

ESRD Survey Training

ESRD Core Survey Field Manual Version 1.2





ESRD Core Survey Field Manual

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Tab 1: ESRD Core Survey Process

The ESRD Core Survey Process

The ESRD Core Survey Process is intended to increase the efficiency and effectiveness of ESRD surveys with focus on contemporary issues in dialysis care. The contemporary issues of the ESRD Core Survey are:

Themes of the ESRD Core Survey:

- **Data Use:** Facility-specific and patient-specific data are central to the ESRD Core Survey for focusing the survey process reviews and monitoring the facility practices/outcomes where the need for improvement is indicated. When available, patient-specific data are used to develop risk-adjusted rates for the comparative review of facilities.
- **Infection Prevention and Control:** With infection identified as the second leading cause of death in dialysis patients, the review of infection control is significantly increased in the ESRD Core Survey. Aspects inherent to the dialysis facility milieu place the patients at increased risk for transmission of blood-borne infections. The Core Survey includes the use of innovative observational checklists and a detailed QAPI infection control review to assure a comprehensive look at all components of the facility infection control program. Focusing on infection control in the ESRD Core Survey should keep patients safer from healthcare associated infections and model appropriate infection control practices for providers.
- **QAPI:** The ESRD Core Survey emphasizes the importance of a functional and robust facility-based QAPI program to continually protect patients and assure quality of care. The QAPI review task in the ESRD Core Survey Process is expanded from the traditional survey process, and serves as a model for ESRD providers. Throughout the ESRD Core Survey, documentation of the facility's oversight of its operations, such as audits of staff practices and technical areas, is used in lieu of more time-consuming tasks in the traditional ESRD survey process.

Threads throughout the ESRD Core Survey:

- **Culture of Safety:** The Core Survey emphasizes the importance of a systemic facility culture that supports open communication, consistent reporting of events/errors/near misses without fear of retribution, and clear expectations for staff practices. The ESRD Core Survey uses interviews with patients and all levels of staff and QAPI review to monitor a facility's culture of safety.
- **Safety of Dialysis Delivery:** The technical nature of dialysis treatment places the patients at significant risk if there is isolated or systemic failure to follow precise procedures for operation, maintenance, and monitoring of the water/dialysate, dialyzer reprocessing and dialysis delivery equipment/systems. The ESRD Core Survey Process takes a focused approach to review of the critical elements of dialysis technical systems that have clear potential to impact patient safety.
- **Patient Voice:** The ESRD Core Survey process places emphasis on listening to the individual patient's point of view and to collective patients' voices regarding care received and presence (or absence) of an environment where patient input is sought and welcomed.

Presentation:

- **Tasks:** To promote consistency the ESRD Core Survey process is described in detailed steps for each task of the survey process. Regulatory references are provided for surveyors to obtain additional information.
- **Tools:** Many of the survey tasks are accompanied by survey tools which aid in the administration of that task. The existence of survey tools is designated with a ▲ on the ESRD Core Survey.
- **Triggers:** Each survey task includes a list of "triggers" which, if identified during administration of that core survey task, indicate that deficient practice is present and that citation or further investigation into that area is warranted to assure patient safety and quality of care.

ESRD Core Survey Process

Purposes:

- 1) To most efficiently utilize survey resources to identify deficient facility practices which have real potential for negatively impacting dialysis patient safety and clinical outcomes;
and
- 2) To maximize the impact the survey may have on improving patient outcomes through individualizing focus of each survey on the clinical areas where performance improvement is indicated in that facility based on facility-specific data and information

Using the ESRD Core Survey Process: The ESRD Core Survey process is organized by review areas/survey tasks 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 which, if identified by the surveyor during the ESRD Core Survey activity, denotes that a citation may be indicated or more comprehensive investigation into that area should be conducted to determine if and what level of citation is indicated. 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 task or trigger in the Core Survey. Note that not all Core Survey tasks are appropriate for extension, as they are already comprehensive reviews of that area as written, i.e., Presurvey Preparation, Patient Sample Selection, and Entrance Conference.

Facility-based survey: This survey process is intended to determine that the individual dialysis facility (i.e., single Medicare certification number) and the associated on-site staff 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 conduct the care/duties in that area. The facility record reviews must be of those for that facility only.

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

➡ **Presurvey Preparation:** ▲

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

Review the most current Dialysis Facility Report (DFR): *At a minimum, review the narrative portions and the facility and comparative outcomes for the indicators specified in the Presurvey Preparation section of the “ESRD Core Survey Data Tools” for the current fiscal year. If the facility outcomes 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 section of the “ESRD Core Survey Data Tools” 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, etc.).*

➡ **Introductions:**

Purpose - To introduce the survey team, announce the survey, and to give the 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 from the “ESRD Core Survey Data Tools” for the current fiscal year. Explain that these are the items the survey team will need to conduct the survey and that the facility should provide the materials on the first 3 pages, i.e., patient-specific and facility current clinical outcomes information, within 3 hours for discussion during the Entrance Conference.*

➡ **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 these four patient-related areas of the facility: *This is a “flash” look at the patient-related areas listed below, looking for observable indicators of patient safety concerns.*

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. Getting an idea of whether the facility culture supports open communication, clarity for staff on the expectations of their roles, and all levels of staff engaged in identifying and effectively addressing risks and errors in its operations is important to evaluating the strength of the QAPI program and how patients are protected from recurring medical errors. To help understand the role the direct care staff play in this process asking technicians and nurses about actions taken when errors or “near misses” occur can demonstrate if the program is active and effective. Asking staff questions about the facility culture early in the survey is recommended.*

Examples of questions for staff:

- What can a technician or nurse here do to prevent or reduce treatment errors?
- What errors or near misses are staff expected to report?
- Do you feel comfortable reporting errors, or making suggestions for improvement at the facility?
- How and to whom would you report an error or near miss you observed or were involved in?
- Would your reporting responsibility be different if you made the error or near miss or simply observed it?
- How would you expect the error or near miss to be addressed? What is your role in follow up?
- How are you involved in the QAPI program? What are the goals and activities of the QAPI Team?

In-center dialysis patient treatment area - Observe a sample of 25% (minimum of 3) dialysis stations with patients undergoing treatments and the availability and functionality of emergency resuscitation and evacuation equipment. 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.”

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)

- Clear 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)
- Functional emergency resuscitation equipment (i.e., AED/defibrillator, oxygen, suction, emergency medications) not present (V413); emergency evacuation equipment insufficient or unavailable (V415)
- Hemodialysis machines in obvious poor repair (e.g., alarms not functional, missing components) (V403)
- If dialyzer reuse, strong 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: 2 or more carbon tanks, with sampling port between not present (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: absence of functioning resistivity monitor, no audible AND visible alarm in patient treatment area, absence of automatic divert-to-drain or automatic cut-off valve to stop water flow to the dialysis stations if resistivity falls <1 megohm, DI not monitored twice/day (V202, 203)
- Water distribution equipment in obvious 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 obvious 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 full of blood, leaking, port caps off (V343)
- Stored dialyzers not protected from unauthorized access (V321)

- Reprocessing room or equipment in obvious 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 layout, infection control and availability of emergency equipment with method for summoning immediate assistance.*

Triggers for citation or more investigation of concerns:

- Insufficient space in home dialysis patient training area to prevent cross-contamination between patients if >1 patient trained at a time (V404)
- Insufficient methods to provide home dialysis 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)
- No functional emergency resuscitation equipment present or immediately available (V413)
- No method for summoning immediate assistance for patient or solitary staff (V402)

Extending the 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)

➡ Entrance Conference: ▲

Purpose - To communicate with facility administrative personnel and determine the data-driven focus areas of the survey for patient care/management and QAPI review, based on facility DFR and current facility outcomes data

Explain purpose and timeline for the survey

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

Obtain documentation of current patient-specific and facility clinical outcomes data from the *Entrance Conference Materials List*.

Review and discuss with the administrative person the current patient outcomes data submitted.

Compare the current facility outcome averages listed in the “% Met Goal” column from the *Clinical Outcomes Tables* to the applicable “**Threshold for % Met Goal**” on the *Clinical Outcomes Thresholds Table 1* in the “*ESRD Core Survey Data Tool*” for the current fiscal year. **Ask** about actions being taken for improvement in the areas where these 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 should be the clinical areas where improvement is currently needed.

*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 thresholds listed in the *Clinical Outcomes Thresholds Table 1* for that area, DO NOT include that as a data-driven focus area for review.*

➡ **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 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. Include an observation of the care for at least one patient with a central venous catheter (CVC), and one patient with an AV fistula/graft (AVF/AVG). 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.

- Pre-dialysis vascular access care and initiation of hemodialysis
- Discontinuation of a patient's hemodialysis treatment and post-dialysis vascular access care (CVC and AVF/G)
 - *For facilities with poor infection outcomes, observe 1-2 additional vascular access care opportunities each for patients with CVC and AVF/G*
- Cleaning and disinfection of the dialysis station between patients
- Preparation of the dialysis machine and extracorporeal circuit
- Dialysis Supply Management: *While conducting the above observations, note the supply management and supply contamination prevention activities.*

Triggers for citation or more investigation of concerns:

- Observed trends of breaches in infection control patient care practices:
 - Hand hygiene and glove use (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 vascular access care (V550)
- Not adequately disinfecting the HD station & equipment between patients (V122)
- 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 monitor 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, if possible, preparing and administering medications to 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 procedures above, looking 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:** The only exceptions to this requirement are when there is a patient emergency, and when there is only 1 RN on duty who may be required to deliver care to an HBV+ patient and HBV susceptible patients on the same shift, e.g., medication administration, CVC access.
- When only 1 RN is on duty, poor infection control separation between care to HBV+ and HBV susceptible patients (V131)
- 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)

➡ Patient Sample Selection:

Purpose - To select a core patient sample that represents the facility systems for patient care and management in the data-driven focus areas, i.e., clinical areas where facility data indicates improvements are needed, and 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 on the Entrance Conference Materials List

Select 10% of the total number of patients on census (minimum 4; maximum 10) representing all dialysis modalities offered at the facility. Attempt to include in-center hemodialysis patients from different days/shifts. You may expand the patient sample if indicated. Select patients using the criteria below:

Criteria for patient selection:

- **Unstable** - To review the facility process for interdisciplinary team (IDT) functionality in the patient assessment and plan of care process for the most fragile patients
- **New admission <90 days** - To review 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.
- **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.
- **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.
- **Not meeting outcome goals in the data-driven focus areas** selected during the Entrance Conference. Using the patient-specific information submitted on the Entrance Conference Materials List, i.e., the lists of patients' names in the Clinical Outcomes tables; lists of patients' labs, hospitalization logs, infection logs. Select patients with trends of not meeting outcome goals in the data-driven focus areas for the survey.
- **Based on observations and complaints** - You may also sample patients for whom you identified possible concerns during the survey. Patients involved with a complaint being investigated during the survey may also be included in the patient sample.

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; maximum of 10) representing every dialysis modality provided at the facility, for “Patient Interviews” and “Medical Record Review.”

Record the patient sample - Designate the rationale 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.

➡ **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 staff 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” procedures and the amount of carbon in the system (empty bed contact time-EBCT). If the facility is using a continuous on-line chlorine monitor, **ask** about periodic (usually daily) validation testing with an alternate method.

- **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.
- **Observe deionization(DI) and resistivity monitor and alarm, if present, and interview** about the presence of an automatic divert-to-drain or automatic cut-off valve to stop 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).

Interview the person responsible for microbiological 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.

Review facility 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: 3 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 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:

- Chlorine removal/carbon system
 - 2 or more carbon tanks with sample port between **not** present (V192)
 - Insufficient carbon empty bed contact time (<10 minutes total EBCT)-verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)
 - Observed total chlorine test result greater than maximum allowable level; 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.

- RO
 - RO % rejection and product water conductivity or TDS not monitored daily or alarm non-functional, not audible in patient treatment area (V200)

Extending should include an interview with technical administrative staff. **Note** that the absence of functional methods for monitoring RO function and warning staff of problems is citable on identification.

If the water treatment components appear in obvious disrepair, consider reviewing the pre-treatment and water distribution components for compliance with the applicable V-tags (V188-191, V198-215).

- DI, if present
 - Resistivity monitor or alarm non-functional; alarm not audible **and** visible in patient treatment area; resistivity not monitored and recorded at least twice per treatment day (V202, 203)
 - Automatic divert-to-drain or automatic cut-off valve to stop water flow to the dialysis machines not present or non-functional (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.

- Interviews
 - 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, etc. (V260)

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).

- Log reviews
 - 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, 196, 199, 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 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, etc.

➔ **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 they are reprocessed or, 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.*

Focused interview with 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:

- **QA audits - Review** 12 months of facility documentation of the following reuse observational audits. For clarification, 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, 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 (V321)
- Knowledge deficit of reuse tech in key patient safety areas per interview guide (V309, 319, 320, 328, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)
- QA audits listed above not done or incomplete - **Extend** to review all of the required QA audits for reuse (V362-368)
- 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.

➡ **Dialysis Equipment Maintenance Review:** ▲

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

Interview machine maintenance personnel – *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).*

➡ **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., Environmental Tour, Water/dialysate review and Dialysis Equipment Maintenance (if 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, observe the care delivery. Look for adherence to infection control practices.*

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.

- 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 (V628).

***Extending** review of the home 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.*

➡ **Patient Interviews:** ▲

Purpose - To listen to the patients' voices as recipients of the care provided at the facility, to evaluate patients' understanding of their rights and responsibilities, to determine how safe 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. Interview home patients in the facility or ask the home training nurse to contact the patient to alert him/her that the surveyor will be calling for an interview.*

*After attempting to interview the sampled patients in person or by phone, 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.*

*Individualize patient interviews to focus on each patient's issues, however **ask** at least the "core" questions listed on the applicable ESRD Core Survey Patient Interview Worksheet.*

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.

➡ **Medical Record Review:** ▲

Purpose - To verify the provision of safe, effective, interdisciplinary care through the staff 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 in the area/rationale 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 area/rationale for sampling that patient, using the following guidelines:

Dialysis prescription/medication orders and dialysis treatment records for all sampled patients (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.
- **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 poor outcomes, i.e., not meeting goals, 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 for monitoring the patient's outcome(s), recognizing when a problem exists or a goal is not reached, and taking action to address it.

