"/> V130 <input type="checkbox"/> V585	<input type="checkbox"/> No
What training did you have in infection prevention and control?	<input type="checkbox"/> V132	<input type="checkbox"/> No
QAPI	Concern Identified?	
How do you and the QAPI team evaluate the home HD training and support program as part of the facility's QAPI program?	<input type="checkbox"/> V626	<input type="checkbox"/> No
How do you assess home HD patients' satisfaction? What do you do to prevent home HD patients' involuntary transfers and involuntary discharges?	<input type="checkbox"/> V636 <input type="checkbox"/> V766 <input type="checkbox"/> V767	<input type="checkbox"/> No
How do you address in QAPI problems that threaten the health and safety of home HD patients and that require immediate correction?	<input type="checkbox"/> V640	<input type="checkbox"/> No
Recordkeeping	Concern Identified?	
How do you assure that home HD patients' medical records are maintained and complete, even when they see their physicians in their offices?	<input type="checkbox"/> V731	<input type="checkbox"/> No
What is your system for documenting preventive maintenance and/or exchange of home HD machines and other home dialysis equipment?	<input type="checkbox"/> V403 <input type="checkbox"/> V597	<input type="checkbox"/> No

➔ **TASK: Home Dialysis Training and Support Review:** ▲

Purpose - To verify that patients/caregivers receive adequate training and subsequent support to facilitate safe and successful home dialysis. If the dialysis facility provides only home dialysis training and support, the survey must include all applicable survey tasks, e.g., Presurvey Preparation, Entrance Conference, Patient Sample Selection, Environmental “Flash” Tour, Water/dialysate Review, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review.

Interview the home training nurse(s) *about the home training and support program in evaluating patient candidacy, training patient/caregiver, demonstration of patient/caregiver comprehension; providing IDT support and QAPI oversight. You may need to interview different home training nurses for home hemodialysis and peritoneal dialysis.*

Observe the direct care of home dialysis patient(s) *if the opportunity arises during the survey when a home dialysis patient is being treated or trained at the facility. Look for adherence to infection control standards.*

Interviews and medical record reviews with/of home dialysis patients are conducted during Patient Interviews and Medical Record Reviews.

Triggers for citation or more investigation of concerns:

- Home training nurse(s) interview or observation of care identifies concerns about knowledge, infection control practices or other aspects of the home training program-*for infection control concerns, refer to the applicable triggers for infection control listed at Observations of Hemodialysis Care and Infection Control Practices task.*
- Patient/caregiver interviews identify concerns about the adequacy of training, competency and support from the IDT, i.e., registered dietitian and master's prepared social worker, physician, home training nurse (V581, 585, 586, 592)
- Medical record reviews of home dialysis patients identify concerns related to training or monitoring of home dialysis patients, including monitoring water/dialysate quality for HHD patients, if applicable (V585, 586, 593-595).
- The facility does not evaluate home program outcomes separately in QAPI (V626, 628).

Extending *review of the home dialysis training and support program may include review of the patient/caregiver training materials (V585), sampling additional home dialysis patients for interview or medical record review, and further evaluation of the surveillance of the home dialysis environment, i.e., home visits (V589).*

Note: *If there are long term care (LTC) residents on census of the ESRD facility who are receiving HHD or PD treatments at their LTC facility, the surveyor is expected to **extend** the review of the care of these residents. Follow the current CMS Survey and Certification guidance for review of the care of the home dialysis LTC resident.*



ESRD Core Survey Field Manual

Tab 12: Patient Interviews

- ESRD Core Survey Interview Worksheet: In-center HD Patient
- ESRD Core Survey Interview Worksheet: PD Patient
- ESRD Core Survey Interview Worksheet: Home HD Patient
- Task: Patient Interviews

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
IN-CENTER HEMODIALYSIS PATIENT**

Patient Name: _____ **ID#:** _____ **Date/Time:** _____

Facility: _____ **Surveyor:** _____

Explain the purpose of the interview. **Core questions** (required) are **theme-based**. If you have identified additional issues during the survey, ask appropriate **extended questions** (optional). Note that some of the core questions may not be applicable to the patient sampled as involuntarily discharged. Establish rapport with the patient.

Core Questions	Concern Identified?	
[Modality knowledge & satisfaction] What were you told about other treatment options and their risks and benefits, including those treatment options that are not offered here? How did you choose in-center hemodialysis (listen for inappropriate steering to in-center HD for the benefit of the provider)? How satisfied are you with in-center hemodialysis? What were you told about your condition and why your kidneys failed?	<input type="checkbox"/> V458 <input type="checkbox"/> V461	<input type="checkbox"/> No
[Education/knowledge] What have you been told about the different vascular access types? [If the patient has a CVC] How was it decided you would have a CVC? What education have the staff given you about infection prevention, personal care, quality of life, rehabilitation, and your rights and responsibilities?	<input type="checkbox"/> V562 <input type="checkbox"/> V555 <input type="checkbox"/> V451	<input type="checkbox"/> No
[Emergency procedures] What were you taught about what to do if you need to disconnect from the machine and evacuate from the facility in an emergency? What have you been told to do if there is an emergency or disaster and you cannot get your dialysis here?	<input type="checkbox"/> V412 <input type="checkbox"/> V409	
[Patient & staff partnership/care planning] How are you encouraged to participate in planning your care? Does the staff ask and consider your needs, wishes, and goals? How does the staff help you address barriers to meeting your goals (targets)? Does the staff discuss dialysis prescription changes with you before making them?	<input type="checkbox"/> V456 <input type="checkbox"/> V541	<input type="checkbox"/> No
[Patients' rights] Do dialysis staff members treat you with respect and dignity? Do they protect your privacy during dialysis?	<input type="checkbox"/> V452 <input type="checkbox"/> V454	<input type="checkbox"/> No
[Patient voice/culture of safety] How are you encouraged to speak up and make suggestions or comments about the facility and your care here? If you had a concern, how would you file a grievance here or elsewhere? How safe from retaliation would you feel voicing a concern, making a suggestion, or filing a grievance? If you were afraid of retaliation, could you file a grievance anonymously?	<input type="checkbox"/> V627 <input type="checkbox"/> V467 <input type="checkbox"/> V636 <input type="checkbox"/> V465 <input type="checkbox"/> V466	<input type="checkbox"/> No
[Physical environment/infection control] How clean, comfortable, and safe do you think this facility is? Do staff members change their gloves and wash their hands before caring for you?	<input type="checkbox"/> V111 <input type="checkbox"/> V113 <input type="checkbox"/> V401 <input type="checkbox"/> V405	<input type="checkbox"/> No
[Treatment issues] Have you ever had any problems or symptoms during dialysis? If so, how and how quickly did the staff address them?	<input type="checkbox"/> V543 <input type="checkbox"/> V713	<input type="checkbox"/> No
[Staffing] Are there enough staff, i.e., nurses, technicians, dietitians, and social workers at this facility to meet your needs? Does the staff respond to your machine alarms quickly?	<input type="checkbox"/> V757 <input type="checkbox"/> V758	<input type="checkbox"/> No
[Physical/mental functioning] Have you been offered a survey that asks how your health and symptoms affect your energy, activity level, and lifestyle? How was the survey and its use explained to you? If problems were identified on the survey, how did the staff address them?	<input type="checkbox"/> V552	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V__	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
IN-CENTER HEMODIALYSIS PATIENT**

Extended Questions

Patients' Rights and Responsibilities	Concern Identified?	
How do staff members make sure you can understand information they give you? How comfortable do you feel asking questions? How well do you feel staff answer your questions?	<input type="checkbox"/> V453	<input type="checkbox"/> No
Has anyone talked with you about your right to have an advance directive (living will, durable power of attorney for healthcare decisions, do not resuscitate order)?	<input type="checkbox"/> V457	<input type="checkbox"/> No
Treatment Issues	Concern Identified?	
Who reviews your lab values with you? How is your dialysis adequacy? Does dialysis usually get you to your weight and blood pressure goal? If not, do you know why not? What has the staff done to help you reach these goals?	<input type="checkbox"/> V544 <input type="checkbox"/> V543 <input type="checkbox"/> V504	<input type="checkbox"/> No
What have you been told about the risks of covering your access during dialysis?	<input type="checkbox"/> V562 <input type="checkbox"/> V407	<input type="checkbox"/> No
(If reuse) What were you told about dialyzer reuse? How do you know that you get your dialyzer each treatment?	<input type="checkbox"/> V312 <input type="checkbox"/> V348	<input type="checkbox"/> No
Infection Control	Concern Identified?	
What have you been taught about washing your hands, cleaning the skin over your fistula or graft (if applicable) before treatment, and washing your hands after treatment before you leave this dialysis facility?	<input type="checkbox"/> V562	<input type="checkbox"/> No
Emergency Preparedness	Concern Identified?	
What would you do if you were at home and had chest pain, your access would not stop bleeding, or you had signs and symptoms of a clotted access or access infection?	<input type="checkbox"/> V412 <input type="checkbox"/> V768	<input type="checkbox"/> No
Interdisciplinary Clinical Care	Concern Identified?	
What has the dietitian told you about food options, meal preparation, nutritional supplements, medications, the emergency diet, and adjusting your diet to meet nutritional goals? What other things has the dietitian helped you with?	<input type="checkbox"/> V545	<input type="checkbox"/> No
What has the social worker told you about living with kidney disease? How has the social worker helped you and your family cope with kidney disease and treatment? What else has the social worker helped you with?	<input type="checkbox"/> V552 <input type="checkbox"/> V555	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PD PATIENT**

Patient Name: _____ **ID#:** _____ **Date/Time:** _____

Facility: _____ **Surveyor:** _____

Interview sampled PD patients (or care partners) who are alert, oriented, and mentally competent to interview in person or by phone. If you are unable to interview a sampled PD patient (or care partner), select another PD patient for interview to assure the PD patient’s point of view is represented. Explain the purpose of the interview. **Core questions** (required) are **theme-based**. If you have identified additional issues during the survey, ask appropriate **extended questions** (optional). Note that some of the core questions may not be applicable to the patient sampled as involuntarily discharged.

Core Questions	Concern Identified?	
[Modality knowledge & satisfaction] What were you told about other treatment options and their risks and benefits, including those treatment options that are not offered here? How did you choose PD (listen for inappropriate steering to PD for benefit of provider)? How satisfied are you with PD? What have you been told about your condition and why your kidneys failed?	<input type="checkbox"/> V458 <input type="checkbox"/> V461	<input type="checkbox"/> No
[Education/knowledge] What have you been told about infection prevention, disposal of used supplies, quality of life, rehabilitation, your rights and responsibilities, who to contact for problems 24/7, and what to do in an emergency or if something prevents you from doing PD?	<input type="checkbox"/> V585 <input type="checkbox"/> V555 <input type="checkbox"/> V562 <input type="checkbox"/> V451	<input type="checkbox"/> No
[Patient & staff partnership/care planning] How are you encouraged to participate in planning your care? Does the staff ask about and consider your needs, wishes, and goals? How does the staff help you to address barriers to meeting your goals (targets)? Does the staff discuss dialysis prescription changes with you before making them?	<input type="checkbox"/> V456 <input type="checkbox"/> V541	<input type="checkbox"/> No
[Patients’ rights] Do dialysis staff members treat you with respect and dignity and protect your privacy during training and facility visits?	<input type="checkbox"/> V452 <input type="checkbox"/> V454	<input type="checkbox"/> No
[Patient voice/culture of safety] How are you encouraged to speak up and make suggestions or comments about the facility and your care here? If you had a concern, how would you file a grievance here or elsewhere? How safe from retaliation would you feel voicing a concern, making a suggestion, or filing a grievance? If you were afraid of retaliation, could you file a grievance anonymously?	<input type="checkbox"/> V627 <input type="checkbox"/> V467 <input type="checkbox"/> V636 <input type="checkbox"/> V465 <input type="checkbox"/> V466	<input type="checkbox"/> No
[Home training] How did your home training nurse know you (and your care partner if applicable) were ready to do PD at home? Who is your contact (care coordinator) at the facility? How satisfied were you with the training you received before going home to do your treatments??	<input type="checkbox"/> V586 <input type="checkbox"/> V590 <input type="checkbox"/> V587	<input type="checkbox"/> No
[Staffing] Is there enough staff to meet your needs? How often do you see the home training nurse, dietitian, social worker, and physician? Is that often enough for you to feel supported in your home treatments? How often do you have contact with them between appointments?	<input type="checkbox"/> V592 <input type="checkbox"/> V757 <input type="checkbox"/> V560	<input type="checkbox"/> No
[Physical/mental functioning] Have you been offered a survey that asks how your health and symptoms affect your energy, activity level, and lifestyle? How was the survey and its use explained to you? If problems were identified on the survey, how did the staff address them?	<input type="checkbox"/> V552	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PD PATIENT**

Extended Questions

Patients' Rights and Responsibilities	Concern Identified?	
How do staff make sure you can understand information they give you? How comfortable do you feel asking questions? How well do you feel staff answer your questions?	<input type="checkbox"/> V453	<input type="checkbox"/> No
Has anyone talked with you about your right to have an advance directive (living will, durable power of attorney for healthcare decisions, do not resuscitate order)?	<input type="checkbox"/> V457	<input type="checkbox"/> No
Training and Support for Home Care	Concern Identified?	
How often do you send/take flow sheets to the facility? Who reviews them with you?	<input type="checkbox"/> V587	<input type="checkbox"/> No
Have you ever had to contact the home dialysis staff after hours? What happened?	<input type="checkbox"/> V585 <input type="checkbox"/> V768	<input type="checkbox"/> No
Management of PD Prescription	Concern Identified?	
Who reviews your lab values with you? How is your dialysis adequacy? How do you decide the fluid removal goal during dialysis and what PD solution to use? Does PD usually get you to your goal weight and blood pressure? How do you monitor and control your blood pressure?	<input type="checkbox"/> V544 <input type="checkbox"/> V543 <input type="checkbox"/> V504	<input type="checkbox"/> No
How often does the staff review your medications with you? What medications, if any, do you get at the facility or take at home to treat anemia (ESAs and iron) or bone disease (phosphate binder, vitamin D analog, calcimimetic agent)? What were you and/or your partner taught about giving medications, storing them, and side effects to watch for?	<input type="checkbox"/> V506 <input type="checkbox"/> V547 <input type="checkbox"/> V546 <input type="checkbox"/> V548	<input type="checkbox"/> No
Infection Control	Concern Identified?	
What have you been taught about signs of a catheter exit site infection or peritonitis and what would you do if you had any of these symptoms?	<input type="checkbox"/> V585	<input type="checkbox"/> No
Interdisciplinary Clinical Care	Concern Identified?	
What has the dietitian told you about food options, meal preparation, nutritional supplements, medications, the emergency diet, and adjusting your diet to meet nutritional goals? What other things has the dietitian helped you with?	<input type="checkbox"/> V545	<input type="checkbox"/> No
What has the social worker told you about living with kidney disease? How has the social worker helped you and your family cope with kidney disease and treatment? What else has the social worker helped you with?	<input type="checkbox"/> V552 <input type="checkbox"/> V555	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
HOME HEMODIALYSIS PATIENT**

Patient Name: _____ **ID#:** _____ **Date/Time:** _____

Facility: _____ **Surveyor:** _____

Interview sampled home HD patients (or care partners) who are alert, oriented, and mentally competent to interview in person or by phone. If you are unable to interview a sampled home HD patient (or care partner), select another home HD patient for interview to assure the home HD patient's point of view is represented. Explain the purpose of the interview. **Core questions** (required) are **theme-based**. If you have identified additional issues during the survey, ask appropriate **extended questions** (optional). Note that some of the core questions may not be applicable to patients sampled as involuntarily discharged.

