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): *Note how the facility is ranked on the State Profile/Outcomes List. Refer to the guidance in the Presurvey Preparation section of the current fiscal year "ESRD Core Survey Data Tools" worksheet for review of the DFR, and comparison of the facility outcomes and trends with national averages. If the facility outcomes are worse than the national average, plan to include that area as a **preliminary data-driven focus are**a.*

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, Ambu bag) 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 is present: 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. **Interview** *about the DI system, and determine if there is a plan to use DI as back-up. If DI is present or included in a back-up plan, **ask** about the presence of an automatic divert-to-drain or automatic 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 or has been used in past 12 months: 2 months of resistivity readings at least twice per treatment day
  - Product water chemical analysis-12 months
  - Microbiological monitoring of water, including in the reuse room, and dialysate; both colony forming units (CFU) and endotoxin units (EU)-6 months
- **Practice audits of the operators' compliance with 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)

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*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 (if part of a back-up plan, each trigger below should be included in the plan)
    - 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:*
  - o Observations of reprocessing procedures -each reuse technician observed at least semi-annually
  - o Observations of preparation of dialysis machines with reprocessed dialyzers, i.e., germicide tests, priming, 2 persons identification of patient/dialyzer quarterly
  - o 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, 1RN and 1 PCT
- Registered dietitian
- Master's prepared social worker
- Water treatment personnel - *during "Water Treatment and Dialysate Review"*
- Reuse technician - *during "Dialyzer Reprocessing/Reuse Review"*
- Home training nurse(s) - *during "Home Dialysis Training and Support Review"*
- Machine/equipment technician - *during "Dialysis Equipment Review"*

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

➡ **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)

- o 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
- o 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 3areas:

➢ **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