

ESRD Core Survey Process

Purposes:

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

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

Audits of personnel practice: The Core Survey process includes the expectation that the dialysis facility will continuously monitor its operations, including auditing staff competency and compliance with implementation of technical and patient care procedures, to assure patient safety. The Core Survey supports the requirements of the ESRD CfC and recommendations of the Centers for Disease Control and Prevention (CDC). These requirements include at least annual audits through direct observation of facility staff while performing water testing, dialysate mixing and testing, dialysis equipment operation (V260), dialyzer reprocessing/reuse procedures (V360, 367, 368), and direct patient care infection prevention practices (V132, 142, 147). During the course of a Core Survey, surveyors should expect to see that the required staff practice audits are conducted by observers who possess the qualifications and training to evaluate the accuracy of the specific procedure implementation. The practice audit documentation must clearly show that the observed staff demonstrated competency in the procedure(s), or what lapses in practice were observed. When lapses in practices are observed, facility documentation must demonstrate evidence of follow up with investigation and performance improvement actions.

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

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

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

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

➡ **TASK: Presurvey Preparation ▲**

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

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

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

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

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

➡ **TASK: Introductions**

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

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

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

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

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

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

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

Examples of questions for staff:

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

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

Triggers for citation or more investigation of concerns:

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

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

Triggers for citation or more investigation of concerns:

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

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

Triggers for citation or more investigation of concerns:

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

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

Triggers for citation or more investigation of concerns:

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

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

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

➔ **TASK: Entrance Conference ▲**

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

Obtain and Review documentation of current facility and patient-specific clinical outcomes data submitted from/on the Entrance Conference Materials List/Clinical Outcomes Tables. *Review this information prior to the Entrance Conference, to be prepared to ask for clarifications, and discuss possible areas of concern. Compare the current facility outcomes listed in the “% of (HD or PD) Pts with” columns of the facility-completed HD and PD Clinical Outcomes Tables to the applicable entry in the “US Threshold” columns from the Clinical Outcomes Thresholds Table in the “ESRD Core Survey Data Worksheet” for the current fiscal year. Note which clinical areas the facility outcomes are worse than national averages by checking the appropriate box.*

Explain purpose and timeline for the survey

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

Discuss with the administrative person the current facility and patient outcomes data submitted. *Ask (briefly) about actions being taken for improvement in the clinical areas where national thresholds are not currently achieved (based on your review of the facility Entrance Conference Materials/Clinical Outcomes Tables).*

Determine the data-driven focus areas for the survey (clinical areas for review): The data-driven focus areas for the survey are the clinical areas where improvement is currently needed at that facility. *Discuss the selection of the data-driven focus areas for the survey with the administrative person. If SHR &/or SRR on the DFR are high, include hospitalization/readmission as a data-driven focus area. If the facility is currently meeting the thresholds in an area where the DFR review indicated problems, performance improvement may have taken place. Upon validation of the improvement, you may choose not to include that as a data-driven focus area for review.*

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

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

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

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

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

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

Triggers for citation or more investigation of concerns:

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

Medication preparation and administration: *Observe this process using the applicable observational checklist. Attempt to capture two observations of different staff preparing and administering medications for one to two 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)
- Not disposing needles in Sharps containers (V121)

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 two observations of each procedure. If the surveyor determines that more observations are indicated, two additional observations of the applicable procedure(s) should be sufficient to determine the presence of deficient practice.