Core Questions	Concern Identified?	
[Modality knowledge & satisfaction] What were you told about other treatment options and their risks and benefits, including those treatment options that are not offered here? How did you choose home HD (listen for inappropriate steering to home HD for the benefit of the provider)? How satisfied are you with home hemodialysis? What have you been told about your condition and why your kidneys failed?	<input type="checkbox"/> V458 <input type="checkbox"/> V461	<input type="checkbox"/> No
[Education/knowledge] What have you been told about risks and benefits of vascular access types, infection prevention, disposal of used supplies, quality of life, rehabilitation, your rights and responsibilities, who to contact for problems 24/7, and what to do in an emergency or if something prevents you from doing home HD?	<input type="checkbox"/> V562 <input type="checkbox"/> V555 <input type="checkbox"/> V451 <input type="checkbox"/> V585	<input type="checkbox"/> No
[Patient & staff partnership/care planning] How are you encouraged to participate in planning your care? Does staff ask about and consider your needs, wishes, and goals? How does the staff help you address barriers to meeting your goals (targets)? Does the staff discuss dialysis prescription changes with you before making them?	<input type="checkbox"/> V456 <input type="checkbox"/> V541	<input type="checkbox"/> No
[Patients' rights] Do dialysis staff members treat you with respect and dignity and protect your privacy during training and visits to the facility?	<input type="checkbox"/> V452 <input type="checkbox"/> V454	<input type="checkbox"/> No
[Patient voice/culture of safety] How are you encouraged to speak up and make suggestions or comments about the facility and your care here? If you had a concern, how would you file a grievance here or elsewhere? How safe from retaliation would you feel voicing a concern, making a suggestion, or filing a grievance? If you were afraid of retaliation, could you file a grievance anonymously?	<input type="checkbox"/> V627 <input type="checkbox"/> V467 <input type="checkbox"/> V636 <input type="checkbox"/> V465 <input type="checkbox"/> V466	<input type="checkbox"/> No
[Home training] How did your training nurse know you (and your care partner, if applicable) were ready to do HD at home? Who is your contact (care coordinator) at the facility? How satisfied were you with the training you received before going home to do your treatments?	<input type="checkbox"/> V586 <input type="checkbox"/> V590	<input type="checkbox"/> No
[Staffing] Is there enough staff to meet your needs? How often you see the home training nurse, dietitian, social worker, and physician? Is that enough for you to feel supported in your home treatments? How often do you have contact with them between appointments?	<input type="checkbox"/> V592 <input type="checkbox"/> V757 <input type="checkbox"/> V560	<input type="checkbox"/> No
[Physical/mental functioning] Have you been offered a survey that asks how your health and symptoms affect your energy, activity level, and lifestyle? How was the survey and its use explained to you? If problems were identified, how did the staff address them?	<input type="checkbox"/> V552	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V__	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
HOME HEMODIALYSIS PATIENT**

Extended Questions

Patients' Rights and Responsibilities	Concern Identified?	
How do staff make sure you can understand information they give you? How comfortable do you feel asking questions? How well do you feel staff answer your questions?	<input type="checkbox"/> V453	<input type="checkbox"/> No
Has anyone talked with you about your right to have an advance directive (living will, durable power of attorney for healthcare decisions, do not resuscitate order)?	<input type="checkbox"/> V457	<input type="checkbox"/> No
Training & Support for Home Care	Concern Identified?	
How often do you send/take dialysis treatment records to the facility? Who reviews them with you?	<input type="checkbox"/> V587	<input type="checkbox"/> No
Did anyone come to your home to test your water quality before you started home HD (unless using bagged dialysate)? How and how often do you or facility staff test the water/dialysate? Where would you get backup dialysis if there was a problem with your water or machine?	<input type="checkbox"/> V593 <input type="checkbox"/> V594 <input type="checkbox"/> V595 <input type="checkbox"/> V596	<input type="checkbox"/> No
Have you ever had to contact the home dialysis staff after hours? What happened?	<input type="checkbox"/> V585 <input type="checkbox"/> V768	<input type="checkbox"/> No
Management of Home Hemodialysis Prescription	Concern Identified?	
Who reviews your lab values with you? How is your dialysis adequacy? How do you decide how much fluid to remove during dialysis? Does home HD usually get you to your goal weight and blood pressure? What symptoms do you have during or after dialysis? How do you monitor and control your blood pressure?	<input type="checkbox"/> V544 <input type="checkbox"/> V543 <input type="checkbox"/> V504	<input type="checkbox"/> No
How often does the staff review your medications with you? What medications, if any, do you get at the facility or take at home to treat anemia (ESAs and iron) or bone disease (phosphate binder, vitamin D analog, calcimimetic agent)? What were you and/or your partner taught about giving medications, storing them, and side effects to watch for?	<input type="checkbox"/> V506 <input type="checkbox"/> V547 <input type="checkbox"/> V546 <input type="checkbox"/> V548	<input type="checkbox"/> No
Infection Control	Concern Identified?	
What have you been taught about the signs of an access infection and what would you do if you had any of these symptoms?	<input type="checkbox"/> V585	<input type="checkbox"/> No
Interdisciplinary Clinical Care	Concern Identified?	
What has the dietitian told you about food options, meal preparation, nutritional supplements, medications, the emergency diet, and adjusting your diet to meet nutritional goals? What other things has the dietitian helped you with?	<input type="checkbox"/> V545	<input type="checkbox"/> No
What has the social worker told you about living with kidney disease? How has the social worker helped you and your family cope with kidney disease and treatment? What other things has the social worker helped you with?	<input type="checkbox"/> V552 <input type="checkbox"/> V555	<input type="checkbox"/> No

➔ **TASK: Patient Interviews:** ▲

Purpose - To listen to the patients' voices as recipients of the care provided at the facility, to determine if patients receive unbiased and adequate information on modality choice, to evaluate patients' understanding of their rights and responsibilities, to determine how comfortable patients feel to voice concerns or make suggestions, and to assess their satisfaction with their care at the facility

Interview the sampled patients selected during “Patient Sample Selection:” *To ensure the survey process includes sufficient attention to the point of view and care experience of the patients, attempt to interview as many of the “interviewable” sampled patients as possible, i.e., they are alert, oriented, and not mentally impaired to the point that the interview would yield unreliable results.*

*After attempting to interview the sampled patients, if the survey team is not able to interview at least 4 of the sampled patients, **interview additional alert and oriented patients to obtain a minimum of 4 patient interviews representing all dialysis modalities provided at the facility.** Enter these additional patients on the Patient Roster and designate that they were interviewed. Unless their interview indicates a reason to do so, you are not required to review their medical records.*

Patients may be interviewed in person or by phone. The surveyor should offer each patient the choice to conduct the interview by phone. Expect that some patients may not feel fully comfortable being interviewed in the patient treatment or waiting areas, where staff may overhear what is said. For home dialysis patients not in the facility, ask the home training nurse to contact the patient to alert him/her that the surveyor will be calling them for an interview.

*Individualize patient interviews to focus on each patient's issues and the criteria for sampling them, however **ask** at least the “core” questions listed on the applicable ESRD Core Survey Interview Worksheet. For patients sampled due to being involuntarily discharged, some of the Interview Guide “core” questions may not be applicable.*

Triggers for citation or more investigation of concerns:

Patients express concerns regarding:

- Patients' rights and responsibilities (V451)
- Education about transplant and all options of dialysis modalities and settings, including those not offered at the facility (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- How to prevent infections and protect their dialysis access (V562)
- The safety and comfort of the physical environment of the facility (V401, 402)
- Disaster preparedness at home and how to evacuate the facility in an emergency (V409, 412)
- Communication with the IDT and involvement in planning their care (V501, 541)
- Staff proficiency in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff, e.g., nursing, dietitian, social worker, patient care technicians (V757-759)
- Culture of Safety: freedom to report care concerns, ask questions, make suggestions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training and IDT support of home dialysis patients and caregivers to facilitate successful home dialysis (V585, 592)

Extending patient interviews may include asking questions of additional applicable patients focused on the specific area(s) of concerns.



ESRD Core Survey Field Manual

Tab 13: Medical Record Review

- Medical Record Review: In-center Hemodialysis
- Medical Record Review: Peritoneal Dialysis
- Medical Record Review: Home Hemodialysis
- Task: Medical Record Review

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
IN-CENTER HEMODIALYSIS (ICHD)**

Patient Name: _____ ID #: _____
 Facility: _____ Surveyor: _____
 Admit Date: _____ Review Date: _____
 DOB: _____ Age: _____ HD Access: Fistula Graft Catheter Catheter >90 days
 Diagnosis: _____

Criteria for Sampling: _____ Sections in this worksheet completed: _____

YOU ARE NOT REQUIRED TO COMPLETE ALL OF THE SECTIONS FOR EACH PATIENT.
 HOWEVER SECTION 1 MUST BE COMPLETED FOR ALL ICHD PATIENTS SAMPLED.

All medical record reviews in the ESRD Core Survey are focused reviews, looking at the care provided to and monitoring of each sampled patient related to the criteria used to select them. For all active sampled patients, review the patient's dialysis/medication orders, and the documentation of their dialysis treatments in Section 1. The remainder of each medical record review should be focused on the components of the record related to that patient's sampling criteria in the applicable sections of this worksheet. Refer to "Patient Sample Selection" of the ESRD Core Survey Process for sampling criteria.

Note: For closed record review of patients sampled due to being **involuntarily discharged**, follow the ESRD Core Survey Process and current CMS Survey and Certification guidance.

Section 1: Complete for ALL SAMPLED ICHD patients (except closed record review for involuntary discharge). The review of the patient's treatment orders and dialysis treatment records shows the facility practices in implementation of the patient's physician orders/dialysis prescription/plan of care, the safety of the hemodialysis treatment, fluid/BP management and patient monitoring before, during and after dialysis.

Record the current dialysis treatment and medication orders:

Treatment Orders: Date: _____ EDW: _____ Frequency: _____ days/week
 Dialyzer: _____ Dialysate: _____ BFR: _____ DFR: _____
 Treatment duration: _____ hours _____ minutes Heparin/anticoagulant: _____
 ESA dose: _____ Frequency: _____ Iron: _____ Vitamin D: _____
 Other meds/treatments: _____

Review 2-3 consecutive weeks of HD treatment records. RECORD EXCEPTIONS and VARIANCES ONLY. Check if no exceptions.

(Number) _____ treatment records reviewed between _____ and _____

EXCEPTIONS	DATES/COMMENTS
Safety checks not documented:	
<input type="checkbox"/> Independent pH/conductivity(V250)	
<input type="checkbox"/> Machine alarm check (V403)	
Reuse dialyzer checks not documented:	
<input type="checkbox"/> Germicide presence (V350)	
<input type="checkbox"/> Germicide absence of residual (V353)	
<input type="checkbox"/> Patient/dialyzer ID by 2 (V348)	

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
IN-CENTER HEMODIALYSIS (ICHD)**

Patient Name: _____ ID #: _____
 Facility: _____ Surveyor: _____

EXCEPTIONS	DATES/COMMENTS
Adequacy plan not implemented (V544):	
<input type="checkbox"/> BFR, DFR, time, dialyzer type	
Meds/treatments not administered as ordered:	
<input type="checkbox"/> Anemia management (V547)	
<input type="checkbox"/> Mineral metabolism (V546)	
<input type="checkbox"/> Incorrect dialysate(V541)	
<input type="checkbox"/> Antihypertensives (V543)	
<input type="checkbox"/> Other	
BP/fluid management (V543):	
<input type="checkbox"/> Hypertension	
<input type="checkbox"/> Hypotension	
<input type="checkbox"/> Dry/target weight not achieved	
<input type="checkbox"/> >5% target weight removed in < 4hr tx; or UFR >15mL.kg/hr (review for trends)	
Patient monitoring:	
<input type="checkbox"/> No assessment pre and/or post dialysis (V543)	
<input type="checkbox"/> Not monitored per policy (V543)	
<input type="checkbox"/> Access function and/or care not documented (V550):	
<input type="checkbox"/> Unusual or adverse events (V634)	

- Did you identify trends in omitted machine and dialyzer safety checks, failure to monitor the patient and machine per facility policy, or failure to implement the patient's ordered dialysis prescription or medications? No Yes-Explain _____

If yes to the above question, citation at the applicable V-tag for the care element as listed in the table above may be indicated.

- Did you identify trends of problems with the patient's blood pressure, fluid, and weight management? No Yes Explain _____

If yes: Is there evidence that facility staff recognized the trend as a problem, acted with interventions aimed at resolution/improvement, and changed strategies when interventions were unsuccessful?

- **If yes-no citation is indicated**
- **If no-citation at V543 may be indicated**

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
IN-CENTER HEMODIALYSIS (ICHD)**

Patient Name: _____ ID #: _____
Facility: _____ Surveyor: _____

Section 2: Complete for ICHD patients sampled due to NOT MEETING GOALS (“OUTLIERS”) IN THE DATA-DRIVEN FOCUS AREAS for this survey - if the patient was sampled due to trends poor outcomes in data-driven focus areas, record in this section.

Note: This is a focused review intended to look at facility systems for addressing poor patient outcomes in the data-driven focus areas. You are not expected to search each patient's record for all of their outcomes. If, during your review of the data-driven focus areas used for selecting that patient, you discover poor outcomes for the patient in another area, use your judgment on whether reviewing the additional area would be of value, and follow this guidance for that area, as well.

Review the medical record documentation related to the outcome/area, e.g., progress notes, physician's orders, patient assessment, plan of care to assess the facility's activities for monitoring the patient's outcome, recognizing that there is a problem, and taking action to address it. **For poor outcomes in laboratory values** (i.e., anemia, adequacy, mineral metabolism, albumin): also review the current 3 months of lab results in that area. Reference target values are listed on the Measures Assessment Tool (MAT).

Notes: _____

For each area reviewed in Section 2 for the patient (use back for additional review areas & notes):

- Is there evidence that the patient's outcome in the data-driven focus area(s) used for sampling them has improved and their goal(s) currently met?
 - Yes - no further review is needed**, no citation in that area is indicated
 - No** - is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement/resolution; and changed strategies if no improvement?
 - **Yes** - no citation is indicated.
 - **No** - citation in that outcome area at the applicable Patient assessment or Plan of care V-tag is indicated.

Notes: _____

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
IN-CENTER HEMODIALYSIS (ICHD)**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Section 3: Complete for ICHD patients listed as “UNSTABLE:” Review the IDT documentation in progress notes, physician's orders, assessments, physical and mental functioning surveys (age-appropriate HRQOL survey), plans of care, etc. pertaining to the **two** most recent patient assessment and plan of care periods. The IDT process and content of the patient assessments and plans of care are more important than the format or timelines.

Why was this patient identified by the IDT as “unstable?” _____

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members (physician, RN, registered dietitian, master's prepared social worker at a minimum)?
 Yes No (V501, 541)

- Was an assessment of the patient conducted and the clinical and psychosocial issues contributing to the patient's instability addressed through revised care interventions? Yes No - *citation at the applicable Patient assessment or Plan of care V-tag may be indicated.*

Notes: _____

Section 4: Complete for ICHD patients NEWLY ADMITTED (<90 DAYS): Looking at the process for assuring the patient new to the dialysis facility was appropriately evaluated on admission prior to the first dialysis and during their first weeks receiving care at the facility. *Review the admission orders, lab results and progress notes.*

- Is there evidence that the patient had orders from a physician or non-physician practitioner, if allowed by state law, and was evaluated by an RN prior to their first dialysis treatment at the facility? Yes No (V715)

- Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated? Yes No (V125, 126, 506)

- Is there evidence facility staff evaluated and addressed issues related to the patient's labs, fluid management, dialysis-related and other clinical and psychosocial problems? Yes No - *citation at the applicable patient assessment or plan of care V-tag may be indicated.*

Notes: _____

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS**

Patient Name: _____ ID #: _____
 Facility: _____ Surveyor: _____
 Admit Date: _____ Review Date: _____
 DOB: _____ Age: _____ Peritoneal catheter Fistula Graft CVC
 Diagnosis: _____
 Criteria for Sampling: _____ Sections of this worksheet completed _____

YOU ARE NOT REQUIRED TO COMPLETE ALL OF THE SECTIONS FOR EACH PATIENT, HOWEVER SECTION 1 MUST BE COMPLETED FOR ALL PD PATIENTS SAMPLED.

All medical record reviews in the Core Survey are focused reviews, looking at the care provided to and monitoring of each sampled patient related to the criteria used to select them. For all active sampled patients, review the patient's dialysis/medication orders, and the documentation of their peritoneal dialysis treatments in Section 1. The remainder of each medical record review should be focused on the components of the record related to that patient's sampling criteria in the applicable sections of this worksheet. Refer to "Patient Sample Selection" of the ESRD Core Survey Process for sampling criteria.

Note: For **LTC residents receiving home dialysis in their LTC facility**, and closed record review of patients sampled due to being **involuntarily discharged**, follow the ESRD Core Survey Process and current CMS Survey and Certification guidance.

Section 1: Complete for ALL SAMPLED PD patients (except closed record review for involuntary discharge). The review of the PD patient's treatment orders and dialysis treatment records/flowsheets should be focused on whether the patient/caregiver followed dialysis orders, and if and how staff members monitor the PD patient's treatments and address issues and trends. Look for documentation of staff actions in progress notes, plan of care revisions, etc. to address trends. Note that timeliness of staff review of PD treatment records/flowsheets depends on when the patient provides them, but must be at least every 2 months.

Record the current treatment and medication orders:

Treatment Orders: Date: _____ EDW: _____ APD CAPD
 APD cycles/day: _____ Dialysate: _____ Volume: _____ Dwell: _____
 CAPD exchanges/day: _____ Dialysate: _____ Volume: _____ Dwell: _____
 ESA dose: _____ ESA frequency: _____ Other meds/treatments: _____

Review 8-12 consecutive weeks of PD "flowsheets." RECORD EXCEPTIONS/VARIANCES ONLY. Check if no exceptions.

(Number of weeks) _____ Flowsheets reviewed between _____ and _____

EXCEPTIONS	DATES/COMMENTS
Treatment delivered different from ordered:	
<input type="checkbox"/> # of CAPD exchanges, volume (V544)	
<input type="checkbox"/> # of APD cycles, volume (V544)	
<input type="checkbox"/> Dialysate (V544)	

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

EXCEPTIONS	DATES/COMMENTS
Treatment delivered different from ordered:	
<input type="checkbox"/> Anemia management (V547)	
<input type="checkbox"/> Other parenteral medications	
BP/fluid management (V543):	
<input type="checkbox"/> Hypertension	
<input type="checkbox"/> Hypotension	
<input type="checkbox"/> Estimated dry weight not achieved	
<input type="checkbox"/> Patient not recording weight/BP	
Staff monitoring:	
<input type="checkbox"/> Flowsheets not reviewed (V587)	
<input type="checkbox"/> No flowsheets in chart (V587)	
<input type="checkbox"/> Unusual or adverse events (V634)	
Other concerns identified:	

- Is there evidence that the facility home training/support staff monitored the patient's home dialysis through routine review of their PD flowsheets? **Yes** **No**-(V587) Explain _____
- Did you identify trends in the patient or caregiver not following their dialysis prescription or parenteral medication orders? **Yes** **No**-Explain _____
- Did you identify trends in problems with the patient's blood pressure, fluid or weight management? **Yes** **No**-Explain _____

If yes to either of the above 2 questions: Is there evidence that the home training/support staff recognized that there was a problem, acted with interventions aimed at resolution/improvement, and changed strategies when interventions were unsuccessful?