- 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 took actions toward improvement/resolution.

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, 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*

“Unstable” patients - *Review the IDT documentation in progress notes, physician's orders, assessments, results of physical and mental functioning surveys (KDQOL-36 or other age-appropriate 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.

Newly admitted patients (<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.

Home HD and PD dialysis patients - *If an interview with patient or staff indicates possible concerns related to inadequate training for the patient and/or caregiver, review documentation of training.*

- **Home HD patients:** *In addition to the above areas applicable to a sampled home HD patient, review documentation of water/dialysate chemical and microbiological quality, as applicable for the hemodialysis equipment in use.*
- **LTC residents receiving home dialysis at the LTC facility:** *If there are long term care (LTC) residents on census who receive home hemodialysis or peritoneal dialysis treatments 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.*

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. For more information, refer to the current CMS Survey and Certification guidance on “Dialysis Admission, Transfer and Discharge Practices”

*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 may need to **interview** the facility qualified social worker and other applicable staff 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, that 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
- 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.

➡ **Personnel Interviews:** ▲

Purpose - To assess 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 in-person or offer to interview by phone- *You may 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.

➡ **Personnel Record Review:** ▲

Purpose - To verify that personnel have the qualifications 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.

Review selected personnel files: *Select a minimum of 3 personnel files to review for verification of the accuracy of the facility-submitted documentation. Select the files using the criteria below:*

- Identified concerns 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.

➡ **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, take actions to attain and sustain improvements, and support a facility-wide "Culture of Safety" that assures optimum patient safety

The QAPI review is divided into 3 General 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 in the technical areas.

Note: The Quality assessment and performance improvement 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 of water/dialysate, equipment maintenance/repair, and dialyzer reuse programs through review of outcomes and practice audits.

Segment II: Review of Quality Assessment and Performance Improvement in three critical priority areas for ALL facilities and in the data-driven focus areas and survey findings areas of this facility survey. This involves a detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and addressing 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, you will "follow" 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 assures patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients, communication of clear expectations of staff, and 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. You will review the facility staff complaint/suggestion log.
- **Patient engagement:** Looking at the facility program for assessing and addressing patients' mental and physical health outcomes. You will also review 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 to enable 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 you to determine if the facility has identified the same concerns 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 you will focus on during Segment II.*

Review the QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-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 dashboard or other 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, as required in the Conditions for Coverage:

- **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 dialysate ph/conductivity; testing water for total chlorine and microbiological sample collection (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 (V635)

Segment II: Review of Quality Assessment and Performance Improvement 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 Team 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 focused QAPI review on the aspects of care related to specific-cause categories. Examples are: for high rates of deaths due to **infection causes** the QAPI Team 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 QAPI Team 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.

➤ **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.

Review the past 6 months of QAPI documentation in these areas:

- **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 person to show you the QAPI documentation of oversight for surveillance and vaccinations including:
 - Hepatitis B patient surveillance and 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
- 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 took meaningful actions to investigate the problem, implement performance improvement plans, and monitor them for effectiveness V637).
- **Staff education and visual practice audits for infection control:** *Ask:* What are staff taught about the prevention of infections in dialysis? How often are they re-educated in infection prevention? How often do you visually audit personnel infection control practices? 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 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. There should be evidence of actions taken toward improvement when lapses in practices were observed, i.e., applicable staff involved in the investigation into issues surrounding the practices such as low staffing, and development and implementation of improvement plans, rather than not just counseling or reeducating (V637, 142).
- **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/or 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 (e.g., you observed staff not identifying patients' reprocessed dialyzers as required, and select an error to follow when a patient was dialyzed on another patient's dialyzer). Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI Team 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 determine 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, **Review** those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask: How does the QAPI Team prioritize their performance improvement activities? How did the QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did they 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 the QAPI Team take?

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

- Expect to see evidence that the facility QAPI Team:
 - 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 true 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 clear expectations of staff practices. A culture of safety supports complete staff and patient engagement and assures 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 in 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, e.g., KDQOL-36? 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 by the QAPI Team.*

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

- Expect to see that the QAPI Team 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 QAPI Team 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 QAPI Team 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 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 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 person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient.

- 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 in 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 (V638)
- Promote 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 meaningful efforts are being made to promote 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

Outline of ESRD Core Survey Process

Presurvey Preparation:

- *Review the most current dialysis facility report following "Data Tools" guidance*
- *Contact the ESRD Network about quality concerns*
- *Review facility complaint & survey history*
- *Copy Entrance Conference Materials list from the "Data Tools" worksheet*

Introductions: *Contact the person in charge; explain purpose of the survey; present them w/ Entrance Conference Materials list to complete w/in 3 hours for Entrance Conference*

Environmental "Flash" Tour: *Observe the 4 patient-related areas below; 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 of functionality of emergency equip*

Triggers:

- Dummy drip chambers present (V400, 403)
- Vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- 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 (V413); insufficient or unavailable emergency evacuation supplies (V415)
- Hemodialysis machines in obvious poor repair (V403)
- If dialyzer reuse, noticeable strong germicide odors (V318)
- Disrespectful communication or actions toward patients (V452, 627)
- Failure to offer patients privacy & confidentiality (V454)

- **Water treatment/dialysate preparation area:** *Observe the 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: absence of functioning resistivity monitor & alarm visible & audible in tx area, absence of automatic divert-to-drain or auto cut-off valve, DI not monitored twice/day (V202, 203)
- Water distribution equip in obvious 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)
- Reprocessing room or equip in obvious disrepair (V318, 403)
- Dirty dialyzers kept at room temperature >2 hrs (V331)
- Dialyzer refrigerator temperature 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

- **Home dialysis training area:** *Observe the physical layout, infection control & availability of emergency equip with method for summoning 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 emergency resuscitation equip or immediately available (V413)
- No method for summoning immediate assistance (V402)

Triggers for extending the tour to other areas:

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

Entrance Conference: *with the facility administrative person*

- *Explain purpose & timeline of survey; Ask questions from "Entrance Conference Questions"*
- *Obtain current facility outcomes on completed Entrance Conference Materials List*
- *Review & discuss the current facility outcomes with the administrative person*
- *Compare the current facility outcomes in "Met Goal" column of Entrance Conference Materials List with applicable "Threshold for % Met Goal" in "Clinical Outcomes Threshold Table 1" in "Data Tools" worksheet*
- *Determine the data-driven focus areas for survey clinical reviews (areas where 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:*

- Pre-dialysis vascular access care & initiation of hemodialysis
- Discontinuation of a patient's HD tx & post-dialysis vascular access care (CVC & AVF/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:
 - Hand hygiene & glove use (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 vascular access care (V550)
 - Not adequately disinfecting the HD station/equip between patients (V122)
- 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)

Outline of ESRD Core Survey Process

- 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)
 - When 1 RN on duty, poor infection control separation between care to HBV+ & susceptible patients (V131)
 - 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 List**
 - **Select 10% of total # of patients on census (min 4, max 10) representing all modalities offered, using criteria below:**
 - “Unstable” patients
 - New admissions <90 days
 - Involuntary discharges in past 12 months, not previously investigated by State Agency
 - LTC residents receiving home dialysis at the LTC facility
 - Not meeting goals in the data-driven-focus areas for the survey
 - Observed w/concerns or involved in a complaint to be investigated
 - **Record the patient sample w/rationale used for selecting them (as listed above)**
- **Water Treatment & Dialysate Review:** *Review the critical water treatment components with the person(s) responsible for the activity & daily monitoring:*
 - **Observe the total chlorine test; interview about maximum allowable total chlorine: actions taken for breakthrough; amount of carbon (EBCT) present; validating on-line chlorine monitor, if present**
 - Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-verify this by interview or record review; surveyors not expected to calculate (V195)
 - Observed total chlorine test result greater than maximum allowable level; test done incorrectly or with incorrect reagents/equip (V196)
 - Staff unaware of max allowable level of 0.1mg/L total chlorine & breakthrough procedures (V260)
 - **Observe the reverse osmosis (RO) unit, water quality monitor & alarm; interview about monitoring RO function by % rejection & water quality by TDS or conductivity**

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Outline of ESRD Core Survey Process

- Germicide not stored, mixed or handled per manufacturer's DFU (V339)
 - Reuse tech interview w/inadequate knowledge of key patient safety areas (V309, 319, 320, 328, 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, 356, 635)
- For centralized reprocessing, refer to the current CMS Survey & Certification guidance*

Dialysis Equipment Maintenance:

- **Interview machine maintenance personnel** 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 equipment 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 and Dialysis Equipment Maintenance (if applicable to the equipment in use), Personnel Record Review, and QAPI Review

- **Interview the home training nurse(s)** about 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, observe the care.
 - **Interview home dialysis patients** during Patient Interviews; if not at the facility, ask the home training nurse to contact the patient to alert that the surveyor will be calling to interview.
 - **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 monitoring home dialysis patients (V585, 586, 593-595)
 - Not evaluating home program outcomes separately in QAPI (V628)
 - If care was observed, refer to the triggers for infection control in Observations of HD Care

Patient Interviews:

Interview the sampled patients, minimum of 4 patients interviewed. If <4 sampled patients can be interviewed, select additional alert patients to interview for total of at least 4. For home patients, ask nurse to alert patient about interview. Refer to the Core Survey Patient Interview worksheets.

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 in the area/rationale used for sampling the patient

- **Review the medical records of all sampled patients** (10% census as selected at Patient Sample Selection)
 - **For ALL sampled patients, review the dialysis prescription/orders, medication orders, & the documentation of dialysis delivery** (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
 - **For PD:** looking for staff monitoring patient's adherence to orders, BP/fluid management
 - **Patients w/poor outcomes in data-driven focus areas: review parts of medical record about THAT area** (e.g., 3 mos of THAT lab result, progress notes, medication orders, care plans, etc.)
 - Looking for facility actions for monitoring, recognizing the poor outcomes, & addressing it through taking actions to help patient reach outcome goals
 - **Unstable patients: review IDT activities during the 2 most recent assessment/plan of care periods in progress notes, orders, assessments, plans of care**
 - Looking at the functionality of the IDT for addressing the reasons patient was deemed 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
 - **Home HD patients: review water/dialysate quality testing appropriate to equip in use**
 - **For Involuntarily discharged patients & home dialysis LTC residents follow the current CMS Survey & Certification guidance for review**
- 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

Outline of ESRD Core Survey Process

Personnel Interviews: Interview in-person or by phone: med director, master's social worker, registered dietitian, 2-3 nursing staff (min. 1 RN & 1 PCT) & nurse manager (if necessary). Refer to the Core Survey Interview worksheets. Note that the water/dialysate, reuse, equipment maintenance & home training staff are interviewed during those survey tasks.

Triggers:

- 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:

- Review the facility-completed "Personnel File Review" worksheet
- Select a minimum of 3 personnel files to review/compare to facility documentation for accuracy
- 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 Review: Prepare for QAPI review by communicating with survey team about areas of concern. Determine the focus areas to review during Segment II Performance Improvement (i.e., data-driven focus areas & survey findings)

Review the QAPI documentation for the past 6 months while interviewing the facility-based responsible person

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Segment I: Monitoring care & facility operations

- Clinical & operational indicators: Review (briefly) facility QAPI dashboard or summarizing info to verify that all expected clinical & operational indicators are being monitored-refer to table/list of indicators in "QAPI Review Worksheet"
- Oversight of technical operations & practice audits: Review QAPI documentation of review/discussion/audits of:
 - 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: Quality Assessment & Performance Improvement in 3 critical priority areas & data-driven focus areas & survey findings (areas of risk) Review/Interview re QAPI activities for the 3 critical priority areas & focus areas specific to this survey.

- 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 list; 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: Review visual audits of staff while caring for patients; infection control education & each staff member visually audited at least annually; applicable staff included in performance improvement plan development

- 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: The 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 a responsible person.
- Data-driven focus areas & survey findings: Review the 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 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 "ESRD 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 (e.g., KDQOL-36) are tracked & trended in QAPI; what the threshold is for patient referrals
 - Review QAPI Team analysis/discussion/action for patient QOL 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 them to show how it was investigated, resolved & result reported to patient
 - 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)
- Promote a culture of quality & safety (V627)

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

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

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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)
- 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 (V413); insufficient or unavailable emergency evacuation supplies (V415)
- Hemodialysis machines in obvious poor repair (V403)
- If dialyzer reuse, noticeable strong 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: absence of functioning resistivity monitor & alarm visible & audible in tx area, absence of automatic divert-to-drain or auto cut-off valve, DI not monitored twice/day (V202, 203)
- Water distribution equip in obvious 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)
- Reprocessing room or equipment in obvious 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 emergency resuscitation equip or immediately available (V413)
- No method for summoning immediate assistance (V402)

Extending the tour to other areas:

- 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)

Observations of Hemodialysis Care and Infection Control Practices:

Observations of direct staff delivering care

- Observed trends of breaches in infection control patient care practices:
 - Hand hygiene & glove use (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 vascular access care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- 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)
- When 1 RN on duty, poor infection control separation between care to HBV+ & susceptible patients (V131)
- 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-verify this by interview or record review, surveys not expected to calculate (V195)
- Observed total chlorine test result greater than maximum allowable level; test done incorrectly or with incorrect reagents/equip (V196)
- Staff unaware of max allowable level of 0.1mg/L total chlorine & breakthrough procedures (V260)

Reverse osmosis system

- Absence of RO % rejection & product water TDS monitor & alarm audible in patient tx area (V200)

ESRD Core Survey Process Triggers

DI, if present

- 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 auto cut-off 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 procedures (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, 196, 199, 213, 252, 253)
- Microbiological results exceeding action/maximum levels & no documentation of appropriate actions taken (V178, 180)
- Practice audits of staff conducted < 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 (V339)
- Reuse tech interview w/inadequate knowledge of key patient safety areas (V309, 319, 320, 328, 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, 356, 635)

For centralized reprocessing, refer to the current CMS Survey & Certification guidance

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 monitoring home dialysis patients (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)
- 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:

- 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 - *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:

- 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:

- Administer oversight of all facility operations: monitor all areas & conduct practice 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)
- Promote a culture of quality & safety (V627)



ESRD Core Survey Field Manual

Tab 3: Presurvey Preparation & Introductions

- Excerpts from ESRD Core Survey Process
- Data Tools Worksheet
- CMS 3427 End Stage Renal Disease Survey and Certification Report (03/12)
- Personnel File Review Worksheet

➡ **Presurvey Preparation:** ▲

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

Review the most current Dialysis Facility Report (DFR): *At a minimum, review the narrative portions and the facility and comparative outcomes for the indicators specified in the Presurvey Preparation section of the “ESRD Core Survey Data Tools” for the current fiscal year. If the facility outcomes 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 section of the “ESRD Core Survey Data Tools” 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, etc.).*

➡ **Introductions:**

Purpose - To introduce the survey team, announce the survey, and to give the 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 from the “ESRD Core Survey Data Tools” for the current fiscal year. Explain that these are the items the survey team will need to conduct the survey and that the facility should provide the materials on the first 3 pages, i.e., patient-specific and facility current clinical outcomes information, within 3 hours for discussion during the Entrance Conference.*

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ESRD CORE SURVEY DATA TOOLS

Facility: _____ **Date:** _____

CCN: _____ **Surveyor:** _____

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

Contents: There are 3 sections of this Tool:

- I. Presurvey Preparation and Dialysis Facility Report (DFR) Review** guidance for 2012 DFR used during FY 2013, ESRD Network contact, and facility history review
- II. Entrance Conference Materials List with Clinical Outcomes Tables** to be copied and given to the facility during “Introductions” (pages 3-6)
- III. Clinical Outcomes Thresholds Table 1** for comparison with current facility clinical outcomes to determine the data-driven focus areas for the survey

I. PRESURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW:

Review the 2012 DFR for the facility. At a minimum, review the narrative portions on pages 1-4 and the following data elements. **Some elements list 4-year averages (2008-2011), as well as individual years. With standardized mortality (SMR) and transplant rate (STR), the 4-year average is a more consistent measure of facility performance. For standardized hospitalization rate (SHR), the most recent 1-year statistic is most meaningful. Examine trends across years when data are available.**

Flag which elements are worse than expected as compared to the U.S. average listed. Those areas should be considered as **preliminary data-driven focus areas** for the survey.

