DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland   21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-02-ESRD

DATE: **October 21, 2016**

TO: State Survey Agency Directors

FROM: Director
                        Survey and Certification Group

SUBJECT: Release of the Fiscal Year (FY) 2017 Dialysis Facility Reports (DFR) and End
                        Stage Renal Disease (ESRD) Core Survey Materials

---

Memorandum Summary

- **The Centers for Medicare & Medicaid Services (CMS) announces the release of the materials used for ESRD surveys that have been updated for FY 2017.**

- The FY 2017 DFR, Pre-survey DFR Extract files, and State profiles are available to authorized State Survey Agency (SA) personnel on the dialysisdata.org web site.

- The ESRD Core Survey Data Worksheet and other ESRD Core Survey materials have been revised for FY 2017 to align with the FY 2017 DFR.

- The FY 2017 survey materials for the ESRD Core Survey are available on the CMS ESRD Survey and Certification page of the CMS.gov web site at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html

---

Background

The ESRD Core Survey process utilizes facility-specific data from the current FY DFR to individualize recertification surveys of ESRD facilities, and focus clinical care reviews in areas where improvements are indicated at an individual ESRD facility. The DFR for each ESRD facility is updated every FY to include the most recent facility-specific and comparative clinical data available to CMS. Accordingly, the ESRD Core Survey materials are updated each FY to align with the current FY DFR for key data indicators used in the Core Survey Process and associated national thresholds.

To ensure accuracy and standardization of the ESRD surveys, surveyors are expected to access and utilize the DFRs and ESRD Core Survey materials for the current FY for planning and conducting ESRD surveys.

Dialysis Facility Reports (DFR) for FY 2017
The updated State and Region profiles, DFRs, Pre-survey DFR Extracts, and Outcomes Lists for FY 2017 are available in the secure section of the DFR Web site Dialysis Data home page (http://www.dialysisdata.org). The Master Account Holder (MAH) for each State is the person who can manage access to the DFR data and Profiles for their State. If your State MAH is not able to access this information, you may contact UM-KECC at dialysisdata@umich.edu .

In a continuing effort to improve the quality and relevance of the DFR, the FY 2017 DFR has provided on page one of the FY 2017 DFR, in the section "What's New This Year?"

ESRD Core Survey Materials
To align with the updated data in the FY 2017 DFR, the following ESRD Core Survey materials have been revised:

- **FY 2017 ESRD Core Survey Data Worksheet**: The hemodialysis vascular access infection and peritoneal dialysis peritonitis rates have been removed from the "Clinical Outcomes Tables", due to changes in the FY 2017 DFR data. All of the national thresholds for the Core Survey data indicators have been updated in the "Clinical Outcome Thresholds Table", to align with the FY 2017 DFR.

- **ESRD Core Survey Process**: A section regarding how the ESRD facility calculates, trends, and acts upon elevations in dialysis-related infection rates (i.e. vascular access infections, peritoneal dialysis catheter infections, peritonitis) has been added to the Infection Prevention and Control Segment of the Quality Assessment and Performance Improvement (QAPI) Review. Added language regarding following equipment manufacturers' directions for use (DFU) in the triggers section for Observations of Hemodialysis Patient Care.

- **ESRD Core Survey QAPI Review Worksheet:** Revised to align with the changes to the ESRD Core Survey Process.

- **ESRD Core Survey Medical Record Review Worksheets:** Added V-tags to decision-making probes.

- **Outline of ESRD Core Survey Process and Triggers Laminates:** Revised to align with the changes in the ESD Core Survey Process.

- **Measures Assessment Tool (MAT):** In accordance with the DFR and the National Quality Forum endorsed measure #2701, a fluid management standard of "Avoid ultrafiltration rate $\geq$13ml/kg/hr" has been added to the Patient Plan of Care section of the MAT. Deleted reference to National Quality Forum under Psychosocial Status in the Patient Plan of Care section.

Surveyors conducting Medicare ESRD surveys during FY 2017 must ensure they are utilizing the FY 2017 ESRD Core Survey materials.

The attachments to this memo include the nine ESRD Core Survey documents that were revised for FY 2017.

All FY 2017 ESRD Core Survey materials, including the updated ESRD Core Survey Field Manual 1.9 may be accessed on the ESRD Survey and Certification page of the CMS.gov web site at:
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html

Contact: For questions or concerns regarding this memorandum, please contact esrdcoresurvey@cms.hhs.gov.

Effective Date: Immediately. This memorandum should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

Attachment (s):
Attachment 1- ESRD Core Survey Process
Attachment 2- Outline ESRD Core Survey Process
Attachment 3- ESRD Core Survey Triggers
Attachment 4- ESRD Core Survey Data Worksheet for FY 2017
Attachment 5- Measures Assessment Tool (MAT)
Attachment 6- ESRD Core Survey Medical Record Review ICHD
Attachment 7- ESRD Core Survey Medical Record Review PD
Attachment 8- ESRD Core Survey Medical Record Review HHD
Attachment 9- ESRD Core Survey QAPI Review Worksheet

cc: Survey and Certification Regional Office Management

The contents of this memorandum support activities or actions to improve patient or resident safety and increase quality and reliability of care for better outcomes.