- **If yes-no citation is indicated**
- **If no-citation at the applicable V-tag listed in the table above may be indicated**

Notes: _____

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Section 2: Complete for PD patients sampled due to NOT MEETING GOALS (“OUTLIERS”) IN THE DATA-DRIVEN FOCUS AREAS for this survey - If the patient was sampled due to trends of poor outcomes in data-driven focus areas, record in this section.

*Note: This is a focused review intended to look at facility systems for addressing poor patient outcomes in the data-driven focus areas. You are not expected to **search** each patient's record for all of their outcomes. If, during your review of the data-driven focus areas used for selecting that patient, you **discover** poor outcomes for the patient in another area, use your judgment on whether review of the additional area would be of value, and follow this guidance for that area, as well.*

Review the medical record documentation related to the outcome/area, e.g., progress notes, physician's orders, patient assessment, plan of care to assess the facility's activities for monitoring the patient's outcome, recognizing that there is a problem, and taking action to address it. **For poor outcomes in laboratory values** (i.e., anemia, adequacy, mineral metabolism, albumin): also review the current 3 months of lab results in that area. Reference target values are listed on the Measures Assessment Tool (MAT).

Notes: _____

For each area reviewed in Section 2 for the patient (use back for additional review areas & notes):

- Is there evidence that the patient's outcome in the data driven focus area(s) used for sampling them has improved and their goal(s) currently met?
 - Yes - no further review is needed, no citation in that area is indicated**
 - No** - is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement/resolution; and changed strategies if no improvement?
 - **Yes** - no citation is indicated.
 - **No** - citation in that outcome area at the applicable Patient assessment or Plan of care V-tag is indicated.

Notes: _____

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Section 3: Complete for PD patients listed as “UNSTABLE:” Review the IDT documentation in progress notes, physician's orders, assessments, physical and mental functioning surveys (age appropriate HRQOL survey), plans of care, etc. pertaining to the **two** most recent patient assessment and plan of care periods. The IDT process and content of the patient assessment and plan of care are more important than the format or timelines.

Why was this patient identified by the IDT as “unstable?” _____

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members (physician, RN, registered dietitian, master's prepared social worker at a minimum)?
 Yes No (V501, 541)
- Was an assessment of the patient conducted and the clinical and psychosocial issues related to the patient’s instability addressed through revised care interventions?
 Yes No - citation at the applicable Patient assessment or Plan of care V-tag may be indicated.

Notes: _____

Section 4: Complete for PD patients NEWLY ADMITTED (<90 DAYS): Looking at the process for assuring the patient new to the dialysis facility was appropriately evaluated on admission prior to the first dialysis and during their first weeks undergoing training for home PD and receiving care at the facility.
Review the admission orders, lab results and progress notes.

- Is there evidence that the patient had orders from a physician or non-physician practitioner if allowed by state law, and was evaluated by an RN prior to their first dialysis treatment at the facility?
 Yes No (V715)
- Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated? Yes No (V125, 126, 506)
- Is there evidence facility staff evaluated and addressed issues related to the patient’s training needs, labs, fluid management, dialysis-related and other clinical and psychosocial problems?
 Yes No-citation at the applicable patient assessment or plan of care V-tag may be indicated.

Notes: _____

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (HHD)**

Patient Name: _____ ID #: _____
 Facility: _____ Surveyor: _____
 Admit Date: _____ Review Date: _____
 DOB: _____ Age: _____ HD Access: Fistula Graft Catheter Catheter >90 days
 Diagnosis: _____
 Criteria for sampling: _____ Sections in this worksheet completed _____

YOU ARE NOT REQUIRED TO COMPLETE ALL OF THE SECTIONS FOR EACH PATIENT.
 HOWEVER SECTIONS 1 AND "D" MUST BE COMPLETED FOR ALL HHD PATIENTS SAMPLED.

All medical record reviews in the ESRD Core Survey are focused reviews, looking at the care provided to and monitoring of each sampled patient related to the criteria used to select them. For all active sampled patients, review the patient's dialysis/medication orders, and the documentation of their dialysis treatments in Section 1. The remainder of each medical record review should be focused on the components of the record related to that patient's sampling criteria in the applicable sections of this worksheet. Refer to "Patient Sample Selection" of the ESRD Core Survey Process for sampling criteria.

Note: For **LTC residents receiving home dialysis in their LTC facility**, and closed record review of patients sampled due to being **involuntarily discharged**, follow the ESRD Core Survey Process and current CMS Survey and Certification guidance.

Section 1: Complete for ALL SAMPLED HHD patients (except closed record review for involuntary discharge). The review of the HHD patient's treatment orders and dialysis treatment records should be focused on whether the patient/helper followed equipment safety procedures and dialysis orders, and how staff members monitor the HHD patient's treatments and address issues and trends. Look for documentation of staff actions in progress notes, plans of care, etc. Note that timeliness of staff review of HHD treatment records depends on when the patient provides them but should be at least every 2 months.

Record the current dialysis treatment and medication orders:

Treatment Orders: Date: _____ EDW: _____ Frequency: _____ days/week
 Dialyzer: _____ Dialysate: _____ BFR: _____ DFR: _____
 Treatment duration: _____ HD Machine Type _____
 Heparin/anticoagulant: _____ ESA dose/frequency: _____ Other meds/treatments: _____

Review 2-3 consecutive weeks of HHD treatment records. RECORD EXCEPTIONS/VARIANCES ONLY. Check if no exceptions .

(Number) _____ treatment records reviewed between _____ and _____

EXCEPTIONS	DATES/COMMENTS
Safety checks not documented (V585):	<i>Note: Safety checks may vary per HHD equipment in use</i>
<input type="checkbox"/> Independent pH/ conductivity (V250)	
<input type="checkbox"/> Machine alarms checked (V403)	
<input type="checkbox"/> Water total chlorine testing (V595)	
Treatment delivered different from	

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (HHD)**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

ordered:	
EXCEPTIONS	DATES/COMMENTS
<input type="checkbox"/> BFR/DFR/dialyzer/time/dialysate (V544) (i.e. clearance/adequacy)	
<input type="checkbox"/> Heparin/anticoagulant (V544)	
<input type="checkbox"/> Anemia management (V547)	
<input type="checkbox"/> Other medications	
BP/fluid management (V543):	
<input type="checkbox"/> Hypertension	
<input type="checkbox"/> Hypotension	
<input type="checkbox"/> Estimated dry weight not achieved	
<input type="checkbox"/> Patient not recording weight/BP	
Staff monitoring:	
<input type="checkbox"/> Tx records not reviewed (V587)	
<input type="checkbox"/> No treatment records in chart (V587)	
<input type="checkbox"/> Unusual or adverse events (V634)	
Other Concerns Identified:	

- Is there evidence that the facility home training/support staff monitored the patient's home hemodialysis through routine review of their HD treatment records? No Yes-(V587) Explain _____
- Did you identify trends in the patient or caregiver not following the dialysis prescription, and parenteral medication orders? No Yes-Explain _____
- Did you identify trends in problems with the patient's blood pressure, fluid or weight management? No Yes-Explain _____
- Did you identify trends in the patient or caregiver not operating the HD machine and equipment or performing the safety checks as expected? No Yes-Explain _____

If yes to any of the above 3 questions: Is there evidence that the home training/support staff recognized that there was a problem, acted with interventions aimed at resolution/improvement, and changed strategies when interventions were unsuccessful?

- **If yes-no citation is indicated**
- **If no-citation at the applicable V-tag listed in the table above may be indicated**

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (HHD)**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Section 2: Complete for HHD patients sampled due to NOT MEETING GOALS (“OUTLIERS”) IN THE DATA-DRIVEN FOCUS AREAS for this survey-if the patient was sampled due to trends of poor outcomes in data-driven focus areas, record in this section.

*Note: This is a focused review intended to look at facility systems for addressing poor patient outcomes in the data driven-focus areas. You are not expected to **search** each patient's record for all of their outcomes. If during your review of the data-driven focus areas used for selecting that patient, you **discover** poor outcomes for the patient in another area, use your judgment on whether reviewing the additional area would be of value, and follow this guidance for that area, as well.*

Review the medical record documentation related to the outcome/area, e.g., progress notes, physician's orders, patient assessment, plan of care to assess the facility's activities for monitoring the patient's outcome, recognizing that there is a problem, and taking action to address it. **For poor outcomes in laboratory values** (i.e., anemia, adequacy, mineral metabolism, albumin): also review the current 3 months of lab results in that area. Reference target values are listed on the Measures Assessment Tool (MAT).

Notes: _____

For each area reviewed in Section 2 for the patient (use back for additional review areas & notes):

- Is there evidence that the patient's outcome in the data-driven focus area(s) used for sampling them has improved and their goal(s) currently met?
 - Yes - no further review is needed**, *no citation in that area is indicated*
 - No** - is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement; and changed strategies if no improvement?
 - **Yes** - *no citation is indicated.*
 - **No** - *citation in that outcome area at the applicable Patient assessment or Plan of care V-tag is indicated.*

Notes: _____

**ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (HHD)**

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Section 3: Complete for HHD patients listed as "UNSTABLE:" Review the IDT documentation in progress notes, physician's orders, assessments, physical and mental functioning surveys (age appropriate HRQOL survey), plans of care, etc. pertaining to the **two** most recent patient assessment and plan of care periods. The IDT process and content of the patient assessment and plan of care are more important than the format or timelines.

Why was this patient identified by the IDT as "unstable?" _____

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members (physician, RN, registered dietitian, master's prepared social worker at a minimum)?
 Yes No (V501, 541)
- Was an assessment of the patient conducted and the issues related to the patient's instability addressed through revised care interventions? Yes No - *citation at the applicable Patient assessment or Plan of care V-tag may be indicated.*

Notes: _____

Section 4: Complete for HHD patients NEWLY ADMITTED (<90 DAYS): Looking at the process for assuring the patient new to the dialysis facility was appropriately evaluated on admission prior to the first dialysis and during their first weeks undergoing training for HHD and receiving care at the facility. *Review the admission orders, lab results and progress notes.*

- Is there evidence that the patient had orders by a physician or non-physician practitioner if allowed by state law, and was evaluated by an RN prior to their first dialysis treatment at the facility?
 Yes No (V715)
- Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated? Yes No (V125, 126, 506)
- Is there evidence facility staff evaluated and addressed issues related to the patient's training needs, labs, fluid management, dialysis-related & other clinical and psychosocial problems? Yes No - *citation at the applicable Patient assessment or Plan of care V-tag may be indicated.*

Notes: _____

Section "D": Complete for ALL HHD patients SAMPLED:

Monitoring of home hemodialysis water and dialysate quality: RECORD EXCEPTIONS ONLY.
Check if no exceptions.

Review the past 6 months of the water and dialysate quality applicable for the HHD equipment used for the patient's treatments. The requirements for monitoring the water and dialysate quality for home hemodialysis vary according to the HHD equipment. Determine which equipment is in use, and ask staff or review the equipment directions for use and/or facility procedures to become familiar with the testing required.

- Product water chemical analysis (V594); Total Chlorine testing (V595)
- Bacterial and endotoxin content of water and dialysate at least quarterly (V595)

Notes: _____

➔ **TASK: Medical Record Review:** ▲

Purpose - To verify the provision of safe, effective, interdisciplinary care through the documentation in the patients' medical records

Review the medical records for all the sampled patients selected during Patient Sample Selection - All of the medical record reviews are focused reviews, looking at the care provided to each sampled patient related to the criteria used to select them. Review *each* sampled patient's dialysis/medication orders, and the documentation of their dialysis treatments. The remainder of each patient's medical record review should be focused on the components of the record related to the criteria for sampling that patient, using the following guidelines:

For all sampled patients, Review dialysis prescription/medication orders and dialysis treatment records (except closed records of patients involuntarily discharged): Review the patient's current dialysis prescription and medication orders and compare to the documentation of the dialysis treatments delivered:

- **In-center HD patients** - Look at 2-3 consecutive weeks of hemodialysis treatment records for machine safety checks, treatments & medications delivered as ordered, blood pressure/fluid management and patient monitoring per policy.
- **Home HD patients** - Look at 2-3 consecutive weeks of hemodialysis treatment records for staff monitoring of the patient's adherence to treatment & medication orders, machine safety checks, blood pressure/fluid management and recognizing and addressing issues. **Note:** For the sampled home HD patient, also review documentation of water/dialysate chemical and microbiological quality, as applicable for the hemodialysis equipment in use.
- **PD patients** - Look at 8-12 consecutive weeks of PD documentation e.g., flowsheets for staff monitoring of the patient's adherence to treatment & medication orders, blood pressure/fluid management, and recognizing and addressing issues.

Patients sampled due to not meeting goals (“outliers”) in the data-driven focus areas for the survey: Review the patient's trend in outcomes in *that* data-driven focus area, e.g., 3 months of labs. Look at the physician's orders, interdisciplinary progress notes, patient care plans, and other applicable medical record components to assess the facility's actions.

- Expect to see that one or more IDT members were monitoring the patient's outcome in that area, recognized that the patient was not attaining their goal or had a problem in that area, and responded with meaningful interventions aimed at improvement/resolution. When the interventions were unsuccessful, the IDT continued to attain improvement by changing strategies with alternate interventions.

Note: This is a focused review intended to look at facility systems for addressing poor patient outcomes in the data-driven focus areas. You are not expected to **search** each patient's record for all of their outcomes. If, during your review of the data-driven focus areas used for selecting that patient, you **discover** poor outcomes for the patient in another area, use your judgment about whether reviewing the additional area would be of value, and follow the guidance above for that area, as well.

Guidance for review of patients sampled due to anemia management concerns as a data-driven focus area of the survey: Patients with Hgb <10 g/dL: Look for evaluation of the patient for: treatable causes of the anemia, e.g., infection, inflammation, GI blood loss; iron studies such as ferritin, transferrin saturation; symptoms of anemia; erythropoiesis stimulating agent (ESA) prescribed or increased; avoidance of transfusion

Guidance for review of patients sampled due to fluid management concerns as a data-driven focus area: **Patients with >5% average intradialytic fluid removal:** *Look for evaluation and interventions into causes of fluid gains between treatments, and interventions to mitigate the effects of rapid fluid removal during dialysis (e.g. BP drops, cramping, loss of consciousness). Expect to see IDT recognition of the potential risks to the patient posed by both failure to control fluid gain between treatments and consistent rapid fluid removal (e.g. >5% target weight in treatment <4 hours or >15mL/kg/hour in any treatment length), and interventions to minimize those risks.*

Patients sampled as “Unstable” - Review the IDT documentation in progress notes, physician's orders, assessments, results of physical and mental functioning surveys (age-appropriate Healthcare Related Quality of Life-HRQOL survey), plans of care, etc. pertaining to the two most recent patient assessment and plan of care periods. The IDT process and content of the patient assessments and plans of care are more important than the format or timelines.

- Expect to see that an assessment of the patient was conducted and the clinical and psychosocial issues that contributed to the patient’s instability were addressed through revised plan of care interventions. There should be evidence of a functional IDT process, including substantive contributions from and communication among all required IDT members.

Patients sampled as newly admitted (<90 days) - Review the admission orders, labs and progress notes. Look at the process for assuring the new patient was appropriately evaluated on admission, prior to the first dialysis treatment, and during his/her first weeks receiving care at the facility.

- Expect to see that the patient had written orders by a physician or non-physician practitioner (if allowed by state law) and was evaluated by an RN prior to their first dialysis treatment at the facility. The patient must be evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccination and pneumococcal vaccination, if indicated. The facility staff should have evaluated and addressed the issues related to the patient’s labs, fluid management, dialysis-related problems, as well as other clinical, nutritional, and psychosocial needs. For home dialysis patients and their partners, their training and home dialysis environmental needs must be evaluated and addressed.

Patients sampled as LTC residents receiving home dialysis at the LTC facility: Follow the current CMS Survey and Certification guidance for review of the care of the LTC resident receiving home dialysis at the LTC facility.

- Expect to see coordination and communication between the LTC and ESRD IDT to assure the dialysis treatments are delivered in a safe environment, by adequately qualified, trained, and competent caregivers, with on-site oversight by a qualified RN (LPN for PD). The ESRD facility is responsible for monitoring the dialysis care and condition of the resident, in accordance with all applicable requirements in the CfC (e.g. Water/dialysate quality, Infection control, Patients’ rights, Physical environment, Patient assessment, Patient plan of care, Care at Home)

Patients sampled due to observations: Focus review on the circumstances pertinent to the concerns raised from your observations and/or random interview(s) regarding the patient.

Patients sampled as part of a complaint investigation: Follow the applicable complaint investigation process. Note: To preserve the intention of the Core Survey Patient Sample Selection process, patients sampled as part of complaint investigations must not make up more than 25% of the survey patient sample.