Mortality (4 year average)	U.S. Average	Facility
Standardized Mortality Ratio (SMR) - pg. 5 Table 1, 1h Facility SMR for 2008-2011 Facility SMR for 2011 <i>If the facility's SMR for 2008-2011 ≥ 0.89 or the facility's SMR for 2011 ≥ 0.83, plan to place emphasis on the mortality review during QAPI Review Segment II. To prepare, note if either cause of death (Table 1, 1f) for this facility is worse than the U.S. data.</i>	1.00	
Hospitalization (2011 and trend*)	U.S. Average	Facility
Diagnoses - pg. 6 Table 2, 2o <ul style="list-style-type: none"> • Congestive heart failure • Cardiac dysrhythmia • Cardiac arrest 	22% 12.9% 1.4%	
Readmissions within 30 days – pg. 6 Table 2, 2s	31.1%	
Infection/Dialysis Access (2011 and trend*)	U.S. Average	Facility
Deaths due to infection - pg. 5 Table 1, 1f	15.5%	
Hospitalizations for septicemia - pg. 6 Table 2, 2o	11.2%	
HD access-related infection – pg. 11 Table 8, 8f	2.55/100 pt mo	
CVCs in use - pg. 11 Table 7, 7b	21.1%	
Anemia (2011 and trend*)	U.S. Average	Facility
Hemoglobin (HD) <10 g/dL - pg. 10 Table 6, 6i	4.7%	
Hemoglobin (PD) <10 g/dL - pg. 10 Table 6, 6k	11.1%	

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ESRD CORE SURVEY DATA TOOLS**

Dialysis Adequacy (2011 and trend*)	U.S. Average	Facility
URR ≥65 (HD) - pg. 10 Table 6, 6n	97.5%	
Kt/V ≥1.2 (HD) - pg. 10 Table 6, 6s <i>To calculate, subtract 2011 value in 6s for Kt/V < 1.2 from 100%</i>	96.6%	
Missing/Out of Range/Not Performed, Expired pg. 10 Table 6, 6s <i>An elevated value indicates failure to monitor dialysis adequacy, a practice associated with mortality & morbidity. If elevated, review the facility's Kt/V monitoring in Segment I of QAPI Review.</i>	8.1%	
Kt/V ≥1.7 weekly (PD) - pg. 10 Table 6, 6x <i>To calculate, subtract 2011 value in 6x for Kt/V < 1.7 from 100%</i>	89.8%	
Missing/Out of Range/Not Performed, Expired pg. 10 Table 6, 6x <i>An elevated value indicates failure to monitor dialysis adequacy, a practice associated with mortality & morbidity. If elevated, review the facility's Kt/V monitoring in Segment I of QAPI Review.</i>	14.1%	
Transplantation	Average	Facility
1st transplant STR (4 yr) -pg. 8 Table 3, 3h; <i>Enter state & facility avg.</i>	1.22 (state)	
Transplant waitlist (2011 & trend*) - pg. 8 Table 4, 4b	24.4% (U.S.)	
Influenza Vaccination (2011 and trend*)	U.S. Average	Facility
Patients vaccinated (9/1/2010-3/31/2011) - pg. 9 Table 5, 5d	68%	

*Notate trends over years, which are key aspects of facility performance in addition to the value.

Contact the ESRD Network: *Prior to the survey, 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 your State Agency office, in ASPEN, and on the last page 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 the preliminary data-driven focus areas for this survey: _____

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ESRD CORE SURVEY DATA TOOLS

II. ENTRANCE CONFERENCE MATERIALS LIST /CLINICAL OUTCOMES TABLES

Guidance to surveyors: Make a copy of 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 Tool.

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 (no transfer to another outpatient dialysis facility) from the facility in the past 12 months
7. All patients transferred or discharged from the facility as "lost to follow up" (i.e., no outpatient dialysis facility identified as patient's destination) for the past 12 months
8. Residents of long term care facilities receiving dialysis at the LTC facility and the name of the LTC where they are receiving dialysis
9. Hospitalization logs with admitting diagnoses listed for 6 months
10. Infection logs for past 6 months
11. Patient lab results for hemoglobin, Kt/V, URR, corrected calcium, phosphorus and albumin for the current 3 months; separated by modality

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ESRD CORE SURVEY DATA TOOLS

Materials needed by the end of Day 1 of survey:

12. Vaccination information:
- # of patients administered complete series of hepatitis B vaccine _____
 - # of patients administered influenza vaccine between September 1 and March 31 _____
 - # of patients administered pneumococcal vaccine _____
13. Patient care staff schedule for the current time period (last two weeks)
14. Policy and procedure manuals for patient care, water treatment, dialysate preparation and delivery, infection control, and dialyzer reprocessing/reuse, if applicable
- Anemia management protocol
15. Patient suggestion/complaint/grievance log for past 6 months
16. Adverse occurrence (e.g., clinical variances, medical errors, unusual events) documentation for the past 6 months
17. QAPI committee meeting minutes for past 6 months and any supporting materials
18. Copy of CMS-approved waivers for medical director, isolation room, as applicable
19. For Water and Dialysate Review: logs for:
- Daily water system monitoring-3 months
 - Chlorine/chloramines 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
20. For Equipment Maintenance Review: 12 months documentation of preventative maintenance and repair
21. 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

22. Completed "Personnel File Review" Worksheet
23. Completed "CMS 3427-End Stage Renal Disease Application and Survey and Certification Report"

**For Fiscal Year 2013 (10/01/12-9/30/13)
ESRD CORE SURVEY DATA TOOLS**

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

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

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

Measure	MAT Goal Unless Other Specified	% Met Goal or Other Specified	Names of Current Patients Who Did Not Meet Goal (or as listed) in ≥ 2 of Last 3 Mo
Adequacy (3 months) Single pool Kt/V Standardized Kt/V URR	≥ 1.2 for 3tx/week ≥ 2.0 weekly for ≥ 4 tx/week $\geq 65\%$	_____ _____ _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____
Anemia (3 months) Hemoglobin	Refer to MAT	<10 g/dL _____	HD Patients with Hgb <10 in ≥ 2 months 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Mineral & bone (3 mo) Calcium corrected for albumin Phosphorus	Normal for lab; preferred <10mg/dL 3.5-5.5 mg/dL	_____ _____	Patients w/ either goal not met in ≥ 2 mos 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Nutrition Albumin (3 mo)	≥ 4 g/dL for BCG; lab normal for BCP	_____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Fluid management (3 mo) Intradialytic weight loss in treatment length ≤ 4 hours	Average intradialytic weight loss <5% body weight	_____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Vascular access (VA) (12 mo) CVCs in use VA infection rate/100 patient months	\downarrow CVC rates \downarrow VA infection rate	CVC in use % _____ _____	Patients with CVC only ≥ 90 days 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
Hospital readmissions within 30 days (12 mo)	Minimize hospital readmissions	Readmission rate _____	HD patients readmitted to hospital within 30 days of discharge in past 3 months 1. _____ 2. _____ 3. _____ 4. _____
Transplant waitlist for patients <70 years old (12 mo)	Interested patients are referred for transplant unless excluded by area transplant criteria	Transplant waitlist rate _____	Interested patients NOT referred for transplant 1. _____ 2. _____ 3. _____ 4. _____

**For Fiscal Year 2013 (10/01/12-9/30/13)
ESRD CORE SURVEY DATA TOOLS**

Signature of person completing this form _____ Date: _____

Peritoneal Dialysis Clinical Outcomes Table

Measure	MAT Goal Unless Other Specified	% Met Goal or Other Specified	Names of Current Patients Who Did Not Meet Goal as listed
Adequacy (6 mo) Kt/V	≥1.7 weekly	_____	Not met in last 6 months 1. _____ 2. _____ 3. _____ 4. _____
Anemia (3 mo) Hemoglobin	Refer to MAT	<10 g/dL _____	Patients w/Hgb <10g/dL for ≥2 months 1. _____ 2. _____ 3. _____ 4. _____
Mineral/bone (3 mo) Calcium corrected for albumin Phosphorus	WNL for lab; <10 mg/dL 3.5-5.5 mg/dL	_____ _____	Either value out of range for ≥2 months 1. _____ 2. _____ 3. _____ 4. _____
Nutrition (3 mo) Albumin	>4g/dL BCG; lab normal for BCP	_____	1. _____ 2. _____ 3. _____ 4. _____
PD infections Peritonitis rate/100 patient months (12 mo)	Minimize peritonitis episodes <3.0/100 patient months	Peritonitis infection rate _____	Current Patients with peritonitis in past 6 months 1. _____ 2. _____ 3. _____ 4. _____
Hospital readmissions within 30 days (12 mo)	Minimize hospital readmissions	Readmission rate _____	Current PD patients readmitted to hospital within 30 days of discharge in past 3 months 1. _____ 2. _____ 3. _____ 4. _____
Transplant waitlist For patients <70 years old (12 mo)	Interested patients referred for transplant unless excluded by area transplant exclusion criteria	Transplant waitlist rate _____	Interested current patients NOT referred for transplant 1. _____ 2. _____ 3. _____ 4. _____

**For Fiscal Year 2013 (10/01/12-9/30/13)
ESRD CORE SURVEY DATA TOOLS**

III. CLINICAL OUTCOMES THRESHOLDS TABLE 1

During the Entrance Conference review and discuss with the administrative person the current patient outcomes data submitted. *Look at the current facility outcomes listed in the “% Met Goal” column from the Clinical Outcomes Tables on pages 3-6, and compare to the applicable “Threshold for % Met Goal” from the Clinical Outcomes Thresholds Table 1 below.*

Clinical Outcomes Thresholds Table 1 for FY 2013

HD Measure	Threshold for % Met Goal	PD Measure	Threshold for % Met Goal
Adequacy: Single pool Kt/V ≥1.2 Standardized Kt/V ≥2.0 for ≥4x/week or nocturnal URR >65%	≥96.6% Kt/V* Not reported ≥97.5% URR*	Adequacy: Kt/V≥1.7	≥89.8%*
Anemia: Hemoglobin <10 g/dL	≤4.7%*	Anemia: Hemoglobin <10 g/dL	≤11.1%*
Mineral & bone disorder: Calcium corrected for albumin (BCG) <10.0 Phosphorus 3.5-5.5 mg/dL	≥90%** ≥70%**	Mineral & bone disorder: Calcium corrected for albumin (BCG) <10.0 Phosphorus 3.5-5.5 mg/dL	≥90%** ≥70%**
Nutrition: Albumin ≥4.0	≥70%**	Nutrition: Albumin ≥4.0	≥70%**
Fluid management: Intradialytic weight loss <5%	≥90%**	N/A	N/A
Vascular access: CVCs in use HD vascular access infections/100 patient months	≤21.1% ≤2.55*	PD Infection Peritonitis rate/100 patient months	≤3.00***
Hospital readmissions within 30 days	≤31.1%*	Hospital readmissions within 30days	≤31.1%*
Transplant waitlist <age70	≥24.4%*	Transplant waitlist <age 70	≥24.4%*

*2012 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

**2012 DOPPS Practice Monitor

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

Note: If the facility lists >3 patients as “lost to follow up” (#7 on Entrance Conference Materials List), **ask** administrative personnel 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.

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. Note: If the facility has attained improvements and is currently meeting the thresholds in the table above in an area where the DFR showed problems, DO NOT include that as a data-driven focus area for review.*

Record the data-driven focus areas for this survey:

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

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT – Version 2

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** (HD & PD)

21. New services being requested (check all that apply-home training & support **only** must provide both home PD & home HD): (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** (HD & PD)

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) _____

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 provide both home PD and home HD and have a plan/arrangement to provide backup dialysis as needed. A new “home training and support only (HD & PD)” 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*). 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.



ESRD Core Survey Field Manual

Tab 4: Environmental "Flash" Tour

- Excerpt from ESRD Core Survey Process

➡ 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 these four patient-related areas of the facility: *This is a “flash” look at the patient-related areas listed below, looking for observable indicators of patient safety concerns.*

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. Getting an idea of whether the facility culture supports open communication, clarity for staff on the expectations of their roles, and all levels of staff engaged in identifying and effectively addressing risks and errors in its operations is important to evaluating the strength of the QAPI program and how patients are protected from recurring medical errors. To help understand the role the direct care staff play in this process asking technicians and nurses about actions taken when errors or “near misses” occur can demonstrate if the program is active and effective. Asking staff questions about the facility culture early in the survey is recommended.*

Examples of questions for staff:

- What can a technician or nurse here do to prevent or reduce treatment errors?
- What errors or near misses are staff expected to report?
- Do you feel comfortable reporting errors, or making suggestions for improvement at the facility?
- How and to whom would you report an error or near miss you observed or were involved in?
- Would your reporting responsibility be different if you made the error or near miss or simply observed it?
- How would you expect the error or near miss to be addressed? What is your role in follow up?
- How are you involved in the QAPI program? What are the goals and activities of the QAPI Team?