2. **Review Facility Isolation practices:** If there is a hepatitis B positive (HBV+) patient on in-center hemodialysis at the facility:
- *Observe the isolation room/area, and the equipment and supplies contained within it. If possible, observe the care delivery for an HBV+ patient for the observations of direct care procedures in the section above. Observe for separation of care practices from the HBV susceptible patients.*
 - *Review staff/patient assignments for the current week, looking at which patients are concurrently assigned to the staff caring for HBV + 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,)
- Observed trends of breaches in infection control practices when caring for HBV+ patients (V113, 116, 117, 119, 121)
- Staff assigned/delivering care to HBV+ patient and HBV susceptible patients on same shift - *Investigate the extent of the practice* (V110, 131). (**Note:** Exceptions to this should be rare. If this is occurring, the facility's efforts to avoid this situation should be explained and clarified for the surveyor. Examples of such efforts are to schedule patients in a manner to avoid overlap between HBV+ and HBV-susceptible patients or scheduling HBV+ patients on shifts when there are two Registered Nurses (RN) on duty so that one RN may access the HBV+ patient's CVC and administer their medications, while the other RN does so for the other patients. Emergency medical situations may be a justifiable exception.)
- Isolation equipment not dedicated for use on HBV+ patients (V130)
- Non-HBV+ patient(s) dialyzing in the isolation room/area when an HBV+ patient is on in-center HD census (V110, 128, 130)

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

Trigger for citation or more investigation of concerns:

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

➡ **TASK: Patient Sample Selection:** ▲

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

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

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

Criteria for patient selection:

- **Not meeting outcome goals (“outliers”) in the data-driven focus areas** for the survey. *Refer to the patient-specific information submitted from the Entrance Conference Materials List/Clinical*

Outcomes Tables, i.e., the lists of patients, hospitalization logs, and infection logs. Select patients with trends of not meeting outcome goals in the data-driven focus areas for the survey.

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

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

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

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

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

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

- **Observe total chlorine test and interview** *about maximum allowable level of 0.1mg/L total chlorine, chlorine “breakthrough” procedure, and the amount of carbon in the system (empty bed contact time-EBCT). Note that if block carbon is used to supply dechlorinated water to a portable RO unit, there must be evidence from the manufacturer that the system attains equivalency to the 10 minute EBCT requirement, based on performance data of the block carbon. In addition, there must be one dual block carbon system per portable RO unit and each portable RO unit must supply one hemodialysis machine, per manufacturer’s directions. If the facility is using a continuous on-line chlorine monitor, ask about periodic (daily on treatment days) validation testing with an alternate method.*

Triggers for citation or more investigation of concerns:

- Absence of two or more carbon tanks with sample port between (V192)

- Insufficient carbon empty bed contact time (<10 minutes total EBCT) or equivalency documentation for block carbon used with portable RO-verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)
- Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equipment (V196)
- Staff assigned total chlorine testing has inadequate knowledge of testing procedure, 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:** the absence of two carbon tanks with a sample port between in an outpatient water treatment system is citable on identification and should be considered an immediate jeopardy situation.

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

Trigger for citation or more investigation of concerns:

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

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

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

Triggers for citation (Note: if DI is part of a backup plan, all of the triggers below are applicable):

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

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

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

Interview the person responsible for bicarbonate and acid dialysate concentrate mixing regarding verification of proper mixing, testing of acid concentrate, bicarbonate concentrate time frame for use (24

hours or per manufacturer's DFU) and "spiking" (inserting additives) into individual dialysate containers.

Triggers for citation or more investigation of concerns:

- Water/dialysate samples not drawn before disinfection (V254); sampling methods not per CFC (V252, 253, 255, 258)
- Water distribution system not disinfected at least monthly (V219)
- Each HD machine not cultured at least annually (V253)
- Staff unaware of correct dialysate concentrate mixing, acid concentrate batch testing, "spiking", duration of bicarbonate usability, etc. (V229, 233, 235, 236, 260)

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

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

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

Triggers for citation or more investigation of concerns:

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

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

➡ TASK: Dialyzer Reprocessing/Reuse Review ▲

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

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

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

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

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

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

Triggers for citation or more investigation of concerns:

- Improperly performed dialyzer pre-cleaning, header removal/cleaning (V334)
- Water used for pre-cleaning dialyzers not purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V319, 321,339)
- Reuse tech unaware of requirements in key patient safety areas per interview guide (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)
- Reprocessed dialyzers stored for extended periods (V345)
- QA audits listed above not done or incomplete - **Extend** to review all of the required QA audits for reuse (V360-368)
- Reprocessing equipment maintenance and repair activities not documented and/or not per manufacturer's directions (V316, 317)
- Noticeable strong germicide odors and/or patient or staff complaints regarding germicide odors- review the last 12 months of ambient air vapor testing for the germicide (V318)
- Serious adverse events possibly related to dialyzer reprocessing/reuse, e.g., **dialyzing patient on another patient's dialyzer**, without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)-**Extend** to include reuse as a focus area for QAPI Review.