Patients sampled as involuntarily discharged (IVD) - An IVD of a dialysis patient, i.e., no transition of their dialysis care to another outpatient dialysis provider, is a grave situation, because the patient has no

reliable means for obtaining their dialysis treatments, and may expire as a result. The primary focus of your investigation for a patient who has been involuntarily discharged should be on the meaningful actions taken by the facility in attempt to avert the IVD, and to preserve the health and safety of the patient.

Note: The ESRD Conditions for Coverage severely limit the option of involuntarily discharging a patient without transferring the patient's care to another outpatient dialysis facility. When one of the criteria for consideration of involuntary transfer/discharge listed at V766 is identified, the facility and ESRD Network are fully expected to exhaust all resources to address the problems and prevent the patient's transfer or discharge. If there is no resolution, the facility must make meaningful attempts to transfer that patient's care to another outpatient dialysis facility without regard to facility ownership. The only exception to this expectation is in the case of an immediate severe threat to the health and safety of others when the facility may utilize an abbreviated IVD procedure.

***Review** the documentation pertaining to the actions taken in attempt to avert the IVD, to locate and arrange for the transfer of the patient's care to another dialysis provider, and, if all meaningful efforts are unsuccessful, the procedures followed prior to discharging the seriously abusive/disruptive patient. You should **interview** the facility qualified social worker, other applicable staff, and the patient to supplement and/or support the medical record review.*

Guidance for review of IVD of the seriously abusive/disruptive patient: *Note: Patients' rights protect a patient's right to refuse treatment. Therefore, skipping or shortening treatments and/or failing to meet facility set goals for clinical outcomes, as well as verbal outbursts that do not express a credible threat are not acceptable reasons for involuntary discharge.*

Review of the medical record and other documentation must show written evidence of/that:

- The IDT took meaningful actions to attempt to avert the IVD. *At a minimum, these efforts must include a full IDT reassessment of the patient involving the professional IDT, the medical director, and patient's attending physician to investigate and determine the root causes of the patient's disruptive or abusive behavior and actions to resolve the issues **before** considering involuntary discharge of the patient. The facility investigation should include evaluation of possible roles mental illness, cognitive impairment, cultural or language differences or staff behaviors and interactions with the patient may play in the patients' problematic behaviors, with interventions implemented to address and resolve the conflict(s).*
- The facility staff contacted and collaborated with the applicable ESRD Network to resolve the problems, avert the discharge, and, if unsuccessful, facilitate a transfer to another facility.
- The facility staff contacted other dialysis facilities including those outside their corporation to attempt to transfer the patient before considering IVD. The patient's information shared with the contacted facilities was limited to the medical record contents per HIPAA requirements.
- The facility fully implemented/conducted ALL of the above actions **before** proceeding with the procedures for IVD.
- Once the decision for IVD was made, the facility notified the patient at least 30 days before the IVD, notified the applicable ESRD Network, obtained a written physician's order for the IVD, signed by the medical director and the patient's attending physician, and notified the State survey agency of the IVD.

Triggers for citation or more investigation of concerns in Medical Records Reviews:

- Lack of evidence of a functional IDT process to monitor, recognize and address barriers to attaining identified patient outcome goals in one or more clinical and psychosocial areas

- Home dialysis patient interviews or staff interviews indicate concerns about training program- **Extend** to review documentation of patient/caregiver training and demonstration of comprehension (V585, 586)
- Patient or caregiver interviews indicate lack of functional patient education program and patients' rights concerns - **Extend** review to documentation of patient education and patients' rights
- Incomplete, inaccurate, inaccessible or insecure medical records-**Extend** to look at medical records systems (V726)
- Concerns identified in other survey tasks which can be investigated further through medical record review to support or dispel findings

Extending medical record reviews may include review of additional patients' records focused on the area of concern and additional interviews for clarification.



ESRD Core Survey Field Manual

Tab 14: Personnel Interviews

- ESRD Core Survey Interview Worksheet: Medical Director
- ESRD Core Survey Interview Worksheet: Nurse
- ESRD Core Survey Interview Worksheet: Patient Care Technician
- ESRD Core Survey Interview Worksheet: Dietitian
- ESRD Core Survey Interview Worksheet: Social Worker
- ESRD Core Survey Interview Worksheet: CEO/Administrator
- ESRD Core Survey Interview Worksheet: Other Medical Staff
- ESRD Core Survey Interview Worksheet: Orientee
- Task: Personnel Interviews

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
MEDICAL DIRECTOR**

Facility: _____ **Date/Time:** _____

Medical director: _____ **Surveyor:** _____

You are expected to interview the medical director during the survey. Alert the medical director that you would like to interview him/her in person or by phone as their schedule allows. Ask the theme-based **core questions**, and any applicable **extended questions**. Let the survey findings guide the interview.

Core Questions	Concern Identified	
[Patient and staff voice/culture of safety] What do you do to set the tone for the culture of this facility? How do you and facility management encourage patients and staff to openly voice concerns, suggestions and report grievances and errors or near misses? How do you review, evaluate, and act on patient and staff suggestions/complaints/incidents?	<input type="checkbox"/> V627 <input type="checkbox"/> V634	<input type="checkbox"/> No
[Staffing] How do you monitor and address staffing issues, such as staff turnover at this facility? How do you work with the governing body to ensure there are sufficient numbers of qualified staff to meet patients' needs?	<input type="checkbox"/> V757	<input type="checkbox"/> No
[Staff education/training/knowledge] How do you ensure that all staff at this facility are appropriately trained and competent to perform their job responsibilities, including PCTs and anyone performing water treatment and reprocessing (if applicable)?	<input type="checkbox"/> V713 <input type="checkbox"/> V693 <input type="checkbox"/> V696 <input type="checkbox"/> V309	<input type="checkbox"/> No
[Staff & patient partnership in care planning] How do you ensure that patient plans of care are individualized and patients are encouraged to attend plan of care meetings?	<input type="checkbox"/> V541 <input type="checkbox"/> V456	<input type="checkbox"/> No
[Adverse events] When and how are you alerted of adverse events/occurrences or problems at the facility? What is your role regarding the review of occurrences and taking actions to prevent recurrence?	<input type="checkbox"/> V634	<input type="checkbox"/> No
[QAPI] What is your role in the QAPI program? How do you ensure that the QAPI team regularly monitors all required/appropriate quality metrics, and segments the data for each modality and dialysis setting? What is the QAPI process at this facility for data analysis and identification of areas needing improvement? How are these areas prioritized and addressed for performance improvement?	<input type="checkbox"/> V712 <input type="checkbox"/> V628 <input type="checkbox"/> V626	<input type="checkbox"/> No
[Modality] What is this facility's process for ensuring that every patient receives fact-based unbiased education about transplant and all possible dialysis modalities and settings? What is this facility's process for referring candidates for transplant evaluation and to other facilities for dialysis modalities and settings not offered here?	<input type="checkbox"/> V458 <input type="checkbox"/> V553 <input type="checkbox"/> V554	<input type="checkbox"/> No
[Infection control] How are staff, including medical staff, and patients educated about infection prevention? How does this facility monitor whether staff members are following infection control policies & procedures?	<input type="checkbox"/> V132 <input type="checkbox"/> V562 <input type="checkbox"/> V713 <input type="checkbox"/> V715	<input type="checkbox"/> No
[Admissions & Involuntary transfer/discharge] What do you do to prevent situations with patients that may lead to involuntary transfers/discharges? How do you work with the interdisciplinary team and patient care staff to resolve the issues of concern? How do you assure that the interdisciplinary team follows admission/discharge/transfer policies and procedures?	<input type="checkbox"/> V627 <input type="checkbox"/> V715 <input type="checkbox"/> V716 <input type="checkbox"/> V766 <input type="checkbox"/> V767	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V__	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
MEDICAL DIRECTOR**

Extended Questions

Medical Director Responsibilities	Concern Identified	
What are your responsibilities as medical director at this facility? How do you participate in the development, review, and approval of the facility's "patient care policies and procedures manual" and assure that all policies and procedures are adequate, accurate, and up-to-date?	<input type="checkbox"/> V711 <input type="checkbox"/> V712 <input type="checkbox"/> V713 <input type="checkbox"/> V714	<input type="checkbox"/> No
How do you provide oversight to assure that other medical staff members who provide care in the facility are informed about QAPI activities and goals and are adhering to facility policies and procedures?	<input type="checkbox"/> V715 <input type="checkbox"/> V763	<input type="checkbox"/> No
How do you ensure that the water for in-center dialysis and home dialysis (if applicable) is chemically and biologically acceptable?	<input type="checkbox"/> V177 <input type="checkbox"/> V179 <input type="checkbox"/> V595	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
NURSE MANAGER, CHARGE NURSE, STAFF NURSE**

Facility: _____ **CCN:** _____ **Date/Time:** _____

Nurse/Type: _____ **Surveyor:** _____

Ask the theme-based **core questions** (required). If you have identified additional issues during the survey, ask appropriate **extended questions** (optional).

Core Questions	Concern Identified?	
[Staff voice/culture of safety] What do you do to prevent or reduce treatment errors or near misses? What errors or occurrences are expected to be reported at this facility? How comfortable would you feel to report an issue or make a suggestion? How does this facility address an error or near miss involving you or others?	<input type="checkbox"/> V627 <input type="checkbox"/> V634	<input type="checkbox"/> No
[Patient voice/culture of safety] What types of patients' concerns do you respond to, report, and record? How are patients encouraged to voice suggestions and complaints? How do you encourage PCTs to report patient concerns to you? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V627 <input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636 <input type="checkbox"/> V765	<input type="checkbox"/> No
[Staffing] Does this facility have enough qualified and trained staff to meet patients' medical, nutritional, and psychosocial needs? How are direct care staff members routinely scheduled to address vacations, sick calls, etc.? How and how often does the dietitian, social worker, and the patients' nephrologists see and provide services to patients?	<input type="checkbox"/> V757 <input type="checkbox"/> V681 <input type="checkbox"/> V758	<input type="checkbox"/> No
[Patient education/knowledge] What information do you give to patients about their options for transplant and dialysis modalities and settings? How do you evaluate patients' abilities, interests, preferences, and goals? How do you educate patients who have mental illness, cognitive impairment, cultural or language differences? What topics are included in your patient education program?	<input type="checkbox"/> V453 <input type="checkbox"/> V458 <input type="checkbox"/> V512 <input type="checkbox"/> V513 <input type="checkbox"/> V562	<input type="checkbox"/> No
[Staff & patient partnership/care planning] How do patients participate in their plan of care? How do you monitor, recognize, and adjust the plan of care to address patients' barriers to meeting goals (targets), including learning barriers?	<input type="checkbox"/> V456 <input type="checkbox"/> V542 <input type="checkbox"/> V559	<input type="checkbox"/> No
[Monitoring patients/fluid management] How and how often do you monitor in-center patients before, during, and after dialysis? How do you supervise the care the direct care staff provide to patients? How are patients' dialysis treatment records reviewed for accuracy? What is the facility system for monitoring patients' fluid management and fluid removal during dialysis?	<input type="checkbox"/> V503 <input type="checkbox"/> V504 <input type="checkbox"/> V543	<input type="checkbox"/> No
[Infection control] What training did you receive about infection prevention and control? How do you monitor the infection control practices of the direct care staff? What precautions do you and direct care staff take when caring for an HBV+ patient? How are staffing assignments made when HBV+ patients are scheduled?	<input type="checkbox"/> V132 <input type="checkbox"/> V130 <input type="checkbox"/> V131	<input type="checkbox"/> No
[QAPI] How are you included in the facility QAPI activities?	<input type="checkbox"/> V626	<input type="checkbox"/> No
[QAPI/Nurse manager] How do you participate in QAPI? How do you track and trend data for QAPI? What is your role and responsibility in QAPI?	<input type="checkbox"/> V626 <input type="checkbox"/> V628 <input type="checkbox"/> V712	<input type="checkbox"/> No
[Emergency preparedness] What training do you have in dealing with patient emergencies and cardiac arrest? What are patients taught about emergency disconnection and evacuation from the facility, and about preparing for disasters? How do you determine and keep track of which patients need more help with evacuation? How would you contact a physician in an emergency?	<input type="checkbox"/> V409 <input type="checkbox"/> V410 <input type="checkbox"/> V411 <input type="checkbox"/> V412 <input type="checkbox"/> V769	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V _____	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
NURSE MANAGER, CHARGE NURSE, STAFF NURSE**

Extended Questions

Interdisciplinary Clinical Care	Concern Identified?	
How are staffing assignments made taking into consideration patient acuity and special needs?	<input type="checkbox"/> V757 <input type="checkbox"/> V759	<input type="checkbox"/> No
What types of patient issues would you refer to the dietitian or social worker?	<input type="checkbox"/> V509 <input type="checkbox"/> V510	<input type="checkbox"/> No
How do you review patients' immunizations and medication history with them (e.g., allergies, current in-center medications and home medications, over-the-counter medications, supplements, etc.) and assure the accuracy of their medications?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Patients' Rights	Concern Identified?	
How do you show respect to patients and address undesirable patient/staff behaviors? What would you do if you saw a patient being treated disrespectfully?	<input type="checkbox"/> V452	<input type="checkbox"/> No
Infection Control	Concern Identified?	
How do you track infections in the in-center patients?	<input type="checkbox"/> V637	<input type="checkbox"/> No
Did the facility offer you the Hepatitis B vaccine? What vaccinations are patients offered here? How are patients' HBV status monitored? What tracking mechanism do you have to assure that patients get the full HBV vaccination series? How do you track their HBV immunity status after vaccination?	<input type="checkbox"/> V126 <input type="checkbox"/> V124 <input type="checkbox"/> V127	<input type="checkbox"/> No
QAPI	Concern Identified?	
What practice audits of patient care are done at this facility and which ones have you participated in?	<input type="checkbox"/> V638	<input type="checkbox"/> No
How do you and the QAPI team address/correct serious problems that have harmed or may harm patients?	<input type="checkbox"/> V634 <input type="checkbox"/> V640	<input type="checkbox"/> No
How are you informed about and participate in improvement efforts related to patients' satisfaction, grievances, and involuntary discharges that are addressed in QAPI?	<input type="checkbox"/> V636 <input type="checkbox"/> V767	<input type="checkbox"/> No
Qualifications and Training	Concern Identified?	
What responsibilities, if any, do you have for water treatment, reuse, and/or machine maintenance?	<input type="checkbox"/> V681 <input type="checkbox"/> V694 <input type="checkbox"/> V713	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PATIENT CARE TECHNICIAN**

Facility: _____ **CCN:** _____ **Date/Time:** _____

PCT: _____ **Surveyor:** _____

Ask the theme-based **core questions** (required). If you have identified additional issues during the survey, ask appropriate **extended questions** (optional).

Core Questions	Concern Identified?	
[Staff voice/culture of safety] What is your role in keeping patients safe? What occurrences, errors or near misses are you expected to report and to whom? How comfortable would you feel to report an issue or make a suggestion? How does this facility address an error or near miss involving you or others?	<input type="checkbox"/> V627 <input type="checkbox"/> V634	<input type="checkbox"/> No
[Patient voice/culture of safety] What types of patients' concerns do you respond to, report, and record? How are patients encouraged to voice suggestions and complaints? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V627 <input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636 <input type="checkbox"/> V765	<input type="checkbox"/> No
[Staffing] Are there enough qualified and trained staff (RNs, PCTs, RDs, MSWs) in this facility to meet patients' medical, nutritional, and psychosocial needs? Is an RN always on duty when patients are in the dialysis facility?	<input type="checkbox"/> V757 <input type="checkbox"/> V681 <input type="checkbox"/> V759	<input type="checkbox"/> No
[Monitoring patients/fluid management] How and how often do you monitor in-center patients before, during, and after dialysis? When would you notify a nurse if a patient has a problem? What is the facility's system for determining what each patient's fluid removal parameters are?	<input type="checkbox"/> V503 <input type="checkbox"/> V504 <input type="checkbox"/> V543	<input type="checkbox"/> No
[Infection control/PPE] What training did you receive in infection prevention and control? What special precautions do you take when caring for patients who are HBV+? How are staffing assignments made when HBV+ patients are scheduled?	<input type="checkbox"/> V132 <input type="checkbox"/> V113 <input type="checkbox"/> V130 <input type="checkbox"/> V131	<input type="checkbox"/> No
[Patient education/emergency preparedness] What topics are included in the patient education at this facility? How are patients taught emergency disconnect and evacuation from the facility?	<input type="checkbox"/> V412	<input type="checkbox"/> No
[Staff education/emergency preparedness] What emergency preparedness training have you received including handling patients' medical emergencies such as cardiac arrest? How do you know which patients require more help in disconnecting and evacuating?	<input type="checkbox"/> V409 <input type="checkbox"/> V410	<input type="checkbox"/> No
[Staff & patient partnership/care planning] How do you work with the IDT to help patients plan their care? How do you encourage patients to participate in planning their care and collaborate with them to achieve their outcome goals (e.g., fluid, adequacy, calcium, phosphorus, etc.)?	<input type="checkbox"/> V456 <input type="checkbox"/> V559	<input type="checkbox"/> No
[Respectful treatment] How do you work with patients who have mental illness, cognitive impairment, or cultural or language differences? How do you show respect to patients and address undesirable behaviors? What would you do if you saw a patient being treated disrespectfully?	<input type="checkbox"/> V452 <input type="checkbox"/> V693	<input type="checkbox"/> No
[QAPI] How are you included in the facility QAPI activities?	<input type="checkbox"/> V627 <input type="checkbox"/> V626	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V__	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PATIENT CARE TECHNICIAN**

Extended Questions

Interdisciplinary Clinical Care	Concern Identified?	
How and to whom would you report patients' interest in and need for education about other treatment modalities (home dialysis and transplant)?	<input type="checkbox"/> V458	<input type="checkbox"/> No
What types of patient issues would you refer to the dietitian or social worker?	<input type="checkbox"/> V509 <input type="checkbox"/> V510	<input type="checkbox"/> No
Qualifications and Training	Concern Identified?	
What responsibilities, if any, do you have for water treatment, reuse, and/or machine maintenance?	<input type="checkbox"/> V681 <input type="checkbox"/> V694 <input type="checkbox"/> V713	<input type="checkbox"/> No
How do you test dialysate pH and conductivity? What is the safe range for pH and conductivity and what would you do if pH or conductivity are outside the safe range? How do you notify the technical staff if a machine fails a safety test?	<input type="checkbox"/> V249 <input type="checkbox"/> V250 <input type="checkbox"/> V403 <input type="checkbox"/> V713	<input type="checkbox"/> No
Infection Control	Concern Identified?	
Did the facility offer you the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
QAPI	Concern Identified?	
What practice audits of patient care are done at this facility and which ones have you participated in?	<input type="checkbox"/> V638	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
DIETITIAN**

Facility: _____ **Date:** _____

Dietitian: _____ **Surveyor:** _____

Ask the theme-based **core questions** (required). If you have identified additional issues during the survey, ask the appropriate **extended questions** (optional).