In-center dialysis patient treatment area - *Observe a sample of 25% (minimum of 3) dialysis stations with patients undergoing treatments and the availability and functionality of emergency resuscitation equipment. 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.”*

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)
- Clear 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)
- Functional emergency resuscitation equipment (i.e., AED/defibrillator, oxygen, suction, emergency medications) not present (V413)

- Hemodialysis machines in obvious poor repair (e.g., alarms not functional, missing components) (V403)
- If dialyzer reuse, strong 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: 2 or more carbon tanks, with sampling port between not present (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: absence of functioning resistivity monitor, no audible AND visible alarm in patient treatment area, absence of automatic divert-to-drain or automatic cut-off valve to stop water flow to the dialysis stations if resistivity falls <1 megohm, DI not monitored twice/day (V202, 203)
- Water distribution equipment in obvious 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 obvious 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 full of blood, leaking, port caps off (V343)
- Stored dialyzers not protected from unauthorized access (V321)
- Reprocessing room or equipment in obvious 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 layout, infection control and availability of emergency equipment with method for summoning immediate assistance.*

Triggers for citation or more investigation of concerns:

- Insufficient space in home dialysis patient training area to prevent cross-contamination between patients if >1 patient trained at a time (V404)
- Insufficient methods to provide home dialysis 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)
- No functional emergency resuscitation equipment present or immediately available (V413)
- No method for summoning immediate assistance for patient or solitary staff (V402)

Extending the 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

- Excerpt from ESRD Core Survey Process
- Entrance Conference Questions

➡ Entrance Conference: ▲

Purpose - To communicate with facility administrative personnel and determine the data-driven focus areas of the survey for patient care/management and QAPI review, based on facility DFR and current facility outcomes data

Explain purpose and timeline for the survey

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

Obtain documentation of current patient-specific and facility clinical outcomes data from the *Entrance Conference Materials List*.

Review and discuss with the administrative person the current patient outcomes data submitted. *Compare the current facility outcome averages listed in the “% Met Goal” column from the Clinical Outcomes Tables to the applicable “Threshold for % Met Goal” on the Clinical Outcomes Thresholds Table 1 in the “ESRD Core Survey Data Tool” for the current fiscal year. Ask about actions being taken for improvement in the areas where these 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 should be the clinical areas where improvement is currently needed. *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 thresholds listed in the Clinical Outcomes Thresholds Table 1 for that area, DO NOT include that as a data-driven focus area for review.*

**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? _____



ESRD Core Survey Field Manual

Tab 6: Observations of Hemodialysis Care & Infection Control Practices

- Excerpt from ESRD Core Survey Process
- Observations of Hemodialysis Care & Infection Control Practices

➡ **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 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. Include observation of the care for at least one patient with a central venous catheter (CVC), and one patient with an AV fistula/graft (AVF/AVG). 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.*

- Pre-dialysis vascular access care and initiation of hemodialysis
- Discontinuation of a patient's hemodialysis treatment and post-dialysis vascular access care (CVC and AVF/G)
 - *For facilities with poor infection outcomes, observe 1-2 additional vascular access care opportunities each for patients with CVC and AVF/G*
- Cleaning and disinfection of the dialysis station between patients
- Preparation of the dialysis machine and extracorporeal circuit
- Dialysis Supply Management: *While conducting the above observations, note the supply management and supply contamination prevention activities.*

Triggers for citation or more investigation of concerns:

- Observed trends of breaches in infection control patient care practices:
 - Hand hygiene and glove use (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 vascular access care (V550)
- Not adequately disinfecting the HD station & equipment between patients (V122)
- 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 monitor 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, if possible, preparing and administering medications to 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 procedures above, looking 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:** The only exceptions to this requirement are when there is a patient emergency, and when there is only 1 RN on duty who may be required to deliver care to an HBV+ patient and HBV susceptible patients on the same shift, e.g., medication administration, CVC access.
- When only 1 RN is on duty, poor infection control separation between care to HBV+ and HBV susceptible patients (V131)
- 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 OBSERVATIONS OF HEMODIALYSIS CARE AND INFECTION CONTROL PRACTICES

Facility _____ CCN# _____ Surveyor _____

The contents of this survey tool 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. OBSERVATIONS OF HEMODIALYSIS CARE USING OBSERVATIONAL CHECKLISTS: Observe the following activities using the applicable observational checklists in this survey tool:

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. Include observation of the care for at least one patient with a central venous catheter (CVC), and one patient with an AV fistula/graft (AVF/AVG). 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.*

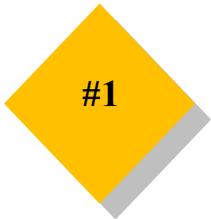
- Pre-dialysis vascular access care and initiation of patients' hemodialysis treatments (**Checklists 1 & 2 for CVC; Checklist 4 for AVF/AVG**)
- Discontinuation of patients' hemodialysis treatments and post-dialysis vascular access care (**Checklist 3 for CVC; Checklist 5 for AVF/AVG**)
 - *For facilities with poor infection outcomes, observe 1-2 additional vascular access care opportunities each for patients with CVC and AVF/AVG*
- 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: *While conducting the above observations, note the supply management and supply contamination prevention activities* (**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 or 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. ISOLATION PRACTICES REVIEW: *If there are hepatitis B positive (HBV+) patient(s) receiving 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. VERIFICATION OF 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: Date/time _____ Station# _____ Staff _____

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

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

Obs. #2: 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 before 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: Date/time _____ Station# _____ Staff _____

Obs. #2: 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

Additional notes: _____

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

Facility _____ Surveyor _____

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

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

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

Obs. #2: 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;

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

ACTION	OBSERVATION 1	OBSERVATION 2
Machine alarms and internal functions (e.g., pressure holding test) tested (V403)	Y/N	Y/N
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
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: Date/time _____ Station# _____ Staff _____

Obs. #2: 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, 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

Dialysis Supply Management and Contamination Prevention

Facility _____ Surveyor _____

Observation #1: Date _____ Time frame from _____ to _____

Observation #2: Date _____ Time frame from _____ to _____

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, O2 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 visably 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

2. ISOLATION PRACTICES: COMPLETE THIS SECTION IF THERE ARE HBV+ PATIENT(S) RECEIVING HEMODIALYSIS AT THE FACILITY.

Determine if there are any HBV+ patients who will be receiving hemodialysis at the facility during the survey. If possible, arrange to observe the care of an HBV+ patient, as one of the Observations of Hemodialysis Care using the checklists in this survey tool.

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.

- 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.

Ask: Direct care staff 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: _____



ESRD Core Survey Field Manual

Tab 7: Patient Sample Selection

- Excerpt from ESRD Core Survey Process
- ESRD Core Survey Worksheet: Patient Roster

➡ Patient Sample Selection:

Purpose - To select a core patient sample that represents the facility systems for patient care and management in the data-driven focus areas i.e., clinical areas where facility data indicates improvements are needed, and 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 on the Entrance Conference Materials List

Select 10% of the total number of patients on census (minimum 4; maximum 10) representing all dialysis modalities offered at the facility. Attempt to include in-center hemodialysis patients from different days/shifts. You may expand the patient sample if indicated. Select patients using the criteria below:

Criteria for patient selection:

- **Unstable** - To review the facility process for interdisciplinary team (IDT) functionality in the patient assessment and plan of care process for the most fragile patients
- **New admission <90 days** - To review 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.
- **Involuntarily discharged (IVD) in the past 12 months, if applicable** - To review facility actions taken in attempt to avert the IVD and processes 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.
- **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 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.
- **Not meeting outcome goals in the data-driven focus areas** selected during the Entrance Conference. Using the patient-specific information submitted on the Entrance Conference Materials List, i.e. the lists of patients' names in the Clinical Outcomes tables; lists of patients' labs hospitalization logs, infection logs. Select patients with trends of not meeting outcome goals in the data-driven focus areas for the survey.
- **Based on observations and complaints** - You may also sample patients for whom you identified possible concerns during the survey. Patients involved with a complaint being investigated during the survey may also be included in the patient sample.

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; maximum of 10) representing every dialysis modality provided at the facility, for “Patient Interviews” and “Medical Record Review.”

Record the patient sample - Designate the rationale 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 WORKSHEET: PATIENT ROSTER

Facility: _____ **CCN:** _____ **Census:** _____

Select 10% of the patient census, representing all dialysis modalities offered at the facility. Select a minimum of 4 and a maximum of 10 following the guidance at Task 5 Patient Sample Selection. You will review the medical records for all of the sampled patients. Attempt to interview as many of the sampled patients as possible.

Patient ID	Patient Name	Reason Sampled	Admit Date	Modality	I/O/R**	Surveyor
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

**I=Interview; O=Observation; R=Record Review



ESRD Core Survey Field Manual

Tab 8: Water Treatment & Dialysate Review

- Excerpt from ESRD Core Survey Process
- Water Treatment and Dialysate Preparation Review Worksheet

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

Purpose - To validate that systems in use and facility oversight of water and dialysate quality protect patients from harm

Review critical water treatment components with staff 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” procedures and the amount of carbon in the system (empty bed contact time-EBCT). If the facility is using a continuous on-line chlorine monitor, **ask** about periodic (usually daily) validation testing with an alternate method.
- **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.
- **Observe deionization(DI) and resistivity monitor and alarm**, if present, **and interview** about the presence of an automatic divert-to-drain or automatic cut-off valve to stop 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).

Interview the person responsible for microbiological 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.

Review facility 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: 3 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 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:

- Chlorine removal/carbon system
 - 2 or more carbon tanks with sample port between **not** present (V192)
 - Insufficient carbon empty bed contact time (<10 minutes total EBCT)-verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)
 - Observed total chlorine test result greater than maximum allowable level; 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.

- RO
 - RO % rejection and product water conductivity or TDS not monitored daily or alarm non-functional, not audible in patient treatment area (V200)

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

- DI, if present
 - Resistivity monitor or alarm non-functional; alarm not audible **and** visible in patient treatment area; resistivity not monitored and recorded at least twice per treatment day (V202, 203)
 - Automatic divert-to-drain or automatic cut-off valve to stop water flow to the dialysis machines not present or non-functional (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.

- Interviews
 - 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, etc. (V260)

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).

- Log reviews
 - 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 (V178,196, 199, 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 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, etc.

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

Facility: _____ CCN: _____ Surveyor _____

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

You may need to interview more than one Technician, based on their responsibilities for water treatment and dialysate preparation.

Carbon System and Chlorine Removal	Trigger Identified?	
OBSERVE: Are there 2 carbon tanks or banks of tanks with a sample port between?	<input type="checkbox"/> V192	<input type="checkbox"/> No
ASK: What is the empty bed contact time (EBCT) of the carbon tanks- <i>note: surveyors are not expected to calculate EBCT. If the technical staff are unable to verbalize, ask for documentation of the EBCT</i>	<input type="checkbox"/> V195	<input type="checkbox"/> No
ASK: What test is done for chlorine/chloramines? When is the test done? What is the maximum allowable result?	<input type="checkbox"/> V196	<input type="checkbox"/> No
ASK: If the maximum level of 0.1 mg/L total chlorine is exceeded, what actions are taken to protect patients from exposure to chlorine/chloramines?	<input type="checkbox"/> V197	<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) If Present	Trigger Identified?	
OBSERVE: Is the DI system being used as the primary purification component (no RO) or as a "polish" to supplement the RO?	N/A	N/A
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 automatic cut-off valve to prevent water with resistivity <1 megohm from reaching the dialysis stations? Is there an ultrafilter after the DI system?	<input type="checkbox"/> V202 <input type="checkbox"/> V203 <input type="checkbox"/> V204	<input type="checkbox"/> No
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?	<input type="checkbox"/> V202 <input type="checkbox"/> V203 <input type="checkbox"/> V260	<input type="checkbox"/> No
Disinfection and Water and Dialysate Microbiological Monitoring	Trigger Identified?	
ASK: How often is the water distribution system disinfected?	<input type="checkbox"/> V219	<input type="checkbox"/> No
ASK: When are water cultures and endotoxin/LALs obtained in relation to disinfection and from which sample sites?	<input type="checkbox"/> V213 <input type="checkbox"/> V254	<input type="checkbox"/> No
ASK: How often are dialysate cultures taken from each hemodialysis machine? How many machines are cultured each month?	<input type="checkbox"/> V253	<input type="checkbox"/> No
ASK: How are samples of water and dialysate collected and how are cultures and LALs performed, e.g., in-house "dip" samplers, in-house LALs, outside lab?	<input type="checkbox"/> V252 <input type="checkbox"/> V253 <input type="checkbox"/> V254 <input type="checkbox"/> V255 <input type="checkbox"/> V256 <input type="checkbox"/> V257 <input type="checkbox"/> -V258	<input type="checkbox"/> No
ASK: What are the action and maximum allowable microbiological levels for product water and dialysate? What actions are taken when those levels are exceeded?	<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 Chemical and Microbiological Monitoring 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</u> (NOT all gauge readings in the water system) <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 Chemical and Microbiological Monitoring Logs (continued)	Trigger Identified?	
REVIEW: <u>If DI present, DI monitoring logs for 3 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



ESRD Core Survey Field Manual

Tab 9: Dialyzer Reprocessing/Reuse Review

- Excerpt from ESRD Core Survey Process
- Dialyzer Reprocessing/Reuse Review Worksheet

➡ **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 they are reprocessed or, 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.