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 are**a.*

Review the facility complaint and survey history for the current 12 to18 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÷ total months patients on HD/PD in 12 months] x 100).* Peritonitis rates are either expressed as episodes per patient year at risk [*episodes÷ (total PD patient months÷ 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

Outline of ESRD Core Survey Process

▲Presurvey Preparation:
➢ ***Review most current dialysis facility*** *report following ESRD Core Survey Data Worksheet guidance; note how facility is ranked on the State Profile/Outcomes list*
➢ ***Review facility complaint & survey history***
➢ ***Copy Entrance Conference Materials/Clinical Outcomes Tables*** *from Data Worksheet*
➢ ***Contact the ESRD Network*** *about quality concerns*

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

Environmental "Flash" Tour: *Observe 4 patient-related areas listed; ASK staff about the facility "culture of safety" in all 4 areas:*
➢ **In-center dialysis patient treatment area:** ***Observe*** *25% (min 3) occupied dialysis stations including the patients, their vascular accesses & surroundings of the stations; check availability & functionality of emergency equipment*
Triggers:
- Dummy drip chambers present in treatment area (V400, 403)
- Vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Evidence of poor staffing to meet patients' needs (V757)
- Blood spills not cleaned up; equip &/or surfaces spattered with blood (V122)
- HD machine transducer protectors wetted with blood not changed (V120)
- Insufficient space to prevent cross-contamination & use emergency equip (V404)
- No functional AED/defibrillator, oxygen, suction, emergency medications, Ambu bag (V413); insufficient or unavailable emergency evacuation supplies (V415)
- Hemodialysis machines in observed poor repair (V403)
- If dialyzer reuse, noticeable germicide odors (V318)
- Disrespectful communication or actions toward patients (V452, 627)
- Failure to offer patients privacy & confidentiality (V454)

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

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

➢ **Home dialysis training area:** ***Observe*** *the physical environment, infection control, availability of emergency equipment & method for summoning immediate assistance*
Triggers:
- Insufficient space to prevent cross-contamination between patients (V404)
- Insufficient patient privacy (V406)
- Blood /PD effluent spills not cleaned; equip or surfaces visibly spattered (V122)
- Absence of functional immediately available emergency resuscitation equipment (V413)
- No method for summoning immediate assistance (V402)
Triggers for extending the tour to other areas:
- Evidence of serious lack of environmental maintenance w/ potential to impact pt. safety, e.g., large areas of water damage, mold, uneven floor surfaces in pt.-related areas; (V401, 402)

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

▲Observations of Hemodialysis Care & Infection Control Practices:
➢ ***Observe direct care staff delivering care to HD patients*** *using observational checklists for:*
  - Initiation of hemodialysis w/central venous catheter (CVC)
  - CVC exit site care
  - Discontinuation of hemodialysis & post-dialysis care of CVC
  - Initiation of hemodialysis w/AVF or AVG
  - Discontinuation of hemodialysis w/AVF or AVG
  - Cleaning & disinfection of the dialysis station between patients
  - Preparation of the dialysis machine & extracorporeal circuit
  - Dialysis supply management
  - Medication preparation & administration
Triggers:
- Observed trends of breaches in infection control patient care practices:
  - Poor hand hygiene & glove use practices (V113)
  - Supplies taken to station not disposed, disinfected or dedicated (V116)
  - Clean dialysis supplies not protected from potential contamination (V119)
  - Breaches in aseptic practices for CVC (V147) or AVF/AVG care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- Use of dummy drip chamber to set up HD machine for treatment (V400, 403)
- Not testing hemodialysis machine alarms per manufacturer DFU (V403)
- Not testing dialysate pH/cond per manufacturer DFUor staff unaware of parameters (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers per DFU (V352, 403)
- Not assessing patients or monitoring during tx per facility policy (V504, 543, 550, 551, 715)

AVF=arteriovenous fistula; **AVG**=arteriovenous graft; **BFR**=blood flow rate; **CVC**=central venous catheter; **DFR**=dialysate flow rate; **DFU**=directions for use; **DI**=deionization; **EBCT**=empty bed contact time; **HD**=hemodialysis; **PCT**=patient care technician; **PD**=peritoneal dialysis; **PM**=preventative maintenance; **RO**=reverse osmosis; **TDS**=total dissolved solids ▲ Indicates a Core Survey worksheet for the task
Centers for Medicare & Medicaid Services - ESRD Core Survey Version 1.5　　　　　　　　　　　　　　　　　　　　　　　Page 1 of 4

Outline of ESRD Core Survey Process

- Medications not prepared in a clean area away from the dialysis stations (V117)
- Single dose vials punctured more than once or used for multiple patients (V118)
- Multidose vials punctured with previously used syringe or needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared/administered by unqualified personnel (V681)
- Not disposing needles in Sharps containers (V121)

➢ *Review Facility Isolation practices: If there is an HBV+ patient on in-center HD;* **Observe** *isolation room/area/equip/supplies;* **Observe care** *as above if possible;* **Review** *staff assignments for current week;* **Ask** *staff about assignments when HBV+ patient is dialyzing*

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

➢ *Verify dialysis treatment prescription delivery: Compare the dialysis prescription/orders with delivered treatment for 4-5 patients (dialysate, dialyzer, BFR, DFR)*

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

▲Patient Sample Selection:
➢ **Review** *patient-specific info from Entrance Conference Materials/Clinical Outcome Tables*
➢ **Select at least 10% of patients on census** *(min 4) w/ all modalities offered w/criteria below:*
  - **Not meeting goals ("outliers") in the data-driven-focus areas** for the survey
  - **"Unstable" patients**
  - **New admissions <90 days**
  - **LTC residents receiving dialysis treatments at the LTC facility**
  - **Observed w/concerns**
  - **Involved in a complaint to be investigated:** *limited to ≤25% of pt. sample*
  - **Involuntarily discharged** in past 12 months, not previously investigated by SA
➢ **Record** *the patient sample w/criteria used for selecting them*

▲Water Treatment & Dialysate Review: *Review critical water treatment components with on-site person(s) routinely responsible for the activity & daily monitoring:*
➢ *Observe total chlorine test; interview about maximum allowable total chlorine; actions taken for breakthrough; amount of carbon (EBCT) present. See notes in Core Survey process re the use of block carbon with portable RO units, the use of and on-line chlorine monitors.*

Triggers:
- Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-*verified by interview or record review* (V195)
- Total chlorine test result >0.1mg/L; done incorrectly or w/ incorrect reagents/equip (V196)
- Staff unaware of correct testing, max level of 0.1mg/L total chlorine & breakthrough procedures (V260)