Core Questions	Concern Identified?	
[Patient & staff voices/culture of safety] What types of patient and staff concerns, suggestions/complaints, errors and near misses are staff taught to respond to, report, and record? How comfortable would you feel to report an issue or make a suggestion? What is your facility's system for reporting resolution?	<input type="checkbox"/> V627 <input type="checkbox"/> V466 <input type="checkbox"/> V765	<input type="checkbox"/> No
[Staffing] Do you have enough time to help in-center and home patients (if applicable) meet their nutritional needs? How often do you have contact with in-center and home (if applicable) patients?	<input type="checkbox"/> V757 <input type="checkbox"/> V681 <input type="checkbox"/> V758	<input type="checkbox"/> No
[Patient education/knowledge] How do you educate and counsel patients and families about the renal diet, labs, and nutritional status and needs, including addressing learning barriers? How do you work effectively with patients who have mental illness, cognitive impairment, cultural or language differences?	<input type="checkbox"/> V562 <input type="checkbox"/> V453	<input type="checkbox"/> No
[Meeting nutritional needs/targets in-center patients] What nutritional issues do you address with in-center patients, including their diet on dialysis days? If you have in-center nursing home patients, how do you communicate and collaborate with NH staff to meet nutritional needs and targets?	<input type="checkbox"/> V545	<input type="checkbox"/> No
[Meeting nutritional needs/targets home patients (if applicable)] What nutritional issues do you address with home patients, including those on dialysis in nursing homes (if applicable)? How and how often do IDT members see and provide services to home patients? How do you communicate and collaborate with NH staff to meet nutritional needs and targets?	<input type="checkbox"/> V545 <input type="checkbox"/> V592	<input type="checkbox"/> No
[Reviewing labs] What are your responsibilities for monitoring lab test results? What is your responsibility if the patient's lab results are outside identified parameters?	<input type="checkbox"/> V505 <input type="checkbox"/> V509 <input type="checkbox"/> V545 <input type="checkbox"/> V559	<input type="checkbox"/> No
[Staff & patient partnership/care planning] How do patients at this facility participate in their plan of care? How do you monitor, recognize, and address patients' nutritional needs and barriers? How do you collaborate with the patient and team to overcome barriers to their goals and clinical targets?	<input type="checkbox"/> V509 <input type="checkbox"/> V542 <input type="checkbox"/> V456 <input type="checkbox"/> V559	<input type="checkbox"/> No
[QAPI] How do you participate in QAPI? What facility-level nutritional and other data do you bring to QAPI meetings?	<input type="checkbox"/> V756 <input type="checkbox"/> V626 <input type="checkbox"/> V630 <input type="checkbox"/> V631	<input type="checkbox"/> No
[Emergency preparedness] What were you taught about emergency preparedness? What do you teach patients about adjusting their diet and fluids if they can't do dialysis in an emergency or disaster?	<input type="checkbox"/> V409 <input type="checkbox"/> V412	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V__	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
DIETITIAN**

Extended Questions

Interdisciplinary Clinical Care	Concern Identified?	
What are your responsibilities related to patient and family diet education when patients switch permanently or temporarily between HD and PD or between standard and longer or more frequent dialysis?	<input type="checkbox"/> V545 <input type="checkbox"/> V562	<input type="checkbox"/> No
How does the interdisciplinary team identify patients as unstable?	<input type="checkbox"/> V520	<input type="checkbox"/> No
Infection Control	Concern Identified?	
Were you offered the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
What training do you have in infection prevention and control?	<input type="checkbox"/> V132	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
SOCIAL WORKER**

Facility: _____ **Date:** _____

Social Worker: _____ **Surveyor:** _____

Ask the theme-based **core questions** (required). If you have identified additional issues during the survey, ask appropriate **extended questions** (optional).

Core Questions	Deficient Practice?	
[Patient & staff voice/culture of safety] What types of patient and staff concerns, suggestions/complaints, errors, and near misses are staff taught to respond to, report, and record? How comfortable would you feel to report an issue or make a suggestion? What is your facility's system for reporting resolution?	<input type="checkbox"/> V627 <input type="checkbox"/> V465 <input type="checkbox"/> V765	<input type="checkbox"/> No
[Staffing] Do you have enough time to help in-center and home patients (if applicable) meet their psychosocial needs? How often do you have contact with in-center and home (if applicable) patients?	<input type="checkbox"/> V757 <input type="checkbox"/> V681 <input type="checkbox"/> V758	<input type="checkbox"/> No
[Patient education/knowledge] How do you educate and counsel patients and families, including those with learning barriers, about coping with kidney failure and dialysis, lifestyle and treatment options, following their treatment plan, and rehabilitation? How do you work effectively with patients who have mental illness, cognitive impairment, cultural or language differences?	<input type="checkbox"/> V562 <input type="checkbox"/> V453	<input type="checkbox"/> No
[Meeting psychosocial needs/targets in-center patients] How do you assess in-center patients' need for and availability of family and other support systems? What psychosocial issues do you address with in-center patients? If you have in-center nursing home patients, how do you communicate and collaborate with NH staff to meet psychosocial needs?	<input type="checkbox"/> V514 <input type="checkbox"/> V552	<input type="checkbox"/> No
[Meeting psychosocial needs/targets home patients] How do you assess patients' need for and availability of family and other support systems when determining candidacy for home dialysis? What psychosocial issues do you address with home patients, including those on dialysis in nursing homes (if applicable)? How and how often do IDT members see and provide services to home patients? How do you communicate and collaborate with NH staff to meet psychosocial needs (if home dialysis is offered in NHs)?	<input type="checkbox"/> V514 <input type="checkbox"/> V552 <input type="checkbox"/> V592	<input type="checkbox"/> No
[Staff & patient partnership/care planning] How do patients at this facility participate in their plan of care? How do you monitor, recognize, and address patients' psychosocial needs and barriers? How do you collaborate with the patient and team to overcome barriers to their goals and clinical targets?	<input type="checkbox"/> V542 <input type="checkbox"/> V456 <input type="checkbox"/> V510 <input type="checkbox"/> V559	<input type="checkbox"/> No
[Physical and mental functioning] When do you offer patients a health-related quality of life survey (e.g., KDQOL-36 or age appropriate), share results with the patient and team, and use them for plan of care and QAPI? What percent of patients were excluded in the last year and why? What are your refusal and annual completion thresholds?	<input type="checkbox"/> V552 <input type="checkbox"/> V628	<input type="checkbox"/> No
[QAPI] How do you participate in QAPI? What facility-level psychosocial and other data do you bring to QAPI meetings? How are patients' satisfaction, grievances, and involuntary discharges addressed in QAPI?	<input type="checkbox"/> V756 <input type="checkbox"/> V626 <input type="checkbox"/> V636	<input type="checkbox"/> No
[Emergency preparedness] What were you taught about emergency preparedness? How do you help patients get care elsewhere during an emergency?	<input type="checkbox"/> V409 <input type="checkbox"/> V412	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V__	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
SOCIAL WORKER**

Extended Questions

Patients' Rights/Education	Deficient Practice?	
What are patients' rights and responsibilities? How and when do they learn their rights? How do you teach and encourage patients to self-advocate? What is the patient care staff taught about the patients' right to self-advocate?	<input type="checkbox"/> V451	<input type="checkbox"/> No
What do you do to assure that patients have their desired level of privacy and confidentiality when they communicate with you?	<input type="checkbox"/> V454	<input type="checkbox"/> No
What do you tell patients about their right to establish an advance directive? What are the facility's policies for honoring advance directives and are patients told about these policies?	<input type="checkbox"/> V457	<input type="checkbox"/> No
Interdisciplinary Clinical Care	Deficient Practice?	
How does the interdisciplinary team identify patients as unstable? What criteria do you use to identify a patient as unstable due to "significant change in psychosocial needs?"	<input type="checkbox"/> V520	<input type="checkbox"/> No
Infection Control	Deficient Practice?	
Were you offered the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
What training do you have in infection prevention and control?	<input type="checkbox"/> V132	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
CEO/ADMINISTRATOR (OPTIONAL)**

Facility: _____ **Date/Time:** _____

CEO/Administrator: _____ **Surveyor:** _____

This interview is optional, but you may wish to interview the CEO/Administrator if you identified an issue in an applicable area during the survey, or where lack of governing body oversight may have contributed to serious findings.

There Are No Core Questions Only Extended Questions

Staff Voice/Culture of Safety	Concern Identified?	
How does this facility promote a facility-wide culture of safety, including encouraging staff to report errors/near misses, or safety risks they identify? What action(s) does this facility take with staff when an error/near miss or safety risk is reported? How does the facility address these to reduce and prevent problems in the future? How do you encourage staff to speak up, and voice comments or suggestions about making improvements at the facility?	<input type="checkbox"/> V627 <input type="checkbox"/> V634 <input type="checkbox"/> V715	<input type="checkbox"/> No
Patient Voice/Culture of Safety	Concern Identified?	
How does this facility encourage patients to voice suggestions, comments, and complaints? What is your system for handling patient complaints, including reporting complaint resolution to the patient?	<input type="checkbox"/> V636 <input type="checkbox"/> V765	<input type="checkbox"/> No
Staffing, Appointments & Continuing Education	Concern Identified?	
How do you assure that there are sufficient numbers of qualified and trained staff, including registered nurses, dietitians, social workers, and technicians to meet the individualized clinical and technical needs of patients based on their acuity and care needs? Is there 24/7 coverage for dialysis patients?	<input type="checkbox"/> V757 <input type="checkbox"/> V758 <input type="checkbox"/> V681	<input type="checkbox"/> No
How do you assure that at least one RN is present at all times when patients are in the dialysis facility?	<input type="checkbox"/> V759	<input type="checkbox"/> No
How do you appoint the medical staff (physicians, advanced practice registered nurses, and physician assistants)?	<input type="checkbox"/> V762	<input type="checkbox"/> No
How does this facility assure that nurses, dietitians, social workers, and patient care technicians working with patients on in-center and/or home dialysis (if applicable) have opportunities for continuing education (internal training and external professional education)?	<input type="checkbox"/> V761	<input type="checkbox"/> No
QAPI	Concern Identified?	
How do you assure that there are appropriate personnel and resources (time and money) for this facility's QAPI program? How do you share the information from QAPI with the governing body for their review?	<input type="checkbox"/> V756	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
CEO/ADMINISTRATOR (OPTIONAL)**

Fiscal Operations	Concern Identified?	
How do you meet the fiscal needs of this dialysis facility's in-center and home training and support program (if applicable)?	<input type="checkbox"/> V754	<input type="checkbox"/> No
Furnishing Services	Concern Identified?	
Are all services under this provider's CCN provided on the main premises or on premises that are contiguous (connected) with the main premises and are under the direction of the same professional staff and governing body as the main premises?	<input type="checkbox"/> V764	<input type="checkbox"/> No
Relationship with ESRD Network	Concern Identified?	
What is this facility's relationship with the ESRD Network to improve quality of care and reduce involuntary discharges?	<input type="checkbox"/> V772 <input type="checkbox"/> V767	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
OTHER MEDICAL STAFF (OPTIONAL)**

Facility: _____ **Date/Time:** _____

Other Medical Staff: _____ **Surveyor:** _____

This interview is optional, but you may wish to interview medical staff other than the medical director if you identified an issue in an applicable area during the survey.

There Are No Core Questions Only Extended Questions

Patient Modality Selection	Concern Identified?	
How do you educate patients, including those with learning barriers, about transplant and all possible dialysis modalities and settings? How do you evaluate patients' abilities, interests, preferences, and goals when determining the dialysis modality and setting most suitable for them and who to refer for transplant?	<input type="checkbox"/> V453 <input type="checkbox"/> V458 <input type="checkbox"/> V512 <input type="checkbox"/> V513	<input type="checkbox"/> No
Patient Partnership/Care Planning	Concern Identified?	
How are patient care plans developed at this facility? How do you participate in patient care planning, including attending patient plan of care meetings? How do your in-center and home patients (if applicable) participate in their plan of care? How do you encourage them to attend plan of care meetings? How do you monitor your patients' conditions and outcomes and adjust their plans of care to address their barriers to meeting goals (targets), including learning barriers?	<input type="checkbox"/> V456 <input type="checkbox"/> V542 <input type="checkbox"/> V559	<input type="checkbox"/> No
Patient Monitoring	Concern Identified?	
How often do you see you in-center and home dialysis patients (if applicable)? How do staff members alert you to problems that a patient is having on in-center or home dialysis?	<input type="checkbox"/> V560 <input type="checkbox"/> V502 <input type="checkbox"/> V503 <input type="checkbox"/> V592	<input type="checkbox"/> No
QAPI	Concern Identified?	
How do you learn about the facility's QAPI activities? What involvement do you have in the facility QAPI program?	<input type="checkbox"/> V763	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
OTHER MEDICAL STAFF (OPTIONAL)**

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**ESRD CORE SURVEY INTERVIEW WORKSHEET:
ORIENTEE (OPTIONAL)**

Facility: _____ **Date/Time:** _____

Name/Type: _____ **Surveyor:** _____

This interview is optional, but you may wish to interview an orientee if you identified an issue with their practice(s). To expand this interview based on the orientee's discipline, you may use the interview worksheet for that staff type.

There Are No Core Questions Only Extended Questions

Orientation & Training	Concern Identified?	
When did you start at this facility? What orientation and training have you had to do your job? What are your job responsibilities at this time while you are in orientation? Who is supervising your work?	<input type="checkbox"/> V713 <input type="checkbox"/> V760 <input type="checkbox"/> V681	<input type="checkbox"/> No
Infection Control	Concern Identified?	
What training did you receive in infection control? Did the facility offer you the Hepatitis B vaccine?	<input type="checkbox"/> V132 <input type="checkbox"/> V126	
Emergency Preparedness	Concern Identified?	
What training did you receive in emergency preparedness? What is the procedure for fire and emergency evacuation from this facility?	<input type="checkbox"/> V409 <input type="checkbox"/> V412 <input type="checkbox"/> V769	

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
ORIENTEE (OPTIONAL)**

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➔ **TASK: Personnel Interviews:** ▲

Purpose - To assess facility-based (not corporate-based) staff knowledge, competence, and their awareness of expectations for safe and effective care aimed at achievement of optimum patient outcomes; to clarify/verify potential survey findings; and to give staff an opportunity to voice concerns

Interview the following staff: *Interviews may be conducted in-person or by phone. Individualize the staff interviews according to the survey issues and concerns, however **ask** the questions listed as “core” in the corresponding ESRD Core Survey interview worksheets:*

- Medical director
- Nurse Manager - *although it is likely that the facility nurse manager will be engaged in and interviewed throughout the survey process, if this is not the case, include her/him in the personnel interviews*
- 2-3 nursing staff members including at a minimum, 1RN and 1 PCT
- Registered dietitian
- Master's prepared social worker
- Water treatment personnel - *during “Water Treatment and Dialysate Review”*
- Reuse technician - *during “Dialyzer Reprocessing/Reuse Review”*
- Home training nurse(s) - *during “Home Dialysis Training and Support Review”*
- Machine/equipment technician - *during “Dialysis Equipment Review”*

Triggers for citation or more investigation of concerns:

- Concerns identified from personnel or patient interviews or other survey tasks that indicate the need to extend certain areas of questions for personnel or interview more personnel to support or dispel findings.



ESRD Core Survey Field Manual

Tab 15: Personnel Record Review

- ESRD Core Survey: Surveyor Worksheet for Personnel Record Review
- Task: Personnel Record Review

ESRD Core Survey: Surveyor Worksheet for Personnel Record Review

Select a minimum of three (3) personnel files to review for verification of the accuracy of facility-submitted documentation. If you need to extend your personnel file review, you may review three (3) more files using the other side of this sheet.

Personnel Name/ID: _____ Date Reviewed: _____

Personnel Name/ID: _____ Date Reviewed: _____

Personnel Name/ID: _____ Date Reviewed: _____

Personnel record reviews identified problems? YES NO

If NO, to indicate your personnel record review is complete, check here:

If YES, complete the following table to indicate potential findings. Document by exception.