Focused interview with 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:

- **QA audits - Review 12 months of facility documentation of the following reuse observational audits.** For clarification, 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, 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 (V321)
- Knowledge deficit of reuse tech in key patient safety areas per interview guide (V309, 319, 320, 328, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)
- QA audits listed above not done or incomplete - **Extend** to review all of the required QA audits for reuse (V362-368)
- 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 WORKSHEET
REUSE: OBSERVATION/INTERVIEW/REVIEW**

Facility: _____ **CCN:** _____

Surveyor: _____ **ID#:** _____

Note: This worksheet is intended for use while conducting “Dialyzer Reprocessing/reuse Review.” The observations of the set up/priming of reprocessed dialyzers in preparation for dialysis, and corresponding germicide tests and safety checks are conducted during “Observations of Hemodialysis Care and Infection Control Practices.”

Reuse Tech: _____ Date/time: _____

Reprocessing Equipment: _____ Germicide: _____

Observations of Reprocessing Area	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 long 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



Preparation of the Hemodialysis Machine/Extracorporeal Circuit

Facility _____ Surveyor _____

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

Obs. #2: 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;

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

ACTION	OBSERVATION 1	OBSERVATION 2
Machine alarms and internal functions (e.g., pressure holding test) tested (V403)	Y/N	Y/N
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
Reprocessed dialyzer: patient and dialyzer matched and identified by 2 people while patient is at dialysis station (V348)	Y/N	Y/N

Additional Notes: _____



ESRD Core Survey Field Manual

Tab 10: Dialysis Equipment Maintenance

- Excerpt from ESRD Core Survey Process
- ESRD Core Survey Interview/Review
Worksheet: Machine/Equipment
Maintenance Technician

➡ **Dialysis Equipment Maintenance Review:** ▲

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

Interview machine maintenance personnel – *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 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
3. Review documentation of calibration of 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, specific 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: _____



ESRD Core Survey Field Manual

Tab 11: Home Dialysis Training & Support Review

- Excerpt from ESRD Core Survey Process
- ESRD Core Survey Interview Worksheet:
PD Training Nurse
- ESRD Core Survey Interview Worksheet:
Home HD Training Nurse

➡ 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., Environmental Tour, Water/dialysate review and Dialysis Equipment Maintenance (if applicable to the equipment in use), Personnel Record Review, and QAPI Review.

Interview the home training nurse(s) about the program for evaluating patient candidacy, training, demonstrating of comprehension, 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, observe the care delivery. Look for adherence to infection control practices.

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.*
- 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 (V628).

Extending review of the home 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 INTERVIEW WORKSHEET:
PD TRAINING NURSE**

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

PD Training Nurse: _____ **ID#:** _____

Surveyor: _____ **ID#:** _____

NOTE: Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**. If the dialysis facility supports home PD performed in LTC settings, follow the survey process in the current CMS Survey & Certification letter for home dialysis in LTC facilities.

Core Questions

	Deficient Practice?	
What do you do to prevent or reduce treatment errors or near misses ? Can you report without fear of reprisal? How would you expect an error/near miss involving you or others to be addressed?	<input type="checkbox"/> V627 <input type="checkbox"/> V634 <input type="checkbox"/> V715 <input type="checkbox"/> V756	<input type="checkbox"/> No
What types of patients' concerns do you respond to, report, and record? How are patients encouraged to voice suggestions and complaints so they don't fear reprisal? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636	<input type="checkbox"/> No
Are there sufficient qualified and trained staff in this facility to meet patients' medical, nutritional, and psychosocial needs (nurses, dietitians, social workers)?	<input type="checkbox"/> V757 <input type="checkbox"/> V758	<input type="checkbox"/> No
How do you ensure that the patient and/or caregiver are well trained and competent ?	<input type="checkbox"/> V586	<input type="checkbox"/> No
What does this facility do for infection control and prevention ?	<input type="checkbox"/> V132 <input type="checkbox"/> V562	<input type="checkbox"/> No
How do you monitor the home PD patient's home adaptation , including visits to the patient's home?	<input type="checkbox"/> V589	<input type="checkbox"/> No
How are home PD patients encouraged to participate in their plan of care?	<input type="checkbox"/> V456 <input type="checkbox"/> V542	<input type="checkbox"/> No
How do you monitor, recognize and address home PD patients' failure to meet outcome targets addressing learning barriers?	<input type="checkbox"/> V559	<input type="checkbox"/> No
How do you participate in QAPI and separately track and trend PD program data , including but not limited to catheter infections and peritonitis?	<input type="checkbox"/> V628 <input type="checkbox"/> V637 <input type="checkbox"/> V756	<input type="checkbox"/> No
What are you and your patients taught about emergency preparedness ?	<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"/> V467	<input type="checkbox"/> No

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

Additional Questions

PD Training & Support	Deficient Practice?	
How and how often do IDT members, including the physician, nurse, dietitian and social worker see and provide services to home PD patients?	<input type="checkbox"/> V588 <input type="checkbox"/> V592	<input type="checkbox"/> No
Patient Assessment & Plan of Care	Deficient Practice?	
How are interested patients evaluated for home PD and/or other modalities including transplant? How do you evaluate the patient's need for a home dialysis partner?	<input type="checkbox"/> V512 <input type="checkbox"/> V513 <input type="checkbox"/> V553 <input type="checkbox"/> V554	<input type="checkbox"/> No
Who is available to provide resources and assistance to respond to questions/concerns from home PD patients/family/care partners 24/7?	<input type="checkbox"/> V585	<input type="checkbox"/> No
How often do you review patients' immunizations and medication history with them (i.e., allergies, home medications, over-the-counter medications, supplements, etc.)?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Infection Control	Deficient Practice?	
Were you and your home PD patients offered the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
How do you train patients who are HBV+?	<input type="checkbox"/> V130 <input type="checkbox"/> V585	<input type="checkbox"/> No
QAPI	Deficient Practice?	
How are home PD patient involuntary transfers and involuntary discharges prevented?	<input type="checkbox"/> V636	<input type="checkbox"/> No
How are problems that threaten the health and safety of home PD patients and that require immediate correction addressed in QAPI?	<input type="checkbox"/> V640	<input type="checkbox"/> No
How does the medical director take responsibility in QAPI for home PD clinical indicators?	<input type="checkbox"/> V629-637, <input type="checkbox"/> V712	<input type="checkbox"/> No
Recordkeeping	Deficient Practice?	
How often are home PD patients' flow sheets/treatment records obtained and reviewed for accurate documentation and used to revise the plan to meet outcomes/goals? Who reviews them?	<input type="checkbox"/> V587 <input type="checkbox"/> V731	<input type="checkbox"/> No

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

Facility: _____ CCN: _____ Date/Time: _____

Home HD Training Nurse: _____ ID#: _____

Surveyor: _____ ID#: _____

NOTE: Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**. If the dialysis facility supports home PD performed in LTC settings, follow the survey process in the current CMS Survey & Certification letter for home dialysis in LTC facilities.

Core Questions

	Deficient Practice?	
What do you do to prevent or reduce treatment errors or near misses ? Can you report without fear of reprisal? How would you expect an error/near miss involving you or others to be addressed?	<input type="checkbox"/> V627 <input type="checkbox"/> V634 <input type="checkbox"/> V715 <input type="checkbox"/> V756	<input type="checkbox"/> No
What types of patients' concerns do you respond to, report, and record? How are patients encouraged to voice suggestions and complaints so they don't fear reprisal? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636	<input type="checkbox"/> No
Are there sufficient qualified and trained staff in this facility to meet patients' medical, nutritional, and psychosocial needs (nurses, dietitians, social workers)?	<input type="checkbox"/> V757 <input type="checkbox"/> V758	<input type="checkbox"/> No
How do you ensure that the patient and/or caregiver are well trained and competent ?	<input type="checkbox"/> V586	<input type="checkbox"/> No
What does this facility do for infection control and prevention ?	<input type="checkbox"/> V132 <input type="checkbox"/> V562	<input type="checkbox"/> No
How do you monitor the home HD patient's home adaptation , including visits to the patient's home?	<input type="checkbox"/> V589	<input type="checkbox"/> No
How is the home environment evaluated prior to home treatment and how is home HD patient's machine and water and dialysate system maintained ?	<input type="checkbox"/> V593-597	<input type="checkbox"/> No
How are home HD patients encouraged to participate in their plan of care?	<input type="checkbox"/> V456 <input type="checkbox"/> V542	<input type="checkbox"/> No
How do you monitor, recognize and address home HD patients' failure to meet outcome targets addressing learning barriers?	<input type="checkbox"/> V559	<input type="checkbox"/> No
How do you participate in QAPI and separately track and trend home HD program data , including but not limited to vascular access and blood stream infections?	<input type="checkbox"/> V628 <input type="checkbox"/> V637 <input type="checkbox"/> V756	<input type="checkbox"/> No
What are you and your patients taught about emergency preparedness ?	<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"/> V467	<input type="checkbox"/> No

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

Additional Questions

Home HD Training & Support	Deficient Practice?
How and how often do IDT members, including the physician, nurse, dietitian and social worker see and provide services to home HD patients?	<input type="checkbox"/> V588 <input type="checkbox"/> V592 <input type="checkbox"/> No
Patient Assessment & Plan of Care	Deficient Practice?
How are interested patients evaluated for home HD and/or other modalities, including transplant? How do you evaluate the patient's need for a home dialysis care partner?	<input type="checkbox"/> V512 <input type="checkbox"/> V513 <input type="checkbox"/> V553 <input type="checkbox"/> V554 <input type="checkbox"/> No
Who is available to provide resources and assistance to respond to questions/concerns from home HD patients/family/care partners 24/7?	<input type="checkbox"/> V585 <input type="checkbox"/> No
How often do you review patients' immunizations and medication history with them (i.e., allergies, home medications, over-the-counter medications, supplements, etc.)?	<input type="checkbox"/> V506 <input type="checkbox"/> No
Infection Control	Deficient Practice?
Were you and your home HD patients offered the Hepatitis B vaccine?	<input type="checkbox"/> V126 <input type="checkbox"/> No
How do you train patients who are HBV+?	<input type="checkbox"/> V130 <input type="checkbox"/> V585 <input type="checkbox"/> No
QAPI	Deficient Practice?
How are home HD patient involuntary transfers and involuntary discharges prevented?	<input type="checkbox"/> V636 <input type="checkbox"/> No
How are problems that threaten the health and safety of home HD patients and that require immediate correction addressed in QAPI?	<input type="checkbox"/> V640 <input type="checkbox"/> No
How does the medical director take responsibility in QAPI for home HD clinical indicators?	<input type="checkbox"/> V629-637, <input type="checkbox"/> V712 <input type="checkbox"/> No
Recordkeeping	Deficient Practice?
How often are home HD patients' flow sheets/treatment records obtained and reviewed for accurate documentation and used to revise the plan to meet outcomes/goals? Who reviews them?	<input type="checkbox"/> V587 <input type="checkbox"/> V731 <input type="checkbox"/> No



ESRD Core Survey Field Manual

Tab 12: Patient Interviews

- Excerpt from ESRD Core Survey Process
- ESRD Core Survey Interview Worksheet: In-center HD Patient
- ESRD Core Survey Interview Worksheet: PD Patient
- ESRD Core Survey Interview Worksheet: Home HD Patient

➡ Patient Interviews: ▲

Purpose - To listen to the patients' voices as recipients of the care provided at the facility, to evaluate patients' understanding of their rights and responsibilities, to determine how safe 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. Interview home patients in the facility if possible or ask the home training nurse to contact the patient to alert him/her that the surveyor will be calling for an interview.*

*After attempting to interview the sampled patients in person or by phone, 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.*

*Individualize patient interviews to focus on each patient's issues, however **ask** at least the “core” questions listed on the applicable ESRD Core Survey Patient Interview Worksheet.*

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 INTERVIEW WORKSHEET:
IN-CENTER HEMODIALYSIS PATIENT**

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

Facility: _____ **CCN:** _____

Surveyor: _____ **#:** _____

From your sample, choose “interviewable” (i.e., alert, oriented, not mentally impaired) in-center HD patients to interview. Explain the purpose of the interview. Ask if the patient would prefer to be interviewed at the facility or by phone. Ask the **core questions**. If an issue is identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
How do the staff at this facility encourage you to give input ? If you had a complaint, how would you file it here or elsewhere?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V627	<input type="checkbox"/> No
Do dialysis staff members treat you with respect and dignity and protect your privacy during dialysis?	<input type="checkbox"/> V452 <input type="checkbox"/> V454	<input type="checkbox"/> No
How do staff encourage you to participate in care planning and consider your needs, wishes and goals ? How do staff help you address barriers to meeting goals (targets)? Do staff discuss changes in your prescription before making them?	<input type="checkbox"/> V456 <input type="checkbox"/> V541	<input type="checkbox"/> No
What were you told about other treatment options ? How did you choose in-center hemodialysis? Are you satisfied with in-center hemodialysis?	<input type="checkbox"/> V458	<input type="checkbox"/> No
What have you been told about your condition, risks and benefits of dialysis and access types, infection prevention, personal care, home dialysis, self-care, quality of life, rehabilitation, transplant, your rights and responsibilities, and what to do in an emergency here or at home, including if you're not able to get to dialysis?	<input type="checkbox"/> V451 <input type="checkbox"/> V562 <input type="checkbox"/> V464	<input type="checkbox"/> No
How safe, clean, and comfortable is this facility?	<input type="checkbox"/> V401 <input type="checkbox"/> V402	<input type="checkbox"/> No
Do you see staff cleaning hands and changing gloves when moving from one patient or station to another?	<input type="checkbox"/> V113	<input type="checkbox"/> No
Have you ever had any problems or symptoms during dialysis and if so, how and how quickly were they addressed?	<input type="checkbox"/> V681 <input type="checkbox"/> V713	<input type="checkbox"/> No
Are there enough staff , i.e., nurses, technicians, dietitians and social workers at this facility to meet your needs ?	<input type="checkbox"/> V757	<input type="checkbox"/> No
Have you been offered a survey that asks how your health and symptoms affect your energy, activity level, and lifestyle? If problems were identified, how were they addressed?	<input type="checkbox"/> V552 <input type="checkbox"/> V628	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V467	<input type="checkbox"/> No