➢ *Observe reverse osmosis (RO) unit, water quality monitor & alarm; interview about monitoring RO function by % rejection & water quality by TDS or conductivity*

Triggers:
- Absence of RO % rejection & product water TDS or conductivity monitor & alarm audible in patient tx area; readings not recorded daily (V199, 200)

➢ *Observe DI,* if present; *Interview* about DI & if it is included in back-up plan; *Ask* about automatic divert-to-drain or stop valve, minimum resistivity, actions if resistivity <1 megohm (STOP dialysis), ultrafilter after DI

Triggers: (if DI is part of back-up plan, all items below must be included in plan)
- Absence of functional resistivity monitor/alarm, visible & audible in patient tx area or not monitored 2x/day (V202, 203); No ultrafilter post DI (V204)
- Absence of a functional automatic divert-to-drain or stop valve (V203)
- Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion i.e., STOP dialysis (V260)

➢ *Interview person(s) responsible for dialysate mixing/testing & microbiological monitoring about proper dialysate mixing, acid batch testing, timeframe for bicarbonate use, "spiking"; microbiological sample sites & techniques, timing, frequency of cultures on each HD machine*

Triggers:
- Water distribution system not disinfected monthly (V219); Water/dialysate samples not drawn b4 disinfection (V254); sampling not per CfC (V253,255,258); HD machines not cultured at least annually (V253)
- Staff unaware of correct dialysate mixing, acid batch testing procedures "spiking", duration of bicarbonate usability, etc. (V229,233, 235, 236, 260)

➢ *Review facility water/dialysate oversight logs:*
  - Total chlorine tests-2 months; Product water chemical analysis-12 months
  - RO monitoring % rejection & product water TDS or conductivity-2 months
  - DI, if present or used in past 12 months: resistivity readings 2x/day-2 months
  - Microbiological results of water (including reuse room) & dialysate-6 months
  - Practice audits of staff conducting water, dialysate testing & procedures-12 months

Triggers:
- Total chlorine >0.1mg/L & no documentation of appropriate actions taken (V197)
- Chemical analysis of product water not done at least annually (V201)
- Irregularities, trends of omitted tests (V178, 180, 196, 199, 200, 202, 203, 213, 252, 253)
- Culture results exceeding action/max levels & no doc of appropriate actions taken (V178, 180)
- Practice audits of staff not conducted at least annually (V260)

▲Dialyzer Reprocessing/Reuse Review: *Observe the high risk components of dialyzer reprocessing & interview the reuse technician:*
  - **Transportation of used/dirty dialyzers** to the reprocessing room/area
  - **Pre-cleaning procedures** rinsing, header removal/cleaning
➢ *Ask* about germicide mixing, storage & spill management; dialyzer labeling/similar names warning; pre-processing before use; water quality & water pressure at pre-rinse sink
➢ *Review 12 months* of documentation of facility oversight of reuse program:
  - **QA audits:** obs of staff reprocessing, setting up for patients' dialysis & dialyzer labeling
  - **Reprocessing equip PM**
  - **Adverse events**/dialyzer complaint log

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

Centers for Medicare & Medicaid Services - ESRD Core Survey Version 1.5   Page 2 of 4

Outline of ESRD Core Survey Process

Triggers:
- Improperly performed pre-cleaning or header removal/cleaning (V334)
- Water used for pre-cleaning **not** purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V321,339)
- Reuse tech w/inadequate knowledge per interview (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
- Reprocessed dialyzers stored for extended periods (V345)
- Reprocessing equip not maintained/repaired per DFU &/or not documented (V316,317)
- QA audits listed not done or incomplete (V360-368)
- Noticeable strong germicide odors or patient/staff complaints (V318)
- Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)

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

▲Dialysis Equipment Maintenance:
➢ *Interview machine maintenance technician about HD machine manufacturer's DFU for PM i.e., prescribed intervals & operating hours for PM*
➢ *Review 12 mos PM logs for 10% of HD machines (min. 3) for compliance with manufacturer's DFU –include home HD machines maintained by the facility in the 10% sample*
➢ *Review 2 mos logs for calibration of equip used for machine PM & pH/conductivity testing*

Triggers:
- Trends of non-adherence to HD machine manufacturer's directions for PM (V403)
- No calibration of pH & conductivity meters or equip calibration meters or not per DFU (V403)
- Obs serious lack of maintenance of ancillary equip w/potential to impact pt safety (V403, 626)

Home Dialysis Training & Support Review: If the dialysis facility provides only home dialysis training and support, the survey must include all applicable survey tasks, e.g., Environmental Tour, Water/dialysate review, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review
➢ *Interview home training nurse(s) re patient candidacy evaluation, training, demo of comprehension, IDT support &QAPI oversight of home training & support programs*
➢ *Observe the direct care of home dialysis patient(s) if the opportunity arises during the survey when a home dialysis patient is being treated or trained at the facility*
➢ *Interview home dialysis patients during Patient Interviews*
➢ *Review medical records of home dialysis patients during Medical Record Review*

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

▲Patient Interviews: *Interview sampled patients, minimum of 4 patients; If <4 sampled patients can be interviewed, select additional alert patients to interview for total of at least 4. For phone interviews with home dialysis patients, ask nurse to alert patient about interview.*
Triggers:

Patients express concerns regarding:
- Patients' rights & responsibilities (V451)
- Education re transplant options & all dialysis modalities &settings (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- How to prevent infections & protect their dialysis access (V562)
- The safety & comfort of physical environment of facility (V401, 402)
- Disaster preparedness & emergency evacuation procedures (V409, 412)
- Communication with IDT & involvement in planning their care (V501, 541)
- Proficiency of staff in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff (V757-759)
- Culture of Safety: freedom to report care concerns, make suggestions, ask questions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training & IDT support of home dialysis patients & caregivers (V585, 592)