Personnel Requirement	If Yes, Check V-Tag & Enter Staff ID	Staff ID	Staff ID	Staff ID
Qualifications & Competency	<input type="checkbox"/> V196 (color blindness, PCT, water tech/supervisor, self care HHD training nurse, nurse manager, charge nurse)			
	<input type="checkbox"/> V307 (reuse tech)			
	<input type="checkbox"/> V681 (all)			
	<input type="checkbox"/> V682 (medical director)			
	<input type="checkbox"/> V683 (medical director waiver)			
	<input type="checkbox"/> V684 (nurse manager)			
	<input type="checkbox"/> V685 (home training RN)			
	<input type="checkbox"/> V686 (charge RN)			
	<input type="checkbox"/> V688 (staff nurse)			
	<input type="checkbox"/> V689 (RD)			
	<input type="checkbox"/> V690 (RD 1 yr)			
	<input type="checkbox"/> V691 (MSW)			
	<input type="checkbox"/> V695 (PCT certification)			
Orientation & Continuing Education	<input type="checkbox"/> V760 (all)			
	<input type="checkbox"/> V761 (all)			
Training on Water & Dialysate	<input type="checkbox"/> V260 (PCT, water tech/supervisor, nurse manager & charge nurse verifying test results)			
	<input type="checkbox"/> V403 (PCT, water tech/supervisor, machine/equipment/maintenance tech)			
Training for Reuse	<input type="checkbox"/> V308 (reuse tech training)			
	<input type="checkbox"/> V403 (PCT, water tech/supervisor, machine/equipment/maintenance tech)			
CPR	<input type="checkbox"/> V410 (nurses, PCTs)			
Training in Infection Control	<input type="checkbox"/> V132, V147 (nurses; PCTs if allowed by state to do CVC care)			
Training in Emergency Preparedness	<input type="checkbox"/> V409			
Vaccinations & Health Monitoring, TB If Required by State	<input type="checkbox"/> V126, V127, V681			

To extend your personnel file review

ESRD Core Survey: Surveyor Worksheet for Personnel Record Review

If you need to extend your personnel file review, you may include three (3) more files.

Personnel Name/ID: _____ Date Reviewed: _____

Personnel Name/ID: _____ Date Reviewed: _____

Personnel Name/ID: _____ Date Reviewed: _____

Complete the following table to indicate potential findings. Document by exception.

Personnel Requirement	If Yes, Check V-tag & Enter Staff ID	Staff ID	Staff ID	Staff ID
Qualifications & Competency	<input type="checkbox"/> V196 (color blindness, PCT, water tech/supervisor, self care HHD training nurse, nurse manager, charge nurse)			
	<input type="checkbox"/> V307 (reuse tech)			
	<input type="checkbox"/> V681 (all)			
	<input type="checkbox"/> V682 (medical director)			
	<input type="checkbox"/> V683 (medical director waiver)			
	<input type="checkbox"/> V684 (nurse manager)			
	<input type="checkbox"/> V685 (home training RN)			
	<input type="checkbox"/> V686 (charge RN)			
	<input type="checkbox"/> V688 (staff nurse)			
	<input type="checkbox"/> V689 (RD)			
	<input type="checkbox"/> V690 (RD 1 yr)			
	<input type="checkbox"/> V691 (MSW)			
	<input type="checkbox"/> V692 (PCT HS diploma)			
	<input type="checkbox"/> V693 (PCT completed training)			
	<input type="checkbox"/> V694 (PCT training content)			
<input type="checkbox"/> V695 (PCT certification)				
Orientation & Continuing Education	<input type="checkbox"/> V760 (all)			
	<input type="checkbox"/> V761 (all)			
Training on Water & Dialysate	<input type="checkbox"/> V260 (PCT, water tech/supervisor, nurse manager? charge nurse?)			
	<input type="checkbox"/> V403 (PCT, water tech/supervisor, machine/equipment/maintenance tech)			
Training for Reuse	<input type="checkbox"/> V308 (reuse tech training)			
	<input type="checkbox"/> V403 (PCT, water tech/supervisor, machine/equipment/maintenance tech)			
CPR	<input type="checkbox"/> V410 (nurses, PCTs)			
Training in Infection Control	<input type="checkbox"/> V132, V147 (nurses; PCTs if allowed by state to do CVC care)			
Training in Emergency Preparedness	<input type="checkbox"/> V409			
Vaccinations & Health Monitoring, TB If Required by State	<input type="checkbox"/> V126, V127, V681			

➔ **TASK: Personnel Record Review:** ▲

Purpose - To verify that personnel have the qualifications, training, and demonstrated competencies to provide safe and effective dialysis care

Review the facility-submitted documentation on the “Personnel File Review” worksheet given to the facility administrative person during the Entrance Conference, or equivalent electronic report.

Review selected personnel files: *Select a minimum of 3 personnel files to review using the following criteria:*

- Concerns identified about the qualifications or competency of specific staff during observations of care or interviews with patients or staff
- The facility-submitted documentation is incomplete or show irregularities/variances for specific personnel

Triggers for citation or more investigation of concerns:

- Personnel lack required qualifications or competency verification (V410, 681)
- Verification review indicates inaccurate or incomplete facility-submitted documentation for 1 or more files.
- PCTs listed with no certification expiration date-*check for hire date within 18 months; Note that medical, military, or other approved leave of absence extends the time allowed for certification/recertification (V695)*

Extending personnel file review may include review of 3 more personnel files to verify accuracy of the facility-submitted documentation or investigate the extent of personnel training and competency issues .



ESRD Core Survey Field Manual

Tab 16: Quality Assessment and Performance Improvement Review

- ESRD Core Survey QAPI Review Worksheet
- Task: Quality Assessment and Performance Improvement Review

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Facility _____ CCN _____ Date _____

Surveyor _____ Facility-based Responsible Person _____

Note on Facility-Based (not Corporate-Based) QAPI: The review of the facility QAPI program must be limited to the information for only the facility being surveyed, and conducted with facility-based (on-site) administrative personnel. The expectation of a facility QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care to and monitoring facility operations of their individual facility. The facility-based staff are expected to recognize when performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.

Preparation for QAPI Review: Although portions of the QAPI review may occur throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey. This enables focus on the facility's QAPI activities in critical priority areas, data-driven focus areas, and survey findings during Segment II of the QAPI Review. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and list the areas for Segment II review.*

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

The QAPI review is divided into 3 Segments of review:

Segment I. Monitoring care and facility operations to verify that the facility QAPI program has sufficient infrastructure, and continuously monitors all areas as expected.

- **Clinical and operational indicators** (pg. 2)
- **Oversight of technical operations and practice audits** (pg. 3)

Segment II. Review of QAPI activities in three critical priority areas for ALL facilities, and in the data-driven focus and survey findings areas specific to this facility survey: A detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and responding in the critical priority and problematic areas to attain and sustain improvements

- **Mortality review** (pg.4)
- **Infection prevention and control** (pgs. 4-6)
- **Medical error/adverse occurrence/clinical variance tracking and investigation system** (pg. 6)
- **Data-driven focus and survey findings areas** for this facility survey (pg. 7)

Segment III. Culture of Safety Review: Verifying the presence of a facility-wide culture that promotes and protects patient safety. The primary components are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated.

- **Risk identification and reporting** (pg. 8)
- **Staff engagement** (pg. 8)
- **Patient engagement** (pg. 9)

Review the facility-based QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-based (not corporate-based) person.

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Segment I: Monitoring Care and Facility Operations

➤ **Clinical and operational indicators monitored**

Review (briefly) the facility-based QAPI documentation to verify that the facility’s QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI program monitors at a minimum all the expected areas of patient clinical management and facility operations. Refer to table of indicators below. Note that not all areas listed in the table are expected to be monitored monthly. This is not a detailed review, but a brief look at the facility’s QAPI summarizing documentation. You will review the facility QAPI performance improvement activities in the critical priority areas, survey data-driven focus areas and survey findings/concerns areas in more detail during Segment II.

Indicators to be routinely monitored: Note that not all areas are required to be monitored monthly

<input type="checkbox"/> Water & dialysate quality(separate in-center & home) (V628)	<input type="checkbox"/> Physical plant safety “rounds,” audits (V628)
<input type="checkbox"/> Dialysis equipment repair and maintenance (V628)	<input type="checkbox"/> Dialyzer Reuse QA audits & adverse events (V635)
<input type="checkbox"/> Personnel qualifications and issues (V628)	<input type="checkbox"/> ESRD Network relationship/communication (including IVDs) (V772)
<input type="checkbox"/> Patient modality choice & transplant referral (V628)	<input type="checkbox"/> Health outcomes-physical and mental functioning (HRQOL results)(V628)
<input type="checkbox"/> Infection prevention and control (separate HD & PD, home & in-center) (V637)	<input type="checkbox"/> Patient satisfaction & grievance/complaints (V636)
<input type="checkbox"/> Mortality-(expirations & causes) (separate HD & PD, home & in-center) (V628)	<input type="checkbox"/> Morbidity-(hospitalizations, admitting diagnoses & readmissions w/in 30days) (separate HD & PD) (V628)
<input type="checkbox"/> Fluid & BP management-(separate HD & PD) (V628)	<input type="checkbox"/> Dialysis adequacy-(separate HD & PD) (V629)
<input type="checkbox"/> Nutritional status (separate HD & PD) (V630)	<input type="checkbox"/> Mineral and bone management (separate HD & PD) (V631)
<input type="checkbox"/> Anemia management (separate HD& PD) (Hgb, transfusions, Tsat%, ferritin) (V632)	<input type="checkbox"/> Vascular access-HD (V633) <input type="checkbox"/> PD access-PD (V633)
<input type="checkbox"/> Medical errors/adverse occurrences/clinical variances-in-center hemodialysis & home dialysis (V634) <ul style="list-style-type: none"> • Cardiac arrest at facility • Deaths during dialysis • Errors in dialysis prescription delivery • Medication errors, omissions, adverse reactions • Transfusion reactions • Incorrect reprocessed dialyzer set up or used • Blood loss • Chlorine/fluoride breakthrough • Machine malfunction w/treatment interruption • Patient transfers to hospital from dialysis • Patient falls; Patient injuries 	
<ul style="list-style-type: none"> • Vascular access events: infiltration, clotting, excessive bleeding, infection • Intradialytic symptoms <ul style="list-style-type: none"> ○ Hypotension w/loss of consciousness ○ Chest pain ○ Severe cramping; nausea/vomiting ○ Pyrogenic reactions • Staff incidents and injuries: <ul style="list-style-type: none"> ○ Needle sticks ○ Blood/body fluid exposures ○ Non-adherence to procedures ○ Patient abuse/disrespect 	

Is the facility routinely monitoring and trending all of the expected areas? **Yes** **No** (V626, 628)-
Explain_____

For the clinical areas, has the facility identified outcome goals which reflect community standards from the current Measures Assessment Tool (MAT)? **Yes** **No** (V628)-Explain_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Segment II: Review of QAPI in Critical Priority & Data-Driven Focus Areas

For ALL facilities, review the mortality, infection prevention and control, and medical error/adverse occurrence investigation systems (i.e., critical priority areas). Individualize your review of the data-driven focus areas and survey findings pertinent to this facility survey. In all areas, conduct a sufficiently detailed review to determine the quality and effectiveness of the facility QAPI actions for addressing problematic areas and attaining and sustaining improvements in outcomes.

- **Mortality review: Review** with the responsible facility-based person the QAPI documentation for evaluation of the facility mortality data. Focus the discussion on the analysis and trending of causes of patient deaths and the relationship to the care received at the facility.

For all facilities, ask: What information do you collect about patient deaths? How does the QAPI Team conduct analysis of individual patient deaths, and recognize trends in causes and contributory factors to deaths?

Is there evidence that the facility reviewed and evaluated all patient deaths, and analyzed trends in causes of patient deaths? Yes No (V628)-Explain _____

For facilities with poor mortality outcomes as noted from the Dialysis Facility Report review during Presurvey Preparation ask: What trends in causes of mortality have you identified? How did you investigate them? What performance improvement strategies have you implemented to address the high mortality ratio and/or adverse trends?

For identified trends in cause of deaths, did the QAPI Team conduct review focused on the aspects of care related to specific-cause categories? (Examples are: for high rates of deaths due to **infection causes** the facility should have looked at the CVC rate and CVC reduction efforts, hospitalization patterns, water/dialysate cultures, staff compliance with infection control practices, etc.; for high rates of HD death due to **cardiac causes** the facility should have looked at HD ultrafiltration rates, length of HD treatments, the use of low potassium (0K+ or 1K+) dialysate, patients' serum bicarbonate levels, etc.) Did the QAPI Team develop, implement and monitor performance improvement actions aimed at addressing contributory factors related to the care received at the facility? Yes No (V628)-Explain _____

- **Infection prevention and control**

This review is intended to assure that the facility's QAPI activities facilitate a multi-faceted and effective facility-wide program for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare associated infections (HAI) acquired at the facility. There are 4 areas of this review:

Infection occurrence tracking/trending/surveillance:

Ask: What types of infections do you record? What information do you record about each infection?

Review: The infection tracking logs.

Are all positive culture results, dialysis access infections, blood stream infections (BSI), and peritonitis episodes, if applicable recorded with sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic susceptibility)? Yes No (V637)-Explain _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Is there evidence that trends in infections were recognized, evaluated/investigated, and performance improvement activities implemented and monitored for effectiveness?

Yes N/A No (V637)-Explain _____

Vaccination: high risk disease-specific management: *Refer to the facility vaccination information obtained from the Entrance Conference Materials list.*

Ask: The responsible facility-based person to show you the QAPI documentation of oversight for surveillance and vaccination for:

- Hepatitis B patient surveillance and susceptible patients and personnel offered vaccination
- Tuberculosis surveillance of patients on admission or exposure
- Influenza vaccinations offered to patients and personnel annually
- Pneumococcal pneumonia vaccination offered to patients
- New Hepatitis C infections (i.e. antibody elevations for facilities that test for HCV) or unexplained ALT elevations

Is there evidence of active QAPI oversight of the above high risk disease surveillance and vaccination programs? Yes No (V637, V125-V127)-Explain _____

If trends of lapses in surveillance or vaccination were identified, did the facility take meaningful actions to investigate the problem, implement performance improvement plans, and monitor them for effectiveness? Yes N/A No (V637)-Explain _____

If HBV conversions, other notifiable diseases or outbreaks were identified, were they reported to the local health department? Yes N/A No (V637)-Explain _____

Staff education and visual practice audits for infection control:

Ask: What are staff taught about the patient care practices for prevention of infections? How often are they re-educated in infection prevention? What methods do you use to visually audit patient care staff infection control practices? How often are the visual audits of patient care staff conducted? If you identify a problem when auditing staff, how do you involve the staff in the development and implementation of the solution?

Review: *The documentation of visual audits of personnel infection control practices while delivering care to patients.*

Is there evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff providing care to patients (e.g. initiation and discontinuation of hemodialysis, vascular assess care, medication preparation and administration, hand hygiene, etc.)? When lapses in practices were observed, were actions taken toward improvement? Were the involved staff included in the investigation into issues surrounding the practices, and development and implementation of improvement plans, rather than just counseling or reeducating? Yes No (V637, V132, V142, V147)-Explain _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Patient education for infection prevention:

Ask: How are patients educated about infection prevention? How are patients encouraged to be engaged in knowing what infection prevention actions (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment) they and staff should be follow? How are the patients encouraged to speak up if they have concerns about personnel infection control practices?

Does the facility's infection prevention and control program include educating patients and their families about strategies for remaining infection-free? Yes No (V637, V562, V585)-Explain _____

For facilities with high rates of infection, high rates of CVC >90 days, or patterns of survey findings in infection control: **Ask:** What investigation have you conducted into your facility's problematic infection issue? What QAPI strategies have you implemented to improve the problem? What improvements have you achieved?

Is there evidence that the facility recognized and acted upon their poor infection outcomes? (*Examples are: for high patient infection rates, fully investigating for trends and causes of the infections, including staff care practices, water/dialysate and dialyzer reprocessing sources, etc. For high rates of CVC >90 days, implementing meaningful strategies for reducing CVC rates*) Yes No (V637)-Explain _____

When reductions in infection rates or CVC >90 days rates were not attained, did the QAPI Team revise and change the performance improvement actions until improvements were achieved ?

Yes N/A No (V637)-Explain _____

- **Medical error/adverse occurrence/clinical variance tracking and investigation system:** The intent of this review is to ensure that there is an effective QAPI system in place for reporting, investigating, and responding to errors/occurrences. **The error/occurrence log is not intended as a source for survey citations except as related to the QAPI process.** *Tell the responsible facility-based person that you will be reviewing the facility error/occurrence log with them.*

Review the facility error/occurrence log for the past 6 months: *Select one error/occurrence to "follow" along with the responsible person. You may randomly select the error or select one pertinent to concerns identified during the survey. Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI actions to prevent future similar occurrences.*

Did the facility thoroughly investigate the error/occurrence to determine why it happened, including interviews with all applicable staff to understand what circumstances surrounded it, and involved those staff members in the development of the plan for resolution? Yes No (V634)-Explain _____

Did the facility implement a meaningful action plan to mitigate factors that contributed to the error/occurrence, monitor the plan for effectiveness in preventing recurrence, and, if a similar error/occurrence happened, revise and implement the revised plan? Yes No (V634)-Explain _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

MAKE ONE COPY OF THIS PAGE FOR EACH FOCUS AREA YOU WILL REVIEW

- **Data-driven focus areas and survey findings areas:** *Using your list of QAPI focus areas from page 1 of this worksheet, Review those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask: How do you prioritize facility performance improvement activities? How did the facility-based QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did you take for improvement, and how were the actions and subsequent outcomes monitored to assure improvements were attained and sustained? If improvements were not attained, what actions did you take?