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

Additional Questions

Patients' Rights and Responsibilities	Deficient Practice?	
What do staff do to 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	Deficient Practice?	
How do you feel after dialysis? Do you get to your target weight? Have you ever had physical problems at home after dialysis?	<input type="checkbox"/> V543	<input type="checkbox"/> No
Infection Control	Deficient Practice?	
What have you been taught about washing hands and cleaning your access site (fistula or graft) before dialysis and washing your hands before leaving the clinic?	<input type="checkbox"/> V562	<input type="checkbox"/> No
Emergency Preparedness	Deficient Practice?	
If your dialysis facility was closed in case of a disaster, what would you do?	<input type="checkbox"/> V412	<input type="checkbox"/> No
Patient Assessment & Plan of Care	Deficient Practice?	
What would you do if you had bleeding from your dialysis access after dialysis or signs and symptoms of access infection or clotting?	<input type="checkbox"/> V550 <input type="checkbox"/> V551	<input type="checkbox"/> No
What has the dietitian told you about food options, meal preparation, 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 have you been told about how to manage your fluid intake and blood pressure?	<input type="checkbox"/> V543	<input type="checkbox"/> No
What has the social worker told you about living with kidney disease? What other things has the social worker helped you with?	<input type="checkbox"/> V514 <input type="checkbox"/> V552	<input type="checkbox"/> No
How often do you see a physician/nurse practitioner/clinical nurse specialist/physician assistant? Is this enough? Do you know how to contact him/her if needed?	<input type="checkbox"/> V560	<input type="checkbox"/> No
How often do staff review your medications with you?	<input type="checkbox"/> V506	<input type="checkbox"/> No
(If reuse) What were you told about dialyzer reuse? How do you know you get your dialyzer each treatment?	<input type="checkbox"/> V312 <input type="checkbox"/> V348	<input type="checkbox"/> No

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

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

Facility: _____ **CCN:** _____

Surveyor: _____ **ID #:** _____

From your sample, choose “interviewable” (i.e., alert, oriented, not mentally impaired) PD patients (or care partners) to interview while in the facility or by phone. Ask the home training nurse to contact the patient to alert him/her that the surveyor will be calling for an interview. Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
How do the staff at this facility encourage you to give input ? If you had a complaint, how would you file it here or elsewhere?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V627	<input type="checkbox"/> No
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
How do staff encourage you to participate in care planning and consider your needs, wishes and goals ? How do staff help you address barriers to meeting goals (targets)? Do staff discuss prescription changes with you before making them?	<input type="checkbox"/> V456 <input type="checkbox"/> V541	<input type="checkbox"/> No
What were you told about other treatment options ? How did you choose PD? Are you satisfied with PD?	<input type="checkbox"/> V458	<input type="checkbox"/> No
What have you been told about your condition, risks and benefits of dialysis types, infection prevention, disposal of used supplies, rehabilitation, quality of life, transplant, 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"/> V451 <input type="checkbox"/> V464 <input type="checkbox"/> V562 <input type="checkbox"/> V585	<input type="checkbox"/> No
Are there enough staff , i.e., home training nurses, dietitians and social workers at this facility to meet your needs ? Do you see these staff members as often as you need to?	<input type="checkbox"/> V582 <input type="checkbox"/> V592 <input type="checkbox"/> V757	<input type="checkbox"/> No
How did your training nurse know you (and your care partner if applicable) were ready to do PD at home ?	<input type="checkbox"/> V586	<input type="checkbox"/> No
How safe, clean, and comfortable is the area for home training and facility visits?	<input type="checkbox"/> V401 <input type="checkbox"/> V402	<input type="checkbox"/> No
Have you been offered a survey that asks how your health and symptoms affect your energy, activity level, and lifestyle? If problems were identified, how were they addressed?	<input type="checkbox"/> V552 <input type="checkbox"/> V628	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V467	<input type="checkbox"/> No

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

Additional Questions

Patients' Rights and Responsibilities	Deficient Practice?	
What do staff do to 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	Deficient Practice?	
How often do you send/take flow sheets to this facility? Who reviews them?	<input type="checkbox"/> V587	<input type="checkbox"/> No
Do the staff ask you how well you are doing on PD?	<input type="checkbox"/> V589	<input type="checkbox"/> No
Management of PD Prescription	Deficient Practice?	
How do you decide the fluid to remove during dialysis and what PD solution to use? Does PD normally get you to your goal weight? How do you monitor and control your blood pressure?	<input type="checkbox"/> V503 <input type="checkbox"/> V504 <input type="checkbox"/> V543	<input type="checkbox"/> No
How often does your nurse review your medications with you?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Infection Control	Deficient Practice?	
What have you been taught about signs of an 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
Patient Assessment & Plan of Care	Deficient Practice?	
What has the dietitian told you about food options, meal preparation, managing fluids, 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? What other things has the social worker helped you with?	<input type="checkbox"/> V514	<input type="checkbox"/> No
How often do you see a physician/nurse practitioner/clinical nurse specialist/physician assistant in the facility or at the office? Is this enough? Do you know how to contact him/her if needed?	<input type="checkbox"/> V560	<input type="checkbox"/> No

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

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

Facility: _____ **CCN:** _____

Surveyor: _____ **#:** _____

From your sample, choose “interviewable” (i.e., alert, oriented, not mentally impaired) home HD patients (or care partners) to interview while in facility or by phone. Ask the home training nurse to contact the patient to alert him/her that the surveyor will be calling for an interview. Explain the purpose of the interview. Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
How do the staff at this facility encourage you to give input ? If you had a complaint, how would you file it here or elsewhere?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V627	<input type="checkbox"/> No
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
How do staff encourage you to participate in care planning and consider your needs, wishes and goals ? How do staff help you address barriers to meeting goals (targets)? Do staff discuss prescription changes with you before making them?	<input type="checkbox"/> V456 <input type="checkbox"/> V541	<input type="checkbox"/> No
What were you told about other treatment options ? How did you choose home hemodialysis? Are you satisfied with home hemodialysis?	<input type="checkbox"/> V458	<input type="checkbox"/> No
What have you been told about your condition, risks and benefits of dialysis types, infection prevention, disposal of used supplies, rehabilitation, quality of life, transplant, 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"/> V451 <input type="checkbox"/> V464 <input type="checkbox"/> V562 <input type="checkbox"/> V585	<input type="checkbox"/> No
Are there enough staff , i.e., home training nurses, dietitians and social workers at this facility to meet your needs ? Do you see these staff members as often as you need to?	<input type="checkbox"/> V582 <input type="checkbox"/> V592 <input type="checkbox"/> V757	<input type="checkbox"/> No
How did your training nurse know you (and your care partner if applicable) were ready to do hemodialysis at home ?	<input type="checkbox"/> V586	<input type="checkbox"/> No
How safe, clean, and comfortable is the area for home training and facility visits?	<input type="checkbox"/> V401 <input type="checkbox"/> V402	<input type="checkbox"/> No
Have you been offered a survey that asks how your health affects your energy, activity level, and lifestyle? If problems were identified, how were they addressed?	<input type="checkbox"/> V552 <input type="checkbox"/> V628	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V467	<input type="checkbox"/> No

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

Additional Questions

Patients' Rights and Responsibilities	Deficient Practice?	
What do staff do to 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	Deficient Practice?	
How often do you send/take flow sheets to this facility? Who reviews them?	<input type="checkbox"/> V587	<input type="checkbox"/> No
Did anyone come to your home to test the water quality before you started home HD? [Unless bagged dialysate] How and how often do you or facility staff test the water/dialysate?	<input type="checkbox"/> V593 <input type="checkbox"/> V594 <input type="checkbox"/> V595 <input type="checkbox"/> V596	<input type="checkbox"/> No
Do the staff ask you how well you are doing on home HD?	<input type="checkbox"/> V589	<input type="checkbox"/> No
Management of Home Hemodialysis Prescription	Deficient Practice?	
How do you decide how much fluid to remove during dialysis? Do you get to your goal weight? What symptoms do you have during or after dialysis? How do you monitor and control your blood pressure?	<input type="checkbox"/> V503 <input type="checkbox"/> V504 <input type="checkbox"/> V543	<input type="checkbox"/> No
How often does the nurse review your medications with you?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Infection Control	Deficient Practice?	
What have you been taught about 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
Patient Assessment & Plan of Care	Deficient Practice?	
What has the dietitian told you about food options, meal preparation, managing fluids, 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? What other things has the social worker helped you with?	<input type="checkbox"/> V514	<input type="checkbox"/> No
How often do you see a physician/nurse practitioner/clinical nurse specialist/physician assistant in the facility or at the office? Is this enough? Do you know how to contact him/her if needed?	<input type="checkbox"/> V560	<input type="checkbox"/> No



ESRD Core Survey Field Manual

Tab 13: Medical Record Review

- Excerpt from ESRD Core Survey Process
- Medical Record Review: In-center Hemodialysis
- Medical Record Review: Peritoneal Dialysis
- Medical Record Review: Home Hemodialysis

➡ **Medical Record Review:** ▲

Purpose - To verify the provision of safe, effective, interdisciplinary care through the staff 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 in the area/rationale 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 area/rationale for sampling that patient, using the following guidelines:

Dialysis prescription/medication orders and dialysis treatment records for all sampled patients (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.
- **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 poor outcomes, i.e., not meeting goals, 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 for monitoring the patient's outcome(s), recognizing that there is a problem and/or goal not reached, and taking action to address it.*

- 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 took actions toward improvement/resolution.

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, follow the guidance above for that area, as well.*

Guidance for review of patients sampled due to anemia management concerns as a data-drive 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*

“Unstable” patients - *Review the IDT documentation in progress notes, physician's orders, assessments, results of physical and mental functioning surveys (KDQOL-36 or other age-appropriate 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.

Newly admitted patients (<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.

Home HD and PD dialysis patients - If an interview with patient or staff indicates possible concerns related to inadequate training for the patient and/or caregiver, review documentation of training.

- **Home HD patients:** In addition to the above areas applicable to a sampled home HD patient, review documentation of water/dialysate chemical and microbiological quality, as applicable for the hemodialysis equipment in use.
- **LTC residents receiving home dialysis at the LTC facility:** If there are long term care (LTC) residents on census who receive home hemodialysis or peritoneal dialysis treatments 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.

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. For more information, refer to the current CMS Survey and Certification guidance on “Dialysis Admission, Transfer and Discharge Practices”

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 may need to *interview* the facility qualified social worker and other applicable staff 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, that 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
- 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 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: _____

Rationale for Sampling: _____ Sections in this tool 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 in the area/rationale 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 rationale/area in the applicable sections of this tool. Refer to "Patient Sample Selection" of the ESRD Core Survey Process.

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 ANY 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: _____

Adequacy plan not implemented (V544):	
<input type="checkbox"/> BFR, DFR, time	
<input type="checkbox"/> 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"/> Estimated dry weight not achieved	
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 and/or adverse events (V634)	
Other Concerns Identified:	

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

If yes to any of the above questions, citation at the applicable V-tag for the care element as listed in the table above 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 POOR OUTCOMES (not meeting goals) IN THE DATA-DRIVEN FOCUS AREAS for this survey - if the patient was sampled due to multiple poor outcomes in data-driven focus areas, record in this section for all of those.

*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, follow this guidance for that area, as well.*

For poor outcomes in laboratory values (i.e., anemia, adequacy, mineral metabolism, albumin): Review the current 3 months of lab results in that area. Reference target values are listed on the Measures Assessment Tool (MAT). Review the other medical record documentation related to that outcome, 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 the goal was not met, and taking actions to address it.

Notes: _____

For poor outcomes in non-laboratory areas (e.g., CVC >90 days, infection, high average intradialytic weight loss, hospital readmissions, eligible patient not referred for transplant, etc.) - Review the medical record documentation related to that 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.

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; and took actions toward improvement/resolution?**
 - **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 (e.g., KDQOL-36 or other age appropriate 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: _____
 Rationale for Sampling: _____ Sections of this tool 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 in the area/rationale 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 rationale/area in the applicable sections of this tool. Refer to "Patient Sample Selection" of the ESRD Core Survey Process.

Note: For closed record review of patients sampled due to being **involuntarily discharged**, follow the ESRD Core Survey Process and the current CMS Survey and Certification guidance. For **LTC residents receiving home dialysis in their LTC facility**, follow the 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/helper 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 (V541):	
<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 (V541):	
<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 and/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, and took actions to address and resolve the issues?

- 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 POOR OUTCOMES (not meeting goals) IN THE DATA-DRIVEN FOCUS AREAS for this survey - If the patient was sampled due to multiple poor outcomes in data-driven focus areas, record in this section for all of those.

*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, follow this guidance for that area, as well.*

For poor outcomes in laboratory values (i.e., anemia, adequacy, mineral metabolism, albumin): Review the current 3 months of lab results in that area. Reference target values are listed on the Measures Assessment Tool (MAT). Review the other medical record documentation related to that outcome, e.g., progress notes, physician's orders, patient assessment/plan of care to assess the facility's actions for monitoring the patient's outcome, recognizing that the goal was not met, and taking action to address it.

Notes: _____

For poor outcomes in non-laboratory areas (e.g., peritonitis, hospital readmissions, eligible patient not referred for transplant, etc.) Review the medical record documentation related to that outcome/area, such as 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.

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; and took actions toward improvement/resolution?
 - **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 (e.g., KDQOL-36 or other age appropriate 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: _____
 Rationale for sampling: _____ Sections in this tool 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 in the area/rationale 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 rationale/area in the applicable sections of this tool. Refer to "Patient Sample Selection" of the ESRD Core Survey Process.

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. For **LTC residents receiving home dialysis in their LTC facility**, follow the 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 if and how staff members monitor the HHD 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. Be aware that some exception categories such as pH/conductivity may not apply depending on the HHD equipment in use. 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: _____ Hours _____ minutes 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):	
<input type="checkbox"/> Independent pH/ conductivity (V250)	
<input type="checkbox"/> Machine alarms check (V403)	
<input type="checkbox"/> Water chlorine testing (V595)	

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

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Treatment delivered different from ordered:	
EXCEPTIONS	DATES/COMMENTS
<input type="checkbox"/> BFR/DFR/dialyzer/time (V544)	
<input type="checkbox"/> Dialysate (V541)	
<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 and/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 HD treatment records? No Yes-(V587) Explain _____
- Did you identify trends in the patient or caregiver not following their 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, and took actions to address and resolve the issues?

- **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 POOR OUTCOMES (not meeting goals) IN THE DATA-DRIVEN FOCUS AREAS for this survey-if the patient was sampled due to multiple poor outcomes in data-driven focus areas, record in this section for all of those.