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

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

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

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

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

▲Personnel Record Review: *Review the facility-completed* "Personnel File Review" *worksheet or equivalent*

➢ *Select a minimum of 3 personnel files to review/compare to facility documentation for accuracy and/or follow up on concerns from survey*

Triggers:
- Personnel lack required quals, training, or competency verification (V410, 681, 684-696)
- 1 or more personnel files validated indicates inaccurate facility-submitted documentation
- PCTs w/o current certification : *check for hire date w/in 18 mos* (V695)

▲Quality Assessment & Performance Improvement (QAPI) Review:

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

➢ *Communicate with survey team about areas of concern. Determine focus areas for review during Segment II (i.e., data-driven focus areas & survey findings)*

➢ *Review QAPI documentation for 6 months; Interview the facility-based responsible person*

Segment I: Monitoring care & facility operations

➢ **Clinical & operational indicators:** *Review (briefly) facility QAPI summarizing info to verify all expected clinical & operational indicators are being monitored-per table/list of indicators in "QAPI Review Worksheet"*

➢ **Oversight of technical operations & practice audits:** *Review QAPI documentation of review/evaluation/audits and performance improvement actions, when indicated in:*
  - **Water/dialysate quality-**monthly cultures, annual water chemical analysis, visual audits of staff conducting testing/operating equip
  - **Dialysis equip-**monthly review of HD machine PM/repairs
  - **Dialyzer reuse/reprocessing-**QA audits done at specified intervals

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

➢ **Mortality review:** *Review documentation of QAPI analysis & discussion about mortality occurrences, causes, & trends. If mortality is ↑, performance improvement strategies for addressing contributory factors related to facility care.*

➢ **Infection prevention/control:** *Review & discuss 4 aspects of program:*
  - **Infection occurrence tracking/trending/surveillance:** *all positive cultures recorded w/sufficient info; trends recognized & addressed; Dialysis-related infection rates routinely calculated, and acted upon (vascular access, PD catheter, peritonitis)*
  - **Vaccination: high-risk disease management:** *Refer to vaccination info from Entrance Conference Materials; all patients tested for HBV & TB; all susceptible patients & staff offered HBV vaccination; patients offered pneumococcal & seasonal influenza vaccines.*
  - **Staff education & audit for infection control:** *Ask how staff are visually audited for infection control pt care practices; Review visual audits of staff while caring for patients;*

At least annual infection control education & visual practice audit for each staff member; applicable staff included in performance improvement plan development
  - **Patient education for infection prevention:** *Ask about patient education & engagement for personal care & expectations of staff delivering care*

➢ **Medical error/adverse occurrence/clinical variance tracking & investigation system:** *Review log for past 6 mos.* **Note:** *Adverse event log review is NOT intended as a source for citations except as related to QAPI process.* **Select an event/occurrence to "follow"** *through the QAPI process with the facility-based responsible person.*

➢ **Data-driven focus areas & survey findings:** *Review QAPI activities for prioritizing, recognizing the problem existed, implementing performance improvement strategies, monitoring for improvements, &, when goals still not met, revising &implementing revised plans to attain & sustain improvements.*

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

➢ **Risk identification and reporting:** *Ask what events are reported & compare with list on table in QAPI Review Worksheet; how "near misses/close calls" are reported & investigated;*

➢ **Staff engagement review:** *Ask how administration supports open, non-judgmental communication with/among all levels of staff; how/what staff are educated about reporting concerns & suggestions for improvement; how staff are given clear expectation of their duties, & how all levels of staff are involved in the facility QAPI activities*
  - *Review staff suggestion/complaint log to ensure there is a functional & responsive system in place for staff to freely voice concerns without fear of retribution*

➢ **Patient engagement review:**
  - **Patient health outcomes, physical & mental functioning***: Ask how scores from patient physical & mental functioning surveys (HRQOL) are tracked & trended in QAPI; what the threshold is for patient refusals.*
    - *Review QAPI Team analysis/discussion/action for patient HRQOL survey outcomes*
  - **Patient grievance/complaint/suggestion system***: Ask how staff are educated on what patient voiced issues to report & how to respond professionally; how patients are encouraged to freely speak up, self-advocate, and voice concerns w/o fear of retribution;*
    - *Review patient grievance/complaint/suggestion log; "follow" a complaint; ask the facility-based responsible person to show how it was investigated, resolved & result reported to patient; You may wish to interview the patient, if indicated*
  - **Patient satisfaction:** *Ask how patients' satisfaction/perceptions of care are assessed. Review summary of most recent patient satisfaction survey. If negative trends in patient responses were identified, ask how that information was used to improve care.*

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

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

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

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

ESRD Core Survey Process Triggers

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

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

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

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

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

Observations of Hemodialysis Care and Infection Control Practices:
Observations of direct staff delivering care
- Observed trends of breaches in infection control patient care practices:
  - Poor hand hygiene & glove use practices (V113)
  - Supplies taken to station not disposed, disinfected or dedicated (V116)
  - Clean dialysis supplies not protected from potential contamination (V119)
  - Breaches in aseptic practices for CVC (V147) or AVF/AVG care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- Use of dummy drip chamber to set up HD machine for treatment (V400, 403)
- Not testing hemodialysis machine alarms per manufacturer DFU(V403)
- Not testing dialysate pH/conductivity per manufacturer DFU or staff unaware of acceptable parameters (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers per DFU (V352, 403)
- Not assessing patients before & after tx or monitoring during tx per facility policy (V504, 543, 550, 551, 715)
- Medications not prepared in a clean area away from the dialysis stations (V117)
- Single dose vials punctured more than once or used for multiple patients (V118)
- Multidose vials punctured with previously used syringe or needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared/administered by unqualified personnel (V681)
- Not disposing needles in Sharps containers (V121)