Extending the facility-based reprocessing/reuse review may include: Observing the complete dialyzer reprocessing procedures, i.e., pre-rinse, automated cleaning, testing, germicide instillation, and labeling

for at least 2-3 dialyzers (V327-345); and additional interviews with reuse technicians and/or technical supervisory personnel.

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

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

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

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

Review PM documentation for 10% of hemodialysis machines (minimum three) *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 two 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 two to three additional months of calibration meter logs, or review of maintenance documentation of equipment that is in observable disrepair (V403).

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

Purpose - To verify that patients/caregivers receive adequate training and subsequent support to facilitate safe and successful home dialysis.

Note: If the dialysis facility provides only home dialysis training and support, in addition to the requirements in the Care at Home Condition for Coverage (CfC), it is also required to be in compliance with all of the ESRD CfC applicable to those services. This includes compliance with the CfC of Infection Control; Water and Dialysate Quality; Physical Environment; Patient's Rights; Patient Assessment; Patient Plan of Care; Quality Assessment and Performance Improvement; Laboratory Services; Personnel Qualifications; Medical Director; Medical Records; and Governance as well as those requirements of Care at Home. The survey of a home dialysis only facility must include all applicable

survey tasks, e.g., Presurvey Preparation, Entrance Conference, Patient Sample Selection, Environmental “Flash” Tour, Water/Dialysate Review, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review.

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

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

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

Triggers for citation or more investigation of concerns:

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

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

➡ TASK: Patient Interviews: ▲

Purpose - To listen to the patients' voices as recipients of the care provided at the facility; to determine if patients receive sufficient unbiased and understandable information on modality options to participate in modality decision-making; to evaluate patients' understanding of their rights and responsibilities; to determine how comfortable patients feel to voice concerns or make suggestions; and to assess their satisfaction with their care at the facility

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

*After attempting to interview the sampled patients, if the survey team is not able to interview at least four of the sampled patients, **interview additional alert and oriented patients to obtain a minimum of four patient interviews representing all dialysis modalities provided at the facility.** Enter these additional*

patients on the Patient Roster and designate that they were interviewed. Unless their interview indicates a reason to do so, you are not required to review their medical records.

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

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

Triggers for citation or more investigation of concerns:

Patients express concerns regarding:

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

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

➡ TASK: Medical Record Review: ▲

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

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

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

prescription and medication orders and compare to the documentation of the dialysis treatments delivered:

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

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

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

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

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

Guidance for review of patients sampled due to fluid management concerns as a data-driven focus area: Patients with >13mL/kg/hr average ultrafiltration rate (UFR) for intradialytic fluid removal: *Look for evaluation and interventions into causes of fluid gains between treatments, and interventions to mitigate the effects of rapid fluid removal during dialysis (e.g. BP drops, cramping, loss of consciousness). Expect to see IDT recognition of the potential risks to the patient posed by both failure to control fluid gain between treatments and consistent rapid fluid removal (>13mL/kg/hour UFR average in any treatment length), and interventions to minimize those risks.*

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

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

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

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

Patients sampled as LTC residents receiving their dialysis treatments at the LTC facility: Follow the current CMS Survey and Certification guidance.

- Expect to see coordination and communication between the LTC and ESRD IDT to assure the dialysis treatments are delivered in a safe environment, by adequately qualified, trained, and competent caregivers, with on-site supervision by a qualified RN (LPN for PD). The ESRD facility is responsible for the qualifications, training, and competency of all staff providing dialysis care in the LTC, as well as for monitoring the dialysis care and condition of the resident, in accordance with all applicable requirements in the CfC, such as, but not limited to Water/dialysate quality; Infection control; Patients' rights; Physical environment; Patient assessment; Patient plan of care; and Personnel qualifications.