*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, follow this guidance for that area, as well.*

For poor outcomes in laboratory values (i.e., anemia, adequacy, mineral metabolism, albumin): Review the current 3 months of lab results in that area. Reference target values are listed on the Measures Assessment Tool (MAT). Review the other medical record documentation related to that outcome, e.g., progress notes, physician's orders, patient assessment/plan of care to assess the facility's actions for monitoring the patient's outcome, recognizing that the goal was not met, and taking action to address it.

Notes: _____

For poor outcomes in non-laboratory areas (e.g., CVC >90 days, infection, hospital readmissions, eligible patient not referred for transplant, etc.) Review the medical record documentation related to that 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 was a problem, and taking action to address it.

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; and took actions toward improvement/resolution?
 - **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 (e.g., KDQOL-36 or other age appropriate 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 results of the water and dialysate quality for the past 6 months. The requirements for monitoring the water and dialysate quality for home hemodialysis vary according to the equipment in use at the patient's home. Determine which equipment is in use, and 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: _____



ESRD Core Survey Field Manual

Tab 14: Personnel Interviews

- Excerpt from ESRD Core Survey Process
- 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

➡ Personnel Interviews: ▲

Purpose - To assess 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 in-person or offer to interview by phone- *You may 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 she/he 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.

➡ Personnel Interviews: ▲

Purpose - To assess 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 in-person or offer to interview by phone- *You may 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 she/he 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.

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

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

Medical director: _____ **ID#:** _____

Surveyor: _____ **ID#:** _____

Alert the medical director that you would like to interview him/her in person or by phone if their schedule allows. You must interview the medical director if you identify a significant problem at the facility. Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
What have you done to set the tone for this facility and its management that encourages patients and staff to openly and directly voice concerns, suggestions and report grievances, errors or near misses to management without fearing retribution or reprisal?	<input type="checkbox"/> V627	<input type="checkbox"/> No
How do you ensure that in all required/appropriate areas of the QAPI program data are regularly monitored; issues addressed; and improvements taken and sustained?	<input type="checkbox"/> V712 <input type="checkbox"/> V626	<input type="checkbox"/> No
How do you monitor and address staff turnover at this facility and work with the governing body to ensure sufficient numbers of qualified staff to meet patients' needs?	<input type="checkbox"/> V757	<input type="checkbox"/> No
How do you ensure that all staff have the appropriate education, training and competency to perform their job responsibilities?	<input type="checkbox"/> V713	<input type="checkbox"/> No
How do you ensure that patient plans of care are individualized? Specifically, how do you monitor and manage adequacy, anemia and fluid removal during dialysis?	<input type="checkbox"/> V541 <input type="checkbox"/> V543 <input type="checkbox"/> V544 <input type="checkbox"/> V547	<input type="checkbox"/> No
What do you do (what is your process) when you receive a patient suggestion/complaint?	<input type="checkbox"/> V765	<input type="checkbox"/> No
How do you maintain and review patient and staff lists of suggestions/complaints/incidents?	<input type="checkbox"/> V627	<input type="checkbox"/> No
What do you do to prevent any involuntary transfers/discharges or facility denial of admissions?	<input type="checkbox"/> V766 <input type="checkbox"/> V767	<input type="checkbox"/> No
How are staff/patients informed about and monitored for appropriate infection control?	<input type="checkbox"/> V713 <input type="checkbox"/> V715	<input type="checkbox"/> No
What is the process for ensuring that every patient is informed about and receives the treatment that he/she chooses unless medically contraindicated?	<input type="checkbox"/> V458 <input type="checkbox"/> V553 <input type="checkbox"/> V554	<input type="checkbox"/> No
What else can you tell me about this facility?	<input type="checkbox"/> V467	<input type="checkbox"/> No

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

Additional Questions

Medical Director Responsibilities	Deficient Practice?	
What does your role as medical director encompass at this facility?	<input type="checkbox"/> V711	<input type="checkbox"/> No
How do you participate in the development, review, and approval of the “patient care policies and procedures manual” for the facility and assure that all policies and procedures are adequate, accurate, and up-to-date?	<input type="checkbox"/> V714	<input type="checkbox"/> No
How do you provide oversight to assure that medical and other staff are adhering to facility policies related to admissions, patient care, infection control and safety?	<input type="checkbox"/> V715	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
NURSE**

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

Nurse: _____ **ID#:** _____

Surveyor: _____ **ID#:** _____

Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
How has the facility leadership defined your role in patient safety ?	<input type="checkbox"/> V627	<input type="checkbox"/> No
What do you do to prevent or reduce treatment errors or near misses at this facility? Can you report without fear of reprisal? How would you expect an error/near miss involving you or others to be addressed?	<input type="checkbox"/> V627 <input type="checkbox"/> V634 <input type="checkbox"/> V715 <input type="checkbox"/> V756	<input type="checkbox"/> No
How are patients encouraged to participate in their plan of care?	<input type="checkbox"/> V456	<input type="checkbox"/> No
What types of patients' concerns do you document and address? How are patients encouraged to voice suggestions and complaints without fear of reprisal? What is your facility's system for reporting resolution to the patient?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636	<input type="checkbox"/> No
Are there sufficient qualified and trained staff in this facility to meet patients' medical, nutritional, and psychosocial needs?	<input type="checkbox"/> V757 <input type="checkbox"/> V758	<input type="checkbox"/> No
How and how often do you monitor in-center patients before, during and after dialysis ?	<input type="checkbox"/> V503 <input type="checkbox"/> V504	<input type="checkbox"/> No
What does this facility do for infection control and prevention ?	<input type="checkbox"/> V132 <input type="checkbox"/> V562	<input type="checkbox"/> No
How do you monitor, recognize and address patients' failure to meet outcome targets addressing learning barriers?	<input type="checkbox"/> V559	<input type="checkbox"/> No
How do you participate in QAPI and learn about QAPI activities? [For nurse manager] How do you track and trend data for QAPI?	<input type="checkbox"/> V626 <input type="checkbox"/> V628	<input type="checkbox"/> No
What have you and patients been taught about emergency preparedness ?	<input type="checkbox"/> V409 <input type="checkbox"/> V412	<input type="checkbox"/> No
How would you work with patients who have mental illness, cognitive impairment, cultural or language differences that may contribute to challenging behaviors as a way to prevent involuntary transfers and involuntary discharges ?	<input type="checkbox"/> V452	<input type="checkbox"/> No
Is there anything else you would like to tell me about this facility?	<input type="checkbox"/> V467	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
NURSE**

Additional Questions

Patient Assessment & Plan of Care	Deficient Practice?	
How are interested patients evaluated for other treatment modalities (home dialysis and transplant)?	<input type="checkbox"/> V553 <input type="checkbox"/> V554	<input type="checkbox"/> No
Who is available to provide resources and assistance to respond to questions/concerns from in-center HD patients/families/partners?	<input type="checkbox"/> V514 <input type="checkbox"/> V552	<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 often do you review patients' immunizations and medication history with them (i.e., allergies, current in-center medications and home medications, over-the-counter medications, supplements, etc.)?	<input type="checkbox"/> V506	<input type="checkbox"/> No
Infection Control	Deficient Practice?	
Were you and in-center HD patients offered the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
How do you care for patients who are HBV-susceptible?	<input type="checkbox"/> V124	<input type="checkbox"/> No
QAPI	Deficient Practice?	
What practice audits of patient care are done at this facility and which ones have you performed?	<input type="checkbox"/> V628	<input type="checkbox"/> No
How are problems that threaten the health and safety of in-center HD patients and that require immediate correction addressed in QAPI?	<input type="checkbox"/> V640	<input type="checkbox"/> No
[Nurse manager] How does the medical director take responsibility in QAPI for in-center HD patients' clinical indicators?	<input type="checkbox"/> V629-637, <input type="checkbox"/> V712	<input type="checkbox"/> No
Recordkeeping	Deficient Practice?	
How often are in-center HD patients' flow sheets/treatment records reviewed for accurate documentation and used to revise the plan to meet outcomes/goals?	<input type="checkbox"/> V559 <input type="checkbox"/> V726	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PATIENT CARE TECHNICIAN**

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

PCT: _____ **ID#:** _____

Surveyor: _____ **ID#:** _____

Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
How has the facility leadership defined your role in patient safety ?	<input type="checkbox"/> V627	<input type="checkbox"/> No
What do you do to prevent or reduce treatment errors or near misses at this facility? How would you expect an error or near miss involving you or someone else to be addressed?	<input type="checkbox"/> V627 <input type="checkbox"/> V634 <input type="checkbox"/> V715 <input type="checkbox"/> V756	<input type="checkbox"/> No
What types of patient concerns were you taught to document and address? How are patients encouraged to voice suggestions and complaints without fear of reprisal?	<input type="checkbox"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V636	<input type="checkbox"/> No
Are there sufficient qualified and trained staff in this facility to meet patients' medical, nutritional, and psychosocial needs?	<input type="checkbox"/> V757	<input type="checkbox"/> No
How and how often do you monitor in-center patients before, during and after dialysis ?	<input type="checkbox"/> V503 <input type="checkbox"/> V504 <input type="checkbox"/> V681	<input type="checkbox"/> No
When would you notify a nurse if a patient has a problem?	<input type="checkbox"/> V681	<input type="checkbox"/> No
What training do you and in-center patients have in infection prevention ?	<input type="checkbox"/> V132 <input type="checkbox"/> V562	<input type="checkbox"/> No
How do you encourage patients to meet outcome targets ?	<input type="checkbox"/> V559	<input type="checkbox"/> No
How would you work with patients who have mental illness, cognitive impairment, cultural or language differences that may contribute to challenging behaviors as a way to prevent involuntary transfers and involuntary discharges ?	<input type="checkbox"/> V452	<input type="checkbox"/> No
How do you participate in and/or learn about QAPI activities ?	<input type="checkbox"/> V626 <input type="checkbox"/> V756	<input type="checkbox"/> No
What are you and the in-center patients taught about emergency preparedness ?	<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"/> V467	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
PATIENT CARE TECHNICIAN**

Additional Questions

Patient Assessment & Plan of Care	Deficient Practice?	
How and who would you report patients' interest in other treatment modalities (home dialysis and transplant) to?	<input type="checkbox"/> V553 <input type="checkbox"/> V554	<input type="checkbox"/> No
Who is available to provide resources and assistance to respond to questions/concerns from in-center HD patients/families/partners?	<input type="checkbox"/> V514 <input type="checkbox"/> V552	<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
Infection Control	Deficient Practice?	
Were you offered the Hepatitis B vaccine?	<input type="checkbox"/> V126	<input type="checkbox"/> No
How do you care for patients who are HBV susceptible?	<input type="checkbox"/> V124	<input type="checkbox"/> No
QAPI	Deficient Practice?	
What practice audits of patient care are done at this facility and which ones have you performed?	<input type="checkbox"/> V637	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
DIETITIAN**

Facility: _____ **CCN:** _____ **Date:** _____

Dietitian: _____ **ID#** _____

Surveyor: _____ **ID#** _____

Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
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"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V467 <input type="checkbox"/> V627	<input type="checkbox"/> No
Are there sufficient qualified and trained staff in this facility to meet patients' (in-center and home, if applicable) medical, nutritional, and psychosocial needs?	<input type="checkbox"/> V757 <input type="checkbox"/> V758	<input type="checkbox"/> No
How do you assess patients' nutritional status and collaborate with the IDT to develop a congruent plan of care that addresses outcomes?	<input type="checkbox"/> V509 <input type="checkbox"/> V542	<input type="checkbox"/> No
How do you encourage patients to participate in their plan of care?	<input type="checkbox"/> V456	<input type="checkbox"/> No
How do you educate patients, including those with learning barriers when monitoring, recognizing and addressing patients' failure to meet outcome targets ?	<input type="checkbox"/> V559 <input type="checkbox"/> V562	<input type="checkbox"/> No
How do you work with patients who have mental illness, cognitive impairment, cultural or language differences that may help the facility better meet patients' medical and nutritional needs to reduce the risk of involuntary transfers/discharges ?	<input type="checkbox"/> V452 <input type="checkbox"/> V766	<input type="checkbox"/> No
How do you participate in QAPI and what topics do you bring to QAPI meetings?	<input type="checkbox"/> V626 <input type="checkbox"/> V756	<input type="checkbox"/> No
What training do you have in infection prevention ?	<input type="checkbox"/> V132	<input type="checkbox"/> No
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"/> V467	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
DIETITIAN**

Additional Questions

Patient Assessment & Care Planning	Deficient Practice?	
What are some nutritional issues you address with patients (in-center and home HD and PD, nursing home residents)?	<input type="checkbox"/> V545	<input type="checkbox"/> No
If your facility does not allow in-center patients to eat at mealtimes during treatment, how do you counsel them to assure that their nutritional needs are met on dialysis days? How do you collaborate with a nursing home staff, if applicable, to help patients meet nutritional outcomes?	<input type="checkbox"/> V545 <input type="checkbox"/> V562	<input type="checkbox"/> No
What are your responsibilities related to diet education when patients switch permanently or temporarily between HD and PD or between standard and more frequent dialysis?	<input type="checkbox"/> V545 <input type="checkbox"/> V562	
How do you identify patients as unstable to increase their frequency of IDT assessment and care planning?	<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

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
SOCIAL WORKER**

Facility: _____ **CCN:** _____ **Date:** _____

Social Worker: _____ **ID#:** _____

Surveyor: _____ **ID#:** _____

Ask the **core questions**. If an issue has been identified in one or more data-driven focus areas, ask appropriate **additional questions**.