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

Verification of dialysis treatment prescription delivery:
- 1 or more patients not dialyzed on ordered prescription (V543, 544)

Water Treatment and Dialysate Review:
Chlorine removal/carbon system
- Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-*verified by interview or record review*(V195)
- Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equip (V196)
- Staff unaware of correct testing, max level of 0.1mg/L total chlorine & breakthrough procedures (V260)

Reverse osmosis system
- Absence of RO % rejection & product water TDS or conductivity monitor & alarm audible in patient tx area; Readings not recorded daily (V199. 200)

ESRD Core Survey Process Triggers

DI, if present (If part of back-up plan, items below must be included in plan)
- Absence of functional resistivity monitor/alarm, visible & audible in patient treatment area or not monitored 2x/day (V202, 203)
- Absence of a functional automatic divert-to-drain or stop valve (V203)
- Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion i.e., stop dialysis (V260)
- No ultrafilter post DI (V204)

Interviews
- Water distribution system not disinfected monthly (V219)Water/dialysate samples not drawn b4 disinfection (V254); sampling not per CfC (V253,255,258); HD machines not cultured at least annually (V253)
- Staff unaware of correct dialysate mixing, acid batch testing procedures "spiking", duration of bicarbonate usability, etc. (V229,233, 235, 236, 260)

Log reviews
- Total chlorine >0.1mg/L & no documentation of appropriate actions taken (V197)
- Chemical analysis of product water not done at least annually (V201)
- Irregularities, trends of omitted tests (V178, 180, 196, 199, 200, 202, 203, 213, 252, 253)
- Microbiological results exceeding action/maximum levels & no documentation of appropriate actions taken (V178, 180)
- Practice audits of staff not conducted at least annually (V260)

Dialyzer Reprocessing/Reuse Review:
- Improperly performed pre-cleaning or header removal/cleaning (V334)
- Water used for pre-cleaning **not** purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V321,339)
- Dialyzers stored for extended periods (V345)
- Reuse tech w/inadequate knowledge per interview (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
- Reprocessing equip not maintained/repaired per DFU &/or not documented (V316,317)
- QA audits listed not done or incomplete (V362-368)
- Noticeable strong germicide odors or patient/staff complaints (V318)
- Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)

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

Home Dialysis Training and Support Review:
- Home training nurse(s) lack knowledge of training or monitoring patients/caregivers
- Patient/caregiver interviews identify concerns (V581, 585, 586, 592)
- Medical record reviews of home dialysis patients identify concerns related to training or patient monitoring (V585, 586, 593-595)

- Not evaluating home program outcomes separately in QAPI (V626, 628)
- If care observed, refer to triggers for infection control in Observations of care

Patient Interviews:
Patients express concerns regarding:
- Patients' rights & responsibilities (V451)
- Education re transplant options & all dialysis modalities &settings (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- How to prevent infections & protect their dialysis access (V562)
- The safety & comfort of physical environment of facility (V401, 402)
- Disaster preparedness & emergency evacuation procedures (V409, 412)
- Communication with IDT & involvement in planning their care (V501, 541)
- Proficiency of staff in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff (V757-759)
- Culture of Safety: freedom to report care concerns, make suggestions, ask questions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training & IDT support of home dialysis patients & caregivers (V585, 592)

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

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

Personnel Record Review:
- Personnel lack required qualifications, training, or competency verification (V410, 681, 684-696)
- 1 or more personnel files validated indicates inaccurate facility-submitted documentation
- PCTs w/o current certification: *check for hire date w/in 18 mos* (V695)

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

Fiscal Year 2017 (10/01/16-9/30/17)
ESRD CORE SURVEY DATA WORKSHEET

Facility:_____ **Date:**_____

CCN: _____ **Surveyor:**_____

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

Contents: There are 3 sections of this worksheet:
  I. **Presurvey Preparation and Dialysis Facility Report (DFR) Review** (pages 1-2)**:** To review and evaluate the facility outcomes data from the FY 2017 DFR, as well as facility survey history review, and ESRD Network contact
  II. **Entrance Conference Materials List with Clinical Outcomes Tables** (pages 3-6)**:** To be copied and given to the facility
  III. **Clinical Outcomes Thresholds Table** (page 7)**:** To compare the current facility clinical outcomes against current national benchmarks and determine the **data-driven focus areas** for the survey

I.   PRESURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW:

Download and Review the FY 2017 DFR for the facility. The DFR and the partially pre-populated "FY 2017 Pre-survey DFR Extract" for each facility, as well as the Region and State Profiles may be accessed at http://www.DialysisData.org. Enter your Username and Password then click "Log in" to log onto the Secure DialysisData.org web site. The *DFR* tab (at the top of the page) is where you may obtain the current DFR for all facilities in your State or Region. The *Profiles* tab (at the top of the page) contains the partially pre-populated FY 2017 Pre-survey DFR Extract for each facility, as well as the Region and State profiles, which contain the Outcomes list.

Note how the facility is ranked on the State Profile/Outcomes List. Review the information about the facility on pages 1-3 of the DFR. To guide your review of the DFR data tables, you may use STAR or download the FY 2017 Pre-survey DFR Extract for the facility.

STAR Users: You do not need to download the pre-populated FY 2017 Pre-survey DFR Extract for the facility. STAR 3.7 and later versions display the key DFR data elements for each facility, automatically uploaded from ASPEN with the survey shell. Follow the guidance on STAR screen [3] in the Presurvey Preparation task.

Non STAR users: Review the FY 2017 Pre-survey DFR Extract in conjunction with the facility DFR. Review each pre-populated data element on the DFR Extract, which are key aspects of facility performance. Note trends in outcomes over the 4 year period. For standardized mortality (SMR) and transplant ratios (STR), the 4-year average is a more consistent measure of facility performance. For standardized hospitalization ratio (SHR) and standardized readmission ratio (SRR) the most recent 1-year statistic is most meaningful.