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

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

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

Note: The ESRD CfC severely limit the option of involuntarily discharging a patient without transferring the patient's care to another outpatient dialysis facility. When one of the criteria for consideration of involuntary transfer/discharge listed at V766 is identified, the facility and ESRD Network are fully expected to exhaust all resources to address the problems and prevent the patient's transfer or discharge. If there is no resolution, the facility must make meaningful attempts to transfer that patient's care to another outpatient dialysis facility without regard to facility ownership. The only exception to this expectation is

in the case of an immediate severe threat to the health and safety of others when the facility may utilize an abbreviated IVD procedure.

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

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

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

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

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

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

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

➡ **TASK: Personnel Interviews:** ▲

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

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

- Medical director
- Nurse manager - *although it is likely that the facility nurse manager will be engaged in and interviewed throughout the survey process, if this is not the case, include her/him in the personnel interviews*
- Two to three nursing staff members including at a minimum, one RN and one PCT
- Registered dietitian
- Master's prepared social worker
- Water treatment personnel - *during “Water Treatment and Dialysate Review”*
- Reuse technician - *during “Dialyzer Reprocessing/Reuse Review”*
- Home training nurse(s) - *during “Home Dialysis Training and Support Review”*
- Machine/equipment technician - *during “Dialysis Equipment Review”*

Triggers for citation or more investigation of concerns:

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

➡ **TASK: Personnel Record Review:** ▲

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

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

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

- Concerns the survey team has identified about the qualifications, training or competency of specific staff during observations, interviews with patients or staff, complaint allegations, etc.;
- 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, training or competency verification (V410, 681, 684-696)
- PCTs listed with no current certification-*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 more personnel files to verify accuracy of the facility-submitted documentation or investigate the extent of personnel qualifications, training, and competency issues.

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

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

Note on Facility-Based (not Corporate-Based) QAPI: The review of the facility QAPI program must be limited to the information for only the facility being surveyed, and conducted with facility-based (on-site) administrative personnel. The expectation of a facility's QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care to and monitoring facility operations of their individual facility. The facility-based staff is expected to recognize when performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.

The QAPI review is divided into Three Segments of review:

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

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

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

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

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

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

Preparation for QAPI Review: Although portions of the QAPI review may occur throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey. This enables focus of the review during Segment II on the facility's QAPI performance improvement activities in the critical priority areas, data-driven focus areas, and survey findings areas. Conducting the review after most of the survey is completed allows the surveyor to determine if the facility has identified the same concerns as the survey team, and what performance improvement actions they have taken to address them. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and make a list of areas to focus on during Segment II, in addition to the three critical priority areas.*

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

Segment I: Monitoring Care and Facility Operations

➤ **Clinical and operational indicators monitored**

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

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

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

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

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

Water and dialysate quality (in-center and home hemodialysis)

- 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 facility staff mixing dialysate concentrates; testing batches of acid concentrate; testing dialysate pH/conductivity; testing water for total chlorine and microbiological sample collection; operating equipment (V260)

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

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

- Expect to see evidence that all of the above reviews and audits were conducted. When problems were identified, expect to see evaluation to determine the cause(s) of the issue and actions taken to resolve it. **Note:** the cycle of elevated water or dialysate cultures "addressed" with disinfection, followed by elevated cultures the following month, "addressed" with disinfection repeated over several consecutive months, is not effective performance improvement and may be risking patient safety.

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

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

➤ **Mortality review:**

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

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

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

For facilities with poor mortality outcomes as noted from the Dialysis Facility Report review during Presurvey Preparation: Ask: What trends in causes of mortality have you identified? How did you

investigate them? What performance improvement strategies have you implemented to address the high mortality ratio and/or adverse trends?

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

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

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

Infection occurrence tracking/trending/surveillance: *Ask:* What types of infections do you record? What information do you record about each infection? What is the facility hemodialysis vascular access infection rate? What is the facility peritoneal dialysis access infection rate? What is the facility peritonitis rate?

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).