Core Questions

	Deficient Practice?	
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"/> V465 <input type="checkbox"/> V466 <input type="checkbox"/> V467 <input type="checkbox"/> V627	<input type="checkbox"/> No
Are there sufficient qualified and trained staff in this facility to meet patients' (in-center and home, if applicable) medical, nutritional, and psychosocial needs?	<input type="checkbox"/> V757 <input type="checkbox"/> V758	<input type="checkbox"/> No
How do you assess patients' psychosocial status and collaborate with the IDT to develop a congruent plan of care that addresses outcomes?	<input type="checkbox"/> V510 <input type="checkbox"/> V542	<input type="checkbox"/> No
How do you encourage patients to participate in their plan of care?	<input type="checkbox"/> V456	<input type="checkbox"/> No
How do you educate patients, including those with learning barriers when monitoring, recognizing and addressing patients' failure to meet outcome targets ?	<input type="checkbox"/> V559 <input type="checkbox"/> V562	<input type="checkbox"/> No
When do you offer patients a health-related quality of life (HRQOL) survey, e.g., KDQOL-36 or age appropriate survey , share results with the patient and team, and use them for plan of care and QAPI? What are your refusal and annual completion thresholds?	<input type="checkbox"/> V552 <input type="checkbox"/> V628	<input type="checkbox"/> No
How do you work with patients who have mental illness, cognitive impairment, cultural or language differences that may contribute to risk of involuntary transfers (IVT)/discharges (IVD) ? What is your role with IVT/IVD?	<input type="checkbox"/> V452 <input type="checkbox"/> V766 <input type="checkbox"/> V767	<input type="checkbox"/> No
How do you participate in QAPI and what topics do you bring to QAPI meetings? How are patients' satisfaction, grievances and involuntary discharges addressed in QAPI?	<input type="checkbox"/> V626 <input type="checkbox"/> V636 <input type="checkbox"/> V756	<input type="checkbox"/> No
What training do you have in infection prevention ?	<input type="checkbox"/> V132	<input type="checkbox"/> No
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"/> V467	<input type="checkbox"/> No

**ESRD CORE SURVEY INTERVIEW WORKSHEET:
SOCIAL WORKER**

Additional Questions

Patients' Rights/Education	Deficient Practice?	
What are patients' rights and responsibilities? How and when do they learn their rights? How do you teach patients 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
Patient Assessment and Plan of Care	Deficient Practice?	
What are some psychosocial issues you address with patients (in-center and home HD and PD, nursing home residents)?	<input type="checkbox"/> V552	<input type="checkbox"/> No
Do you have adequate resources (including time) to do what your job requires, per the Conditions for Coverage?	<input type="checkbox"/> V758	<input type="checkbox"/> No
How do you identify patients as "unstable" for "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



ESRD Core Survey Field Manual

Tab 15: Personnel Record Review

- Excerpt from ESRD Core Survey Process

➡ Personnel Record Review: ▲

Purpose - To verify that personnel have the qualifications 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.

Review selected personnel files: *Select a minimum of 3 personnel files to review for verification of the accuracy of the facility-submitted documentation. Select the files using the criteria below:*

- Identified concerns 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.



ESRD Core Survey Field Manual

Tab 16: Quality Assessment and Performance Improvement Review

- Excerpt from ESRD Core Survey Process
- ESRD Core Survey QAPI Review Worksheet

➡ **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, take actions to attain and sustain improvements, and support a facility-wide "Culture of Safety" that assures optimum patient safety

The QAPI review is divided into 3 General 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 in the technical areas.

Note: The Quality assessment and performance improvement 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 of water/dialysate, equipment maintenance/repair, and dialyzer reuse programs through review of outcomes and practice audits.

Segment II: Review of Quality Assessment and Performance Improvement in three critical priority areas for ALL facilities and in the data-driven focus and survey findings areas of this facility survey. This involves a detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and addressing 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, you will "follow" 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 assures patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients, communication of clear expectations of staff, and 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 among all levels of staff. You will review the facility staff complaint/suggestion log.
- **Patient engagement:** Looking at the facility program for assessing and addressing patients' mental and physical health outcomes. You will also review 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 to enable 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 you to determine if the facility has identified the same concerns 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 you will focus on during Segment II.*

Review the QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-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 dashboard or other 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, as required in the Conditions for Coverage:

- **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 of staff mixing dialysate concentrates; testing dialysate ph/conductivity; testing water for total chlorine and microbiological sample collection at least annually (V260)
- **Dialysis equipment**
 - Review of dialysis machine, equipment and ancillary equipment maintenance and repair monthly (V628)

- **Reuse**
 - Review and verification that all required reuse audits are conducted at the applicable intervals and adverse occurrences related to reuse addressed (V635)

Segment II: Review of Quality Assessment and Performance Improvement 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 Team 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 focused QAPI review on the aspects of care related to specific-cause categories. Examples are: for high rates of deaths due to **infection causes** the QAPI Team 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 QAPI Team 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.

➤ **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.

Review the past 6 months of QAPI documentation in these areas:

- **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 person to show you the QAPI documentation of oversight for surveillance and vaccinations including:
 - Hepatitis B patient surveillance and 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
- 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 took meaningful actions to investigate the problem, implement performance improvement plans, and monitor them for effectiveness V637).
- **Staff education and visual practice audits for infection control:** *Ask:* What are staff taught about the prevention of infections in dialysis? How often are they re-educated in infection prevention? How often do you visually audit personnel infection control practices? 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 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. There should be evidence of actions taken toward improvement when lapses in practices were observed, i.e., applicable staff involved in the investigation into issues surrounding the practices such as low staffing, and development and implementation of improvement plans, rather than not just counseling or reeducating (V637, V142).
- **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/or 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 (e.g., you observed staff not identifying patients' reprocessed dialyzers as required, and select an error to follow when a patient was dialyzed on another patient's dialyzer). Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI Team 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 determine 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, **Review** those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask: How does the QAPI Team prioritize their performance improvement activities? How did the QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did they 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 the QAPI Team take?

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

- Expect to see evidence that the facility QAPI Team:
 - 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 true 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 clear expectations of staff practices. A culture of safety supports complete staff and patient engagement and assures 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 in 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, e.g., KDQOL-36? 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 by the QAPI Team.*

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

- Expect to see that the QAPI Team 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 QAPI Team 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 QAPI Team 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 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 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 person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient.

- 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 in 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 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 (V638)
- Promote 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 meaningful efforts are being made to promote 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 QAPI REVIEW WORKSHEET

Facility _____ CCN _____ Date _____

Surveyor _____ Facility-based Responsible Person _____

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 to enable focus of the review during Segment II on the QAPI activities for recognizing and addressing areas you have identified as problems during the survey. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and list below the areas, in addition to the three critical priority areas, you will focus on during Segment II.*

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

The QAPI review is divided into 3 General 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 technical areas

- **Clinical and operational indicators**
- **Oversight of technical operations and practice audits**

Segment II. Review of Quality Assessment and Performance Improvement in three critical priority areas, 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 addressing the critical priority and problematic areas to attain and sustain improvements

- **Mortality review**
- **Infection prevention and control**
- **Medical error/adverse occurrence/clinical variance tracking and investigation system**
- **Data-driven focus and survey findings areas** for this facility survey

Segment III. Culture of Safety Review: Verifying the presence of a facility-wide culture that assures patient safety, including a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, clear expectations of staff communicated, and complete staff and patient engagement; the 3 review components are:

- **Risk identification and reporting**
- **Staff engagement**
- **Patient engagement**

Review the QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-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 dashboard or other 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.

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Areas 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): <ul style="list-style-type: none"> • Chemical analysis of product water <i>annual & as needed</i> • Monthly water & dialysate microbial content (CFU and LAL) • Total chlorine testing <i>prior to each HD shift or approx q 4 hrs</i> • RO daily monitoring 	
<input type="checkbox"/> Dialysis equipment repair and maintenance (V628)	
<input type="checkbox"/> Physical plant safety “rounds,” audits (V628)	
<input type="checkbox"/> Reuse QA audits & adverse events (V635)	
<input type="checkbox"/> Staff issues (V628) <ul style="list-style-type: none"> • Staff qualifications • Medical staff appointments • Staffing-turnover 	<input type="checkbox"/> ESRD Network relationship/communication (V772) <ul style="list-style-type: none"> • Data submission • Refusal of admission • Involuntary transfer and discharge
<input type="checkbox"/> Patient modality choice & transplant referral (V628) <ul style="list-style-type: none"> • % patients/modality • % patients potential transplant candidates • Transplant referral, status and follow up 	<input type="checkbox"/> Health outcomes-physical and mental functioning (V628) <ul style="list-style-type: none"> • KDQOL-36 (or other age appropriate survey/tool)
<input type="checkbox"/> Mortality-expirations & cause (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-HD (V628) <ul style="list-style-type: none"> • % intradialytic weight loss • BP variances pre and post dialysis • Intradialytic symptoms of depletion 	<input type="checkbox"/> Fluid and BP management-PD (V628) <ul style="list-style-type: none"> • Weight variances • BP variances • Symptoms of fluid overload, dehydration
<input type="checkbox"/> Dialysis adequacy-hemodialysis (V629) <ul style="list-style-type: none"> • Separate conventional, nocturnal and >4x/wk • Residual kidney function monitoring 	<input type="checkbox"/> Dialysis adequacy-peritoneal dialysis (V629) <ul style="list-style-type: none"> • Residual kidney function monitoring
<input type="checkbox"/> Nutritional status (separate HD & PD) (V630) <ul style="list-style-type: none"> • Albumin • Variance from usual body weight 	<input type="checkbox"/> Mineral, bone management (separate HD & PD) (V631) <ul style="list-style-type: none"> • Calcium, phosphorus, iPTH
<input type="checkbox"/> Anemia management (HD) (V632) <ul style="list-style-type: none"> • Hgb • Ferritin & TSAT% or CHR • Symptoms of anemia • Transfusions 	<input type="checkbox"/> Anemia management (PD) (V632) <ul style="list-style-type: none"> • Hgb • Ferritin & TSAT% or CHR • Symptoms of anemia • Transfusions
<input type="checkbox"/> Vascular access-HD (V633) <ul style="list-style-type: none"> • % CVC, AVF, AVG (AVF non-functional) • Efficacy monitoring • Adverse events-clotting, infiltration, infection 	<input type="checkbox"/> Dialysis access-PD (V633) <ul style="list-style-type: none"> • Tunnel & exit site infections • Reduced function/flow impairments • Repositioning/removal/replacements
<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>100cc • Chlorine/chloramine/fluoride breakthrough • Machine malfunction w/treatment interruption • Patient transfers to hospital from dialysis • Patient falls; Patient injuries 	
<input type="checkbox"/> Patient satisfaction & grievance/complaints (V636) <ul style="list-style-type: none"> • Patient satisfaction survey • Complaints/grievances/suggestions voiced or submitted by patients 	
<input type="checkbox"/> Infection prevention and control (separate HD & PD, home & in-center) (V637) <ul style="list-style-type: none"> • Infection occurrence surveillance & recording/antibiotic starts • HBV, TB surveillance • Vaccinations-HBV, influenza, pneumococcal • Staff education & visual practice audits • Patient education 	

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

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 (V627)-Explain_____

Does the QAPI documentation 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? Yes No (V626, 628)-Explain_____

- **Oversight of technical and facility operations and practice audits:** *Review the facility QAPI documentation to ensure routine audits are conducted in these areas, as required in the Conditions for Coverage:*

Water and dialysate quality

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

Dialysis equipment

- Review of dialysis machine, equipment and ancillary equipment maintenance and repair monthly (V627)

Reuse

- Review and verification that all required reuse audits are conducted at the applicable intervals and adverse occurrences related to reuse addressed (V635)

Were all the required monitoring and audits listed above reported to the QAPI Team as completed at the
required intervals? Yes No-Explain_____

If problems were identified in the reviews and audits above, is there evidence the facility QAPI Team
acted to resolve the problem(s) and attain improvements? Yes N/A No-Explain_____

Additional notes: _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Segment II: Review of QAPI in Critical Priority & Data-Driven Focus Areas

Review the facility *Quality Assessment and Performance Improvement* activities in three critical priority areas (mortality, infection prevention and control, medical error/adverse occurrence investigation system) for ALL facilities, and in the data-driven focus and survey findings areas specific to this facility survey (identified areas of patient risk). In all areas, conduct a sufficiently detailed review to determine the quality and effectiveness of the facility QAPI Team 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 focused review on the aspects of care related to specific-cause categories? *Examples are: for high rates of deaths due to **infection causes** the QAPI Team 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 QAPI Team 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**

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 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.

Review the past 6 months of QAPI documentation in these areas:

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.

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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 _____

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 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 QAPI team 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 prevention of infections in dialysis? How often are they re-educated in infection prevention? How often do you visually audit personnel infection control practices? 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 member? When lapses in practices were observed, were actions taken toward improvement, i.e., applicable staff involved in the investigation into issues surrounding the practices such as low staffing, and development and implementation of improvement plans, rather than not just counseling or reeducating? Yes No (V637, V142, V147)-Explain _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Patient education in infection prevention:

Ask: How are patients educated about infection prevention? How are they encouraged to be engaged in knowing what infection prevention actions (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment) they and/or staff should be follow when caring for them? 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 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 (e.g., you observed staff not identifying patients' reprocessed dialyzers as required, and select an error to follow when a patient was dialyzed on another patient's dialyzer). Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI Team 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 does the QAPI Team prioritize their performance improvement activities? How did the QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did they 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 the QAPI Team take?

Focus Area _____

Is there evidence that the QAPI Team 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 activity)? Yes N/A No (V626, 628-637)-Explain _____

Additional Notes: _____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

SEGMENT III: Culture of Safety

Culture of Safety: In healthcare, lessons show that true 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 clear expectations of staff practices. A culture of safety supports complete staff and patient engagement and assures 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 in this “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.*

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 Team 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, e.g., KDQOL-36? 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 by the QAPI Team.*

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

Does the facility's QAPI Team track and trend the % of eligible patients who complete and refuse the physical and mental functioning survey? Does the facility's QAPI Team 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's QAPI Team 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 QAPI Team 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 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 responsible person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient.

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 in negative patient responses were identified, ask: How did you utilize that information to improve programs or care delivery? (V636)



ESRD Core Survey Field Manual

Tab 17: Decision Making

- Excerpt from ESRD Core Survey Process

➡ **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

- Excerpt from ESRD Core Survey Process

➡ **Exit Conference:**

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

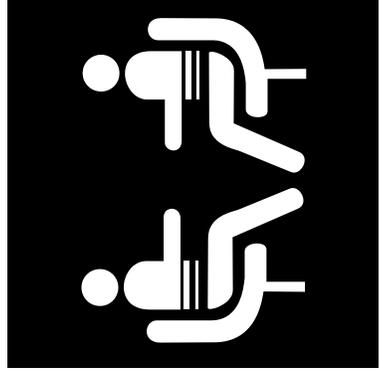
- Verbally present findings in order of severity; do not provide specific V-tags
- Follow relevant SOM & State procedures



ESRD Core Survey Field Manual

Tab 19: Signage-
Routine-Federal-
Survey-in-Progress

Routine Federal Survey in Progress



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