Record in the "Outcome and Trend Conclusions" column of the FY 2017 Pre-survey DFR Extract how the facility compares with U.S. Averages. Note declining or improving trends and flag which elements are worse than the U.S. Average. Consider those clinical areas for **preliminary data-driven focus areas** for the survey. Attach the completed FY 2017 Pre-survey DFR Extract document to this worksheet.

Preliminary data-driven focus areas based on DFR review:

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

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

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

_____
_____
_____
_____

Contact the ESRD Network: *Call the Network to ask about concerns related to involuntary discharges, complaints, and other survey issues related to the ESRD Core Survey process.*

Network person contacted_____**Position:**_____

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

_____
_____
_____

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

_____
_____
_____

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

_____
_____
_____

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

_____
_____
_____

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

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

II. ENTRANCE CONFERENCE MATERIALS LIST/CLINICAL OUTCOMES TABLES
Guidance to surveyors: Make a copy of the Entrance Conference Materials List/Clinical Outcomes Tables (pages 3-6) to give to the facility person in charge during Introductions. Attach the completed copy to this worksheet.

Facility: _____ **Date:** _____

Documents/items needed for the survey: Please return this form to the survey team leader with the current information requested.

Needed within 3 hours:

1. ☐ List of current patients by name, separated into modalities

2. ☐ List of facility key personnel: medical director, administrator, nurse manager, social worker, dietitian, chief technician, and home training nurse(s)

3. ☐ Current in-center hemodialysis patient schedule by days & shifts with any isolation patients identified (seating chart or assignment sheet)

4. ☐ List of patients admitted to this facility within the past 90 days who are currently on census (do not include visiting patients) separated by modality with date of admission

5. ☐ List of patients who have been designated as "unstable" for any month in the past 3 months, including reason for unstable and month

6. ☐ List of all patients who were involuntarily discharged (not transferred to another outpatient dialysis facility) from this facility in the past 12 months

7. ☐ List of all discharged patients categorized as "lost to follow up" (i.e., not transferred out or discontinued dialysis) for the past 12 months

8. ☐ List of home dialysis (HD or PD) patients scheduled to be seen at the facility during the survey

9. ☐ List of residents of long term care facilities WHO RECEIVE THEIR HD or PD AT THE LTC facility and the name of the LTC where they are receiving dialysis

10. ☐ Hospitalization logs with admitting diagnoses listed for 6 months

11. ☐ List of current patients readmitted to the hospital within 30 days of discharge in past 6 months, separated by modality

12. ☐ Infection logs for past 6 months

13. ☐ List of in-center HD patients who are dialyzed with 0 K+ or 1.0 K+ dialysate

14. ☐ All patients' individual laboratory results for hemoglobin, Kt/V, uncorrected calcium, phosphorus and albumin for the current 3 months; separated by modality

Materials needed by the end of Day 1 of survey:

15. ☐ Vaccination information:
    - # of patients who received a complete series of hepatitis B vaccine _____
    - # of patients who received the influenza vaccine between August 1 and March 31 _____
    - # of patients who received the pneumococcal vaccine _____

16. ☐ Staff schedule for the last two weeks by day

17. ☐ Policy and procedure manuals for patient care, water treatment, dialysate preparation and delivery, and dialyzer reprocessing/reuse, if applicable
    - Anemia management protocol

18. ☐ Patient suggestion/complaint/grievance log for past 6 months

19. ☐ Adverse events (e.g., clinical variances, medical errors) documentation for the past 6 months

20. ☐ QAPI team meeting minutes for past 6 months and any supporting materials

21. ☐ Copy of CMS-approved waivers for medical director and/or isolation room

22. ☐ Facility Life Safety Code attestation or waiver (required if in-center or home training tx area does not provide exit at grade level or if the facility is adjacent to an industrial high hazard occupancy)

23. ☐ Staff practice audits for infection prevention while performing direct patient care (12 months)

24. ☐ For Water and Dialysate Review: logs for:
    - Daily water system monitoring-2 months
    - Total chlorine testing-2 months
    - Bacterial cultures and endotoxin results-water and dialysate-6 months
    - Chemical analysis of product water-12 months
    - Staff practice audits for water testing, dialysate mixing & testing and microbiological sampling-12 months

25. ☐ For Equipment Maintenance Review:
    - Documentation of preventative maintenance and repair of hemodialysis machines-12 months
    - Documentation of calibration of equipment used for machine maintenance-12months
    - Documentation of calibration of equipment used to test dialysate pH/conductivity-2 months

26. ☐ For Dialyzer Reprocessing Review, if applicable, logs for:
    - Bacterial cultures and endotoxin results from reuse room sites-6 months
    - Preventative maintenance and repair of reprocessing equipment-12 months
    - Reuse QA audits-12 months

Materials needed by noon on Day 2 of survey

27. ☐ Completed "Personnel File Review" Worksheet (or same information generated electronically)

28. ☐ Completed "CMS 3427-End Stage Renal Disease Application and Survey and Certification Report"