Review documentation of facility dialysis-related infection rates.

Expect to see that the facility routinely calculates dialysis-related infection rates as applicable to the modalities offered (i.e. hemodialysis vascular access, peritoneal dialysis catheter, peritonitis) using an accepted formula. Vascular access and peritoneal dialysis catheter infection rates are generally expressed as events per 100 patient months ($[\#events \div total\ months\ patients\ on\ HD/PD\ in\ 12\ months] \times 100$). Peritonitis rates are either expressed as episodes per patient year at risk $[episodes \div (total\ PD\ patient\ months \div 12\ months)]$ or episodes per 100 patient months; that high infection rates and upward trends are recognized, investigated, and performance improvement actions implemented and monitored for effectiveness (V637).

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

- Hepatitis B patient surveillance; susceptible patients and personnel offered vaccination (V125-127)
- Tuberculosis surveillance of patients on admission or exposure
- Influenza vaccinations offered to patients and personnel seasonally
- Pneumococcal pneumonia vaccination offered to patients
- New Hepatitis C (HCV) infections (i.e. antibody elevation for facilities that test for HCV) or unexplained ALT elevations; HCV surveillance/routine testing including testing on admission.

- Expect to see evidence of active QAPI oversight of the high risk disease surveillance and vaccination programs listed above. If trends of lapses in surveillance or vaccination were identified, that the QAPI Team responded to thoroughly investigate the problem, implement performance improvement actions, and monitor them for effectiveness (V637).

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

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

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

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

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

For facilities with high rates of infection, high rates of CVC >90 days, or patterns of survey findings in infection control: *Ask:* What investigation have you conducted into your facility's problematic infection issue? What QAPI strategies have you implemented to improve the problem? What improvements have you achieved?

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

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

Review the facility error/occurrence log for the past six months: Select one error/occurrence to "follow" along with the responsible person. You may randomly select the error or select one pertinent to

concerns identified during the survey. Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI actions to prevent future similar occurrences.

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

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

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

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

- Expect to see evidence that the facility:
 - Prioritized performance improvement activities to assure the areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner (V639)
 - Routinely monitored the focus area, recognized that a problem/opportunity for improvement existed, thoroughly investigated root/multiple causes of the issues, and developed and implemented performance improvement plans
 - Monitored the performance improvement plan to attain and sustain improvements, or, if goals were still not achieved, revised the actions until improvements were attained and sustained? (note that repeated entries of “will monitor” over several consecutive months without active revisions to action plans is not sufficient evidence of effective QAPI) (V626, 628-637)

Segment III: Culture of Safety

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

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

Ask: How do you define medical errors/adverse occurrences/clinical variances? What occurrences are staff expected to report? **Compare:** the answer (list of occurrences) with the list in the section “Medical error/adverse occurrences/clinical variances” from the table included on page 2 of the “ESRD Core

Survey QAPI Review Worksheet” to ensure that these occurrences, at a minimum are recognized as potentially hazardous and are included in the facility reporting and investigation system.

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

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

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

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

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

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

➤ **Patient Engagement Review**

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

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

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

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

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

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

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

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

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

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

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

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

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

Triggers for citation in QAPI:

The QAPI program does not:

- Administer oversight of all facility operations including monitoring all areas and conducting practice audits as required by the CfC (V132, 260, 362-368, 403)
- Recognize and address risk areas where facility outcomes and/or survey findings indicate performance improvement is needed/indicated (V625-640)

- Follow up on performance improvement plans, resulting in improvements not attained or sustained or recurring similar adverse events (V634, 638)
- Make substantial efforts to establish and maintain a facility-wide culture of safety (V627)- *Consider the survey team's interviews with patients, staff and administrative personnel, along with the above reviews in the Culture of Safety QAPI Review Segment III, to determine if substantial efforts are being made to establish and maintain a facility-wide culture of safety.*

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

➡ **Decision Making:**

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

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

➡ **Exit Conference:**

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

- Verbally present findings in order of severity; do not provide specific V-tags
- Follow relevant State Operations Manual and State procedures