Focus Area _____

Is there evidence that the facility prioritized performance improvement activities to assure areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner? Yes No (V639)-Explain _____

Did the facility routinely monitor the focus area, and **identify the issue or recognize that a problem** or opportunity for improvement existed? Yes No-Explain _____

Did the facility thoroughly **investigate root/multiple causes** of the issue and develop, implement, and monitor performance improvement plans? Yes No-Explain _____

Does the **current QAPI documentation show improvements** have been attained and sustained? Yes No-Explain _____

- **If yes to all above questions:** no further review is needed for that focus area or survey concern/finding-the facility QAPI response was effective-*no citation at QAPI is indicated*

If improvements were not attained, and outcome goals in the focus area are not currently reached, is there evidence the facility revised, implemented and monitored the revised QAPI actions? (*note that repeated entries of "will monitor" without active revisions to action plans is not sufficient evidence of effective QAPI*) Yes N/A No (V626, 628-637)-Explain _____

Additional Notes: _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

SEGMENT III: Culture of Safety

Culture of Safety: The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated. This segment includes reviews of 3 areas:

- **Risk Identification and Reporting:** To verify that there is an effective system in place for reporting all errors/occurrences, “near misses”/“close calls,” and potential risks to patients.

Ask: How do you define medical errors/adverse occurrences/clinical variances? What occurrences are staff expected to report?

Compare: *the answer (list of occurrences) with the list in the section “Medical error/adverse occurrences/clinical variances” from the table on page 2 of this worksheet to ensure that these occurrences, at a minimum are recognized as potentially hazardous and are included in the facility reporting and investigation system.*

Ask: How do you ensure staff report “near misses” and “close calls” when an error/adverse occurrence/clinical variance did not actually occur, but was averted? How do you track and investigate near misses/close calls? *(The evaluation of near misses/close calls has been shown to be a rich source of error/adverse occurrence prevention and highly effective for improving patient safety.)*

Does the facility medical error/adverse occurrence/clinical variance reporting system include all expected error/occurrences, and staff education for reporting defined occurrences and near misses/close calls?

Yes No (V634)-Explain _____

- **Staff Engagement Review:** To verify the presence of open communication between all levels of facility staff where all staff are engaged in the QAPI processes and encouraged to voice concerns without fear of retribution.

Ask: How do you ensure open communication with all levels of staff? How are staff educated about and encouraged to freely report errors/occurrences/clinical variances, and near misses/close calls without fear of retribution? How are staff encouraged to voice concerns about or ideas for improvements in their work environment? How do you engage all levels of staff in QAPI activities? How are staff suggestions, concerns, and complaints recorded and responded to?

Review the Staff Suggestion/complaint log: *Look for evidence that the facility has an organized, facility-based system in place for staff to submit written or verbal suggestions for improvement, communication of concerns about their work environment, and complaints.*

Is there evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment? Do administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues? Yes No (V627) Explain-

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

➤ Patient Engagement Review

Patient health outcomes-physical and mental functioning review: To verify that the facility QAPI program is focused on patients' psychosocial status by regular monitoring through the administration and use of a standardized survey that assesses the patients' physical and mental functioning.

Ask: How do you track and trend eligible patients' scores in an age-appropriate standardized physical and mental functioning survey (HRQOL survey)? What is your facility's threshold for patients completing and refusing the survey annually? (Although it is expected that a few patients may refuse to participate in the assessment of their physical and mental functioning, high refusal rates, e.g., >20% would indicate a problem which should be recognized and addressed with performance improvement actions).

Review the QAPI documentation related to patient physical and mental functioning outcomes monitoring.

Does the facility track and trend the % of eligible patients who complete and refuse the physical and mental functioning survey? Does the facility track and trend the scores on a facility level? Yes No (V628)-Explain _____

If the trends of facility level scores showed a decline or the refusal rate increased, is there evidence that the facility recognized a problem existed, investigated the possible causes, and took meaningful actions to address the issue(s) and attain improvements? Yes N/A No (V628)-Explain _____

Patient grievance/complaint/suggestion system: To verify that the facility is "listening" to the patients and that a patient grievance/complaint submission system is in place that encourages patients to feel free to express concerns without fear of reprisal. *If the patient interviews indicated trends of concerns about reluctance to speak up, plan to spend more time reviewing this area with the responsible facility-based person. Tell the responsible person you will be reviewing the patient grievance/complaint suggestion log with them.*

Ask: How are staff taught to respond to patients' voiced concerns? What types of patient concerns do you educate and expect staff to report and record?

Ask: How are patients educated and encouraged to freely speak up and voice suggestions, concerns, and complaints/grievances without fear of retribution or retaliation? How are their concerns, verbal or written suggestions, complaints/grievances recorded, and responded to? What is your facility's system for communicating with the patient and reporting the resolution to him/her?

Review the patient suggestion/complaint/grievance log with the facility-based responsible person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient. You may wish to interview the involved patient about their experience using the facility suggestion/complaint/grievance system.

Patient Satisfaction Survey: To verify that the facility routinely assesses the patients' satisfaction with the facility and care received and acts upon the identified opportunities to improve care.

Ask: How do you assess patient satisfaction/perceptions of care at this facility?

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Review summary information of the most recent patient satisfaction survey results. If trends in negative patient responses were identified, ask: How did you utilize that information to improve programs or care delivery? (V636)

Is there evidence the facility management and staff educate and encourage patients to verbalize suggestions and concerns in addition to written complaints/grievances? Are staff educated how to respond professionally to patients' verbalized concerns, and report them to their supervisor for recording and follow up? Yes No (V627)-Explain_____

Is there evidence the patient's concern you reviewed was recorded, the circumstances investigated, and mutually acceptable resolution reached? Was the result communicated to the patient? Yes No (V636, 465, 765)-Explain_____

*Note: In the chronic dialysis setting where patients are encouraged to speak freely without fear of reprisal, patient voiced concerns, suggestions and complaints/grievances are **expected** and indicate the presence of a culture of safety. If the facility responsible person states there are no patient suggestions, verbalized or written concerns or complaints/grievances, this may be cause for concern and indication of an absence of open communication and culture of safety.*

Based on your interviews during the survey with staff, patients, and the facility-based QAPI responsible person, and the above reviews in this "Culture of Safety" section, is there evidence that substantial efforts are being made to establish and maintain a facility-wide "culture of safety?" Yes No (V627)-Explain_____

Additional notes: _____

➔ **TASK: Quality Assessment & Performance Improvement (QAPI) Review:** ▲

Purpose - To verify that the facility's QAPI program is sufficiently comprehensive and robust to monitor all facility operations/services, recognize when performance improvement is indicated, respond with effective actions to attain and sustain improvements, and support a facility-wide "Culture of Safety" that assures optimum patient safety

Note on Facility-Based (not Corporate-Based) QAPI: The review of the facility QAPI program must be limited to the information for only the facility being surveyed, and conducted with facility-based (on-site) administrative personnel. The expectation of a facility QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care to and monitoring facility operations of their individual facility. The facility-based staff are expected to recognize when performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.

The QAPI review is divided into 3 Segments of review:

Segment I: Monitoring care and facility operations to verify that the facility QAPI program has sufficient infrastructure, and continuously monitors all areas as expected, including the technical operations. *Note: The QAPI activities for critical priority areas, and the data-driven focus and survey findings areas for this facility will be reviewed in more detail during Segment II of the QAPI review.*

- **Clinical and operational indicators:** A brief look to assure all expected indicators and areas pertinent to dialysis care are continuously monitored.
- **Oversight of technical operations and practice audits** to verify the presence of consistent QAPI oversight and performance improvement actions for water/dialysate, equipment maintenance/repair, and dialyzer reuse programs

Segment II: Review of QAPI activities in three critical priority areas for ALL facilities and in the data-driven focus areas and survey findings areas of this facility survey. A detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and responding in the critical priority and problematic areas to attain and sustain improvements

- **Mortality review:** Looking at the QAPI activities for evaluating and trending patient deaths, and efforts implemented to address adverse trends potentially related to care received at the facility.
- **Infection prevention and control:** A review of the facility program for infection occurrence tracking/trending, vaccination, personnel infection control education and visual auditing, and patient education in infection prevention, toward the goal of reduction of patient infection rates.
- **Medical error/adverse occurrence/clinical variance tracking and investigation system** to verify the presence of an effective system for responding to events, investigating, and addressing causal factors to prevent occurrence or recurrence. During this review, the surveyor "follows" an error/event and the facility performance improvement actions as recorded in the facility system.
- **Data-driven focus and survey findings areas:** Following through with the focuses and findings of the survey, to determine what the facility QAPI activities were for recognition of the problems/risks, and actions taken to address them.

Segment III: Culture of Safety Review: Verifying the presence of a facility-wide culture that promotes and protects patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/events, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated. A facility-wide culture of

safety enables complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients. The culture of safety review has 3 components:

- **Risk identification and reporting:** Looking to see that an effective program exists to identify all risks to patients and facilitate liberal reporting of those risks, including “near misses/close calls” to allow comprehensive investigation and mitigation of risks.
- **Staff engagement:** Looking at the facility's communication systems and role expectations among all levels of staff. The surveyor reviews the facility staff complaint/suggestion log.
- **Patient engagement:** Looking at the facility program for assessing and addressing patients' mental and physical health outcomes. The surveyor also reviews the facility patient grievance/complaint/suggestion system by “following” a patient complaint through the process.

Preparation for QAPI Review: Although portions of the QAPI review may occur throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey. This enables focus of the review during Segment II on the facility's QAPI performance improvement activities in the critical priority areas, data-driven focus areas, and survey findings areas. Conducting the review after most of the survey is completed allows the surveyor to determine if the facility has identified the same concerns as the survey team, and what performance improvement actions they have taken to address them. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and make a list of areas in addition to the critical priority ones to focus on during Segment II.*

Review the facility-based QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-based (not corporate-based) person.

Segment I: Monitoring Care and Facility Operations

➤ **Clinical and operational indicators monitored**

Review the QAPI documentation to verify that the facility's QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI Team monitors at a minimum all the expected areas of patient clinical management and facility operations. Refer to table of indicators in the “ESRD Core Survey QAPI Review Worksheet.” Note that not all areas listed in the table are expected to be monitored monthly.

This is not a detailed review, but a brief look at the facility's QAPI summarizing documentation. You will review the facility QAPI performance improvement activities in the critical priority areas, survey data-driven focus areas and survey findings/concerns areas in more detail during Segment II.

- Expect to see that the facility is routinely monitoring and trending all of the expected areas. For the clinical areas, that the facility has identified outcome goals which reflect community standards from the current Measures Assessment Tool (MAT). The QAPI documentation must show the active involvement of all personnel necessary to adequately address and resolve problems/issues, including all members of the interdisciplinary team, i.e., medical director, nurse manager, masters-prepared social worker, registered dietitian, and other personnel such as technical staff and patient care staff (V626, 628).

➤ **Oversight of technical operations and practice audits:**

Review the facility's QAPI documentation to ensure routine audits in these areas are conducted and discussed, and performance improvement actions taken, when indicated. The following are expected:

Water and dialysate quality

- Review of monthly water and dialysate cultures/endotoxin results, annual product water chemical analysis, and other microbiological monitoring as indicated for the equipment in use (V628)
- Audits at least annually of staff mixing dialysate concentrates; testing batches of acid concentrate; testing dialysate pH/conductivity; testing water for total chlorine and microbiological sample collection; operating equipment (V260)

Dialysis equipment: Review of monthly dialysis machine, equipment and ancillary equipment maintenance and repair (V628)

Reuse: Review and verification that all required reuse audits are conducted at the applicable intervals and adverse occurrences related to reuse addressed. The Reuse QA audits include visual practice audits of staff reprocessing dialyzers, and staff preparing reprocessed dialyzers for patients' treatments (set up) (V635)

- Expect to see evidence that all of the above reviews and audits were conducted. When problems were identified, evaluation was done to determine the cause(s) of the issue, and actions taken to resolve it. Note that the cycle of elevated water or dialysate cultures, "addressed" with disinfection, only to have elevated cultures the following month, "addressed" with disinfection, repeated over and over is not effective performance improvement and may be risking patient safety.

Segment II: Review of QAPI activities in three critical priority areas for ALL facilities and in the data-driven focus and survey findings areas of this facility survey (identified areas of patient risk).

For ALL facilities, review the mortality, infection prevention and control, and medical error/adverse occurrence investigation systems (i.e., critical priority areas). Individualize your review of the data-driven focus areas and survey findings pertinent to this facility survey. In all areas, conduct a sufficiently detailed review to determine the quality and effectiveness of the facility QAPI actions for addressing problematic areas and attaining and sustaining improvements in outcomes.

➤ Mortality review:

Review, with the responsible facility-based person, the QAPI documentation for evaluation of the facility mortality data. Focus the discussion on the analysis and trending of causes of patient deaths and the relationship to the care received at the facility.

For all facilities, ask: What information do you collect about patient deaths? How does the QAPI Team conduct analysis of individual patient deaths, and recognize trends in causes and contributory factors to deaths?

- Expect to see evidence that the facility reviewed and evaluated all patient deaths, and analyzed trends in causes of patient deaths (V628).

For facilities with poor mortality outcomes as noted from the Dialysis Facility Report review during Presurvey Preparation: Ask: What trends in causes of mortality have you identified? How did you investigate them? What performance improvement strategies have you implemented to address the high mortality ratio and/or adverse trends?

- Expect to see, for identified trends in cause of deaths, that the QAPI Team investigated the issues and conducted QAPI review focused on the aspects of care related to specific-cause categories. Examples are: for high rates of deaths due to **infection causes** the facility should have looked at

the CVC rate and CVC reduction efforts, hospitalization patterns, water/dialysate cultures, staff compliance with infection control practices, etc.; for high rates of death due to **cardiac causes** the facility should have looked at HD ultrafiltration rates, length of HD treatments, the use of low potassium (“0K+” or “1K+”) dialysate, patients' serum bicarbonate levels, etc.(V628)

- **Infection prevention and control:** *Infections are a leading cause of death in dialysis patients, and protection from infection is vital to their health and safety. This review is intended to assure that the facility's QAPI activities facilitate a multifaceted and effective facility-wide program for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare associated infections (HAI) acquired at the facility.*

There are 4 areas of the infection prevention and control review :

Infection occurrence tracking/trending/surveillance: *Ask:* What types of infections do you record? What information do you record about each infection?

Review the infection tracking logs.

- Expect to see that all positive culture results, dialysis access, blood stream infections (BSI), and peritonitis episodes, if applicable, are recorded with sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic use); That trends in infections were recognized, evaluated/investigated, and performance improvement strategies implemented and monitored for effectiveness (V637).

Vaccination: high risk disease management: *Refer to the facility vaccination information obtained from the Entrance Conference Materials List. Ask:* The responsible facility-based person to show you the QAPI documentation of oversight for surveillance and vaccinations including:

- Hepatitis B patient surveillance; susceptible patients and personnel offered vaccination (V125-127)
- Tuberculosis surveillance of patients on admission or exposure
- Influenza vaccinations offered to patients and personnel seasonally
- Pneumococcal pneumonia vaccination offered to patients
- New Hepatitis C infections (i.e. antibody elevation for facilities that test for HCV) or unexplained ALT elevations
- Expect to see evidence of active QAPI oversight of the high risk disease surveillance and vaccination programs listed above. If trends of lapses in surveillance or vaccination were identified, that the QAPI Team responded to thoroughly investigate the problem, implement performance improvement actions, and monitor them for effectiveness (V637).

Staff education and visual practice audits for infection control: *Ask:* What are staff taught about the patient care practices for prevention of infections? How often are they re-educated in infection prevention? What methods does the facility use to visually audit patient care staff infection control practices? How often are the visual audits of patient care staff conducted? If visual audits identify a problem with staff, how do you involve those staff in the development and implementation of the solution?

Review the documentation visual audits of personnel infection control practices while delivering care to patients.

- Expect to see evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff member providing care to patients (e.g. initiation and discontinuation of hemodialysis, vascular assess care, medication

preparation and administration, hand hygiene, etc.). There should be evidence of actions taken for improvement when lapses in practices were observed, i.e., involved staff included in the investigation into issues surrounding the poor practices (e.g. low staffing) and development and implementation of improvement plans, rather than just counseling or reeducating (V637, 132, 142, 147).

Patient education for infection prevention: *Ask:* How are patients educated about infection prevention? How are patients encouraged to be engaged in knowing what infection prevention actions (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment) they and staff should follow? How are the patients encouraged to speak up if they have concerns about personnel infection control practices?

- Expect to see that the facility's infection prevention and control program includes educating patients and families about strategies for remaining infection-free (V637, 562, 585).

For facilities with high rates of infection, high rates of CVC >90 days, or patterns of survey findings in infection control: *Ask:* What investigation have you conducted into your facility's problematic infection issue? What QAPI strategies have you implemented to improve the problem? What improvements have you achieved?