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

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

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

Indicator	MAT Goal Unless Other Specified	% of HD Pts with	List Current HD Patients as Stated
Adequacy (3 mo) Single pool Kt/V	≥1.2 for 3 tx/week	Kt/V <1.2 _____%	HD pts **not** meeting goal ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Standardized Kt/V	≥2.0 weekly for ≥4 tx/week	Kt/V <2.0 _____%	
Anemia (3 mo) Hemoglobin – pts' last value of month	For Hgb. <10, focus on symptoms, diagnosis and treatment of anemia	Hgb <10 g/dL _____%	HD pts with Hgb <10 in ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Mineral/bone (3 mo) Calcium (uncorrected)	<10.2mg/dL	Ca >10.2 _____%	HD pts w/Ca >10.2 &/or PO4 >7.0 in ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Phosphorus (PO4)	3.5-5.5 mg/dL	PO4 >7.0 _____%	
Nutrition Albumin (3 mo)	≥4 g/dL for BCG; Lab normal for BCP	Alb <4.0 _____%	HD pts w/ Alb <3.5 in ≥2 mos 1._____ 2._____ 3._____ 4._____ 5._____
Fluid management (3 mo) Avg ultrafiltration rate (UFR)	Avg UFR <13ml/kg/hr	Avg UFR >13 ml/kg/hr _____%	HD pts w/avg UFR>13 ml/kg/hr in ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Vascular access (VA) (12 mo) CVCs only >90 days/3 mo	↓ CVC rate	CVCs only >90 days _____%	HD pts with CVC >90 days/3 mo 1._____ 2._____ 3._____ 4._____ 5._____
Transplant waitlist (12 mo) % of all pts age <70 on waitlist any time during last 12 mo	Interested pts are referred for transplant unless excluded by transplant program evaluation or area transplant programs' listed exclusion criteria	Transplant waitlist rate % _____	Provide a copy of the transplant waitlist, transplant program(s) exclusion criteria, and procedure for candidacy evaluation and referral of patients.

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

Peritoneal Dialysis Clinical Outcomes Table

Indicator	MAT Goal Unless Other Specified	% of PD Pts with	List PD Pts as Stated
Adequacy (6 mo) Kt/V	≥1.7 weekly	Kt/V <1.7 ＿＿＿＿＿％	PD pts **not** meeting goal in last 6 mo 1.＿＿＿＿＿＿＿＿＿＿＿ 2.＿＿＿＿＿＿＿＿＿＿＿ 3.＿＿＿＿＿＿＿＿＿＿＿ 4.＿＿＿＿＿＿＿＿＿＿＿ 5.
Anemia (3 mo) Hemoglobin – pts' last value of month	For Hgb. <10, focus on symptoms, diagnosis and treatment of anemia	Hgb <10 g/dL ＿＿＿＿＿％	PD pts w/Hgb <10g/dL for ≥2 mo 1.＿＿＿＿＿＿＿＿＿＿＿ 2.＿＿＿＿＿＿＿＿＿＿＿ 3.＿＿＿＿＿＿＿＿＿＿＿ 4.＿＿＿＿＿＿＿＿＿＿＿ 5.
Mineral/bone (3 mo) Calcium (uncorrected) Phosphorus (PO4)	<10.2 mg/dL 3.5-5.5 mg/dL	Ca >10.2 ＿＿＿＿＿％ PO4 >7.0 ＿＿＿＿＿％	Pts w/ Ca >10.2 &/or PO4 >7.0 for ≥2 mo 1.＿＿＿＿＿＿＿＿＿＿＿ 2.＿＿＿＿＿＿＿＿＿＿＿ 3.＿＿＿＿＿＿＿＿＿＿＿ 4.＿＿＿＿＿＿＿＿＿＿＿ 5.
Nutrition (3 mo) Albumin	≥4g/dL BCG Lab normal for BCP	Alb <4.0 ＿＿＿＿＿％	PD pts w/Alb <3.5 in ≥2mos 1.＿＿＿＿＿＿＿＿＿＿＿ 2.＿＿＿＿＿＿＿＿＿＿＿ 3.＿＿＿＿＿＿＿＿＿＿＿ 4.＿＿＿＿＿＿＿＿＿＿＿ 5.
Transplant waitlist (12 mo) % of all pts age <70 on waitlist any time during last 12 mo	Interested patients are referred for transplant unless excluded by transplant program evaluation or area transplant programs' exclusion criteria	Transplant waitlist rate % ＿＿＿＿＿	Provide a copy of the transplant waitlist, transplant program(s) exclusion criteria, and procedure for candidacy evaluation and referral of patients

III. CLINICAL OUTCOMES THRESHOLDS TABLE

Prior to the Entrance Conference review the current patient outcomes data submitted. *Compare the current facility outcomes listed in the* **"% of (HD or PD) Pts with"** *columns of the HD and PD Clinical Outcomes Tables to the applicable entry in the "US Threshold" columns from the table below, where available.*
When "Yes" is checked in the "Above/Below Threshold" column, consider including that clinical area as a data-driven focus for the survey.

Clinical Outcomes Thresholds Table for FY 2017

HD Indicators	US Threshold	Above Threshold?
Adequacy: Single pool Kt/V <1.2	**2.5%***	☐ Yes ☐ No
Standardized Kt/V <2.0 if ≥4x/week or nocturnal	**Not reported***	
Anemia: Hemoglobin <10 g/dL	**16.5%***	☐ Yes ☐ No
Mineral/bone: Calcium uncorrected >10.2 mg/dL	**3.2%***	☐ Yes ☐ No
Phosphorus >7.0 mg/dL	**11.8 %***	☐ Yes ☐ No
Nutrition: Albumin <4.0 g/dL BCG; lab normal BCP	**62.6%****	☐ Yes ☐ No
Fluid management: Avg UFR >13 ml/kg/hr.	**7.9%***	☐ Yes ☐ No
Vascular access (VA): CVCs only >90 days/3 mo	**9.9%***	☐ Yes ☐ No
Transplant waitlist <age 70	**22.6%*** See Note	**Below Threshold?** ☐ Yes ☐ No
PD Indicators	US Threshold	Above Threshold?
Adequacy: Kt/V <1.7	**7.5%***	☐ Yes ☐ No
Anemia: Hemoglobin <10 g/dL	**26.4%***	☐ Yes ☐ No
Mineral/bone: Calcium uncorrected >10.2 mg/dL	**3.2%***	☐ Yes ☐ No
Phosphorus >7.0 mg/dL	**11.8%***	☐ Yes ☐ No
Nutrition: Albumin <4.0 g/dL BCG; lab normal BCP	**62.6%****	☐ Yes ☐ No
Transplant waitlist <age 70	**22.6%*** See Note	**Below Threshold?** ☐ Yes ☐ No