- Expect to see that a facility with high patient infection rates has fully investigated for trends and causes of the infections, including but not limited to staff care practices, water/dialysate and dialyzer reprocessing sources. For high rates of CVC >90 days, there should be evidence of meaningful strategies implemented for reducing CVC rates. When reductions in infection rates or CVC >90 days rates are not attained, there should be evidence of revisions and changes in performance improvement actions until improvements are achieved (V637).

➤ **Medical error/adverse occurrence/clinical variance tracking and investigation system:** The intent of this review is to ensure that there is an effective QAPI system in place for reporting, investigating, and responding to errors/occurrences. **The error/occurrence log is not intended as a source for survey citations except as related to the QAPI process.** *Tell the responsible person that you will be reviewing the facility error/occurrence log with them.*

Review the facility error/occurrence log for the past 6 months: *Select one error/occurrence to "follow" along with the responsible person. You may randomly select the error or select one pertinent to concerns identified during the survey. Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI actions to prevent future similar occurrences.*

- Expect to see evidence that the facility thoroughly investigated the error/occurrence by looking at why it happened, including interviews with all applicable staff to understand what circumstances surrounded it, and involved those staff members in the development of the plan for resolution. There must be evidence that the facility implemented a meaningful action plan to mitigate factors that contributed to the error/occurrence, monitored the plan for effectiveness in preventing recurrence, and, if a similar error/occurrence happened, revised and implemented the revised plan (V634).

➤ **Data-driven focus areas and survey findings areas:** *Using your list of QAPI focus areas for the survey, Review those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask: How do you prioritize facility performance improvement activities? How did the facility-based QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did you take for improvement, and how were the actions and subsequent outcomes monitored to

assure improvements were attained and sustained? If improvements were not attained, what actions did you take?

For each data-driven focus area and survey finding area you reviewed:

- Expect to see evidence that the facility:
 - Prioritized performance improvement activities to assure the areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner (V639)
 - Routinely monitored the focus area, recognized that a problem/opportunity for improvement existed, thoroughly investigated root/multiple causes of the issues, and developed and implemented performance improvement plans
 - Monitored the performance improvement plan to attain and sustain improvements, or, if goals were still not achieved, revised the actions until improvements were attained and sustained (V626, 628-637)

Segment III: Culture of Safety

In healthcare, lessons show that assurance of patient safety is only achieved through the implementation of a facility-wide “culture of safety.” The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated. A facility-wide culture of safety enables complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients. This segment includes reviews of the following 3 areas:

- **Risk Identification and Reporting:** To verify that there is an effective system in place for reporting all errors/occurrences, “near misses”/“close calls,” and potential risks to patients

Ask: How do you define medical errors/adverse occurrences/clinical variances? What occurrences are staff expected to report? **Compare:** the answer (list of occurrences) with the list in the section “Medical error/adverse occurrences/clinical variances” from the table included on page 2 of the “ESRD Core Survey QAPI Review Worksheet” to ensure that these occurrences, at a minimum are recognized as potentially hazardous and are included in the facility reporting and investigation system.

Ask: How do you ensure staff report “near misses” and “close calls” when an error/adverse occurrence/clinical variance did not actually occur, but was averted? How do you track and investigate near misses/close calls? **Note:** The evaluation of near misses/close calls has been shown to be a rich source of error/adverse occurrence prevention and highly effective for improving patient safety.

- Expect to see that the facility medical error/adverse occurrence/clinical variance reporting system includes all expected error/occurrences, and staff education for reporting defined occurrences and near misses/close calls (V634)

- **Staff Engagement Review:** To verify the presence of open communication between all levels of facility staff where all staff are engaged in the QAPI processes and encouraged to voice concerns without fear of retribution

Ask: How do you ensure open communication with all levels of staff? How are staff educated about and encouraged to freely report errors/occurrences/clinical variances, and near misses/close calls without fear of retribution? How are staff encouraged to voice concerns about or ideas for improvements in their work

environment? How do you engage all levels of staff in QAPI activities? How are staff suggestions, concerns, and complaints recorded and responded to?

Review the Staff Suggestion/complaint log: Look for evidence that the facility has an organized, facility-based system in place for staff to submit written or verbal suggestions for improvement, communication of concerns about their work environment, and complaints.

- Expect to see evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment. There should be evidence that administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues (V627).

➤ Patient Engagement Review

Patient health outcomes, physical and mental functioning review: To verify that the facility QAPI Team is focused on patients' psychosocial status by regular monitoring through the administration and use of an age-appropriate standardized survey that assesses the patients' physical and mental functioning

Ask: How do you track and trend eligible patients' scores in an age-appropriate standardized physical and mental functioning survey (Health Related Quality of Life-HRQOL survey)? What is your facility's threshold for patients completing and refusing the survey annually? **Note:** Although it is expected that a few patients may refuse to participate in the assessment of their physical and mental functioning, high refusal rates, e.g., >20% would indicate a problem which should be recognized and addressed with performance improvement actions.

Review the QAPI documentation related to patient physical and mental functioning outcomes monitoring.

- Expect to see that the QAPI program tracks and trends the % of eligible patients who complete and refuse the physical and mental functioning survey, and track and trend the scores on a facility level.
- If the trends showed facility-level scores declined or an increase in the refusal rate, there should be evidence that the facility recognized a problem existed, investigated the possible causes, and took meaningful actions to address the issue(s) and attain improvements (V628).

Patient grievance/complaint/suggestion system: To verify that the facility is "listening" to the patients, and that a patient grievance/complaint submission system is in place that encourages patients to feel free to express concerns without fear of reprisal. *If the patient interviews indicated trends of concerns about reluctance to speak up, plan to spend more time reviewing this area with the responsible facility-based person. Tell the responsible facility-based person you will be reviewing the patient grievance/complaint suggestion log with them.*

Ask: How are staff taught to respond to patients' voiced concerns? What types of patient concerns do you educate and expect staff to report and record?

Ask: How are patients educated about and encouraged to freely speak up and voice suggestions and complaints/grievances without fear of retribution or retaliation? How are their concerns, verbal or written suggestions, and complaints/grievances recorded and responded to? What is your facility's system for communicating with the patient and reporting the resolution to him/her?

Review the patient suggestion/complaint/grievance log with the responsible facility-based person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result

communicated to the patient. You may wish to interview the involved patient about their experience using the facility patient suggestion/complaint/grievance system.

- Expect to see that the facility management and staff encourage patients to verbalize suggestions and concerns, in addition to written complaints/grievances. Staff should be educated how to respond professionally to patients' verbalized concerns and to report them to their supervisor for recording and follow up (V627).
- There must be evidence that the patient's concern you reviewed was recorded, the circumstances investigated, mutually acceptable resolution reached, and the result communicated to the patient (V636, 465, 765).

Patient Satisfaction Survey: To verify that the facility routinely assesses the patients' satisfaction with the facility and care received and acts upon the identified opportunities to improve care.

Ask: How do you assess patient satisfaction/perceptions of care at this facility?

Review summary information of the most recent patient satisfaction survey results. If trends of negative patient responses were identified, ask: How did you utilize that information to improve programs or care delivery (V636)?

Note: In the chronic dialysis setting where patients are encouraged to speak freely without fear of reprisal, patient voiced concerns, suggestions and complaints/grievances are expected and indicate the presence of a culture of safety. If the facility responsible person states there are no patient suggestions, verbalized or written concerns or complaints/grievances, this may be a cause for concern and indication of an absence of open communication and culture of safety (V627).

Triggers for citation in QAPI:

The QAPI program does not:

- Administer oversight of all facility operations including monitoring all areas and conducting practice audits as required by the CfC (V132, 260, 362-368, 403)
- Recognize and address risk areas where facility outcomes and/or survey findings indicate performance improvement is needed/indicated (V625-640)
- Follow up on performance improvement plans, resulting in improvements not attained or sustained or recurring similar adverse events (V634, 638)
- Make substantial efforts to establish and maintain a facility-wide culture of safety (V627)-
Consider the survey team's interviews with patients, staff and administrative personnel, along with the above reviews in the Culture of Safety QAPI Review Segment III, to determine if substantial efforts are being made to establish and maintain a facility-wide culture of safety.

Extending the QAPI review should be conducted if there are serious pervasive deficient practices identified during the survey which have not been recognized and/or adequately addressed by the QAPI program. Extending the QAPI review should include investigation into the facility's compliance with the Conditions for Coverage of Medical Director and Governance. This may include interviews with the facility administrator, medical director, and governing body members to determine what administrative failures have contributed to the pervasive problems, through lack of adequate staff and/or resources (V754, 756, 757); lack of staff training and education (V713, 715, 760, 761, 763); and/or lack of involvement or leadership of the medical director (V712, 714).



ESRD Core Survey Field Manual

Tab 17: Decision Making

- Task: Decision Making

➔ **Decision Making:**

Purpose - To facilitate communication and collaboration among survey team members regarding potential survey findings and to prepare for the Exit Conference

- Meet with the survey team to discuss the survey findings
- Refer to reference documents on ESRD decision making
- Make copies of evidence as needed to document survey findings



ESRD Core Survey Field Manual

Tab 18: Exit Conference

- Task: Exit Conference

➔ **Exit Conference:**

Purpose - To notify the facility of the concerns identified during the survey, and the preliminary findings of deficient practice

- Verbally present findings in order of severity; do not provide specific V-tags
- Follow relevant SOM & State procedures



ESRD Core Survey Field Manual

Tab 19: ESRD Core Survey Task Thumbnails

Presurvey Preparation

- * **USE** the “ESRD Core Survey Data Tools” worksheet, section I
- * **REVIEW** the facility current FY Dialysis Facility Report (DFR) accessed at dialysisdata.org
 - * Guided DFR review of key outcomes data
 - * Note where facility does not meet national averages
- * **CONTACT** the applicable ESRD Network
- * **REVIEW** facility survey history
- * **DETERMINE** preliminary data-driven focus areas for survey

- * **COPY** Section II of “ESRD Core Survey Data Tools” worksheet to give to facility during Introductions

Introductions

- * **CONTACT** the person in charge when you arrive

- * **EXPLAIN** who survey team are, why you are there

- * **PRESENT** the person in charge with blank copy of Section II “ESRD Core Survey Data Tools” worksheet-to be completed and returned to survey team within 3 hours

Environmental “Flash” Tour

Looking for observable concerns that may impact patient safety

- * **OBSERVE** 4 patient-related areas
 - * **In-center dialysis patient treatment area**
 - * **Water treatment and dialysate preparation room/area**
 - * **Dialyzer reprocessing room/area**
 - * **Home dialysis training and support area**
- * **ASK** staff in all areas **Culture of Safety** questions from the Core Survey

Entrance Conference

- * **USE “ESRD Core Survey Data Tools” worksheet, sections II and III**
- * **COLLECT and REVIEW** facility-completed Section II “Entrance Conference Materials”.
- * **EXPLAIN** purpose and timeline for survey
- * **ASK** questions about facility operations from “Entrance Conference Questions” or STAR
- * **ENGAGE and DISCUSS** with administrative person, facility-completed data in Section II
- * **COMPARE** “% Met” with National Thresholds (averages) in Section III “ESRD Core Survey Data tools” worksheet
- * **DETERMINE** data-driven focus areas for survey

Observations of Hemodialysis Patient Care and Infection Control Practices

- **OBSERVE** direct care staff delivering care using observational checklists from the “Observations of Hemodialysis Care” worksheet or STAR:
 - * Initiation of HD with Central Venous Catheter (CVC) #1
 - * CVC Exit Site Care #2
 - * Discontinuation of HD with CVC #3
 - * Initiation of HD with AV Fistula or Graft (AVF/G) #4
 - * Discon. of HD with AVF/G #5
 - * Cleaning/disinfection of Dialysis Station #6
 - * Preparation of HD Machine #7
 - * Parenteral Medication Preparation and Administration #8
 - * Dialysis Supply Management and Contamination Prevention #9
- **REVIEW** facility isolation practices
- **VERIFY** dialysis prescription delivery

Patient Sample Selection

- * **REVIEW** patient-specific information in the Entrance Conference Materials submitted by the facility
- * **SELECT** 10% of patient census: all dialysis modalities represented; **minimum of 4, up to 10**
- * **USE Patient selection criteria:**
 - * Unstable
 - * New admission <90days
 - * Involuntarily discharged (not transferred to another facility)
 - * Long Term Care (LTC) resident receiving home dialysis at the LTC
 - * Not meeting goals in data-driven focus areas (“outliers”)
 - * Observed with concern
 - * Involved in complaint allegation being investigated

Water/Dialysate Review

- **USE** Core Survey “Water & Dialysate Review” worksheet or STAR
- **REVIEW critical water treatment components**
 - **OBSERVE** carbon system; total chlorine test; interview
 - **OBSERVE** reverse osmosis unit; quality monitor; alarm; interview
 - **OBSERVE** deionization; resistivity monitor; alarm; interview
- **INTERVIEW on-site personnel:** microbial sampling; disinfection; dialysate mixing/testing
- **REVIEW facility documentation**
 - Total chlorine tests
 - RO function: water quality & % rejection
 - Microbial testing
 - DI resistivity readings
 - Staff audits

Dialyzer Reprocessing/Reuse Review

- * **USE** Core Survey “Reuse Review” worksheet or STAR
- * **OBSERVE** reprocessing area
- * **OBSERVE high risk procedures:**
 - * Transportation of used/dirty dialyzers; interview
 - * Pre-cleaning: header cleaning; reverse ultrafiltration; fiber flush; interview
- * **INTERVIEW** reuse technician: germicide use; dialyzer labeling
- * **REVIEW facility documentation**
 - * Reuse QA audits: labeling; set up for use; reprocessing procedures
 - * Reuse equipment maintenance
 - * Reuse adverse occurrences

Dialysis Equipment Maintenance

- * **USE** Core Survey “Machine Equipment/Maintenance” worksheet or STAR
- * **INTERVIEW HD machine maintenance personnel:** HD machine maintenance DFU
- * **REVIEW** Preventative maintenance documentation for in-center and home HD machines maintained by facility (10% minimum 3)
- * **REVIEW** calibration logs
 - * Meter used for HD machine maintenance and repair
 - * Meters used for testing dialysate conductivity and pH at point of use

Home Dialysis Training and Support Review

- * **INTERVIEW** Home Dialysis Nurse(s) **USE** Core Survey interview guide or STAR
- * **OBSERVE** patient care, if occurring
- * **Also conducted during other survey tasks:**
 - * Patient Interviews
 - * Medical Record Reviews
 - * Environmental “Flash” Tour
- * **FOCUS** on:
 - * Patients’ Rights to be informed of options
 - * Adequate training (newly admitted patients)
 - * Patient and equipment monitoring

Patient Interviews

Listening to the patient “voices”

- * **INTERVIEW** all sampled patients, if possible
- * **Minimum** of 4 “interviewable” patients
 - * Select other patients if <4 from sample possible
- * **ASK** “Core” questions from interview guides or STAR, additional questions as applicable to individual patient

Medical Record Reviews

- * **USE** Medical Record Review worksheets or STAR
- * **REVIEW** medical record for ALL sampled patients
- * **Dialysis prescription/ medication orders and dialysis treatment records** reviewed for ALL active sampled patients
 - * Looking at fluid management, patient monitoring, hemodialysis safety, implementation of plan of care
- * **FOCUS** remainder of review on the care pertaining to the sampling criteria for that patient

Personnel Interviews

Bringing out the staff “voices”

- **Interview:**
 - * Medical Director
 - * Nurse Manager
 - * Nursing Staff (2-3 including RNs, LPNs, PCTs)
 - * Registered Dietitian
 - * Master’s Prepared Social Worker
 - * Home Training Nurse(s)
 - * Water Treatment Tech*
 - * Reuse Tech*
 - * Equipment Maintenance Tech*
*Interview included in Task Review worksheets
- **ASK** the “Core” questions from Core Survey interview guides or STAR, additional questions as guided by the survey issues

Personnel Record Reviews

- * **PRESENT** blank “ESRD Core Survey Personnel File Review” worksheet to facility for completion
- * **REVIEW** facility-submitted documentation
- * **REVIEW** minimum of 3 selected personnel files to:
 - * Validate accuracy of facility documentation
 - * Investigate concerns identified regarding personnel
 - * Investigate incomplete or irregular facility entries

QAPI Review- Use the QAPI Review Worksheet

- * **SEGMENT I:**
 - * **Monitoring** all expected clinical and operational areas
 - * Interdisciplinary Team involvement
 - * Technical operations oversight
- * **SEGMENT II: Performance Improvement in**
 - * Mortality analysis
 - * Infection prevention and control
 - * Error/adverse occurrence/clinical variance tracking, investigation, and resolution—tracer methodology—follow an occurrence
 - * Data-driven focus areas and survey findings
- * **SEGMENT III: Culture of Safety**
 - * Risk/error/occurrence/near miss identification
 - * Staff suggestion/complaint system
 - * Patients' HRQOL; Suggestion/complaint/grievance system; Satisfaction survey

Decision Making & Exit Conference

- * **MEET** as a survey team to discuss survey findings and determine preliminary level of deficient practices
- * **PLAN** for presentation of findings at Exit Conference
- * **PRESENT** findings to facility during Exit Conference
- * **EXPLAIN** to facility that the ESRD Network may assist them with performance improvement of deficient practices identified during survey