*FY2017 DFR National Average **NOTE:** average of monthly facility lab results will likely show more variation and a higher percentage of patients above the threshold for any given month
**DOPPS Practice Monitor, accessed July 26, 2016: patient-level 3 month average through December 2015

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

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

Determine the data-driven focus areas for the survey (clinical areas for review): *Discuss the selection of the data-driven focus areas for the survey with the administrative person. If SHR &/or SRR on 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.*

Record the data-driven focus areas for this survey:

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

Tag	Condition/Standard ➡	Measure ➡	Values ➡	Reference ➡	Source
494.40 Water and dialysate quality:					
V196	Water quality; test for total chlorine	Max. total chlorine (includes chloramines)	≤0.1 mg/L daily/shift	AAMI RD52	Records
V178	Water & dialysate quality/test for microbiological	Action / Max. bacteria – product water / dialysate	50 CFU/mL / <200 CFU/mL		
V180	contamination	Action / Max. endotoxin – product water / dialysate	1 EU/mL / <2 EU/mL (endotoxin units)		
494.50 Reuse of hemodialyzers and blood lines (only applies to facilities that reuse dialyzers &/or bloodlines)					
V336	Dialyzer effectiveness	Total cell volume (TCV) of (hollow fiber dialyzers	Measure original volume/TCV Discard if after reuse <80% of original TCV	KDOQI HD Adequacy 2006 AAMI RD47	Records Interview
494.80 Patient assessment: The interdisciplinary team (IDT), patient/designee, RN, MSW, RD, physician must provide each patient with an individualized & comprehensive assessment of needs					
V502	- Health status/comorbidities	- Medical/nursing history, physical exam findings	Refer to Plan of care & QAPI sections (below) for values	Conditions for Coverage	Chart
V503	- Dialysis prescription	- Evaluate: HD every mo; PD first mo & q 4 mo		KDOQI Guidelines (see POC)	Interview
V504	- BP & fluid management	- Interdialytic BP & wt gain, target wt, symptoms			
V505	- Lab profile	- Monitor labs monthly & as needed			
V506	- Immunization & meds history	- Pneumococcal, hepatitis, influenza; med allergies			
V507	- Anemia (Hgb, Hct, iron stores, ESA need)	- Volume, bleeding, infection, ESA hypo-response			
V508	- Renal bone disease	- Calcium, phosphorus, PTH & medications			
V509	- Nutritional status	- Multiple elements listed			
V510	- Psychosocial needs	- Multiple elements listed			
V511	- Dialysis access type & maintenance	- Access efficacy, fistula candidacy			
V512	- Abilities, interests, preferences, goals, desired participation in care, preferred modality & setting, expectations for outcomes	- Reason why patient does not participate in care, reason why patient is not a home dialysis candidate			
V513	- Suitability for transplant referral	- Reason why patient is not a transplant candidate			
V514	- Family & other support systems	- Composition, history, availability, level of support			
V515	- Current physical activity level & referral to vocational & physical rehabilitation	- Abilities & barriers to independent living; achieving physical activity, education & work goals			
494.90 Plan of care The IDT must collaboratively develop & implement a written, individualized plan of care that specifies the services necessary to address the patient's needs as identified by the comprehensive assessment & changes in the patient's condition, & must include measurable & expected outcomes & estimated timetables to achieve outcomes. Outcome goals must be consistent with current professionally accepted clinical practice standards. Citations are based on facility IDT failure to recognize & implement strategies for improvement when individual patients' outcomes are out of range, not on out-of-range outcomes alone.					
V543	(1) Dose of dialysis/volume status Monitor each treatment	Management of volume status	Euvolemic & pre-BP <140/90; post-BP <130/80 (adult); lower of 90% of normal for age/ht/wt or 130/80 (pediatric) Avoid ultrafiltration rate ≥ 13 ml/kg/hr	KDOQI HD Adequacy 2006 KDOQI Cardiovascular 2005 NQF #2701	Chart Interview
V544	(1) Dose of dialysis (HD adequacy) Monitor adequacy monthly	Adult HD <5 hours 3x/week, minimum spKt/V Adult HD 2x/week, RKF <2 mL/min. HD 2, 4-6x/week, minimum stdKt/V	≥1.2 (or URR≥65); Min. 3 hours/tx if RKF <2ml/min Inadequate treatment frequency ≥2.0/week	NQF #0249 (adult) NQF #1423 (peds) KDOQI HD Adequacy 2006	Chart Interview
V544	(1) Dose of dialysis (PD adequacy – adult) Monitor 1st month & every 4 months	Minimum delivered Kt/V$_{urea}$	≥1.7/week	NQF #0318 KDOQI PD Adequacy 2006	Chart Interview
V544	(1) Dose of dialysis (PD adequacy – pediatric) Monitor 1st month & every 6 months	Minimum delivered Kt/V$_{urea}$	≥1.8/week	KDOQI PD Adequacy 2006	Chart Interview
V545	(2) Nutritional status - Monitor albumin & body wt monthly; monitor other parameters at V509 as needed	Albumin Body weight & other parameters listed at V509	≥4.0 g/dL BCG preferred; if BCP: lab normal % usual wt, % standard wt, BMI, est. % body fat	KDOQI Nutrition 2000 KDOQI CKD 2002	Chart Interview
V545	(2) Nutritional status (pediatric) monitor monthly	Length/ht-for-age % or SD, dry wt & wt-for-age % or SD, BMI-for-ht/age % or SD, head circ/age % (age <3), nPCR	nPCR normalized-HD teen (nPCR and albumin are not predictive of wt loss/nutritional status in younger children)	KDOQI Pediatric Nutrition 2008	Chart Interview
V546	(3) Mineral metabolism & renal bone disease Monitor calcium & phosphorus monthly Monitor intact PTH every 3 months	Calcium uncorrected Phosphorus Intact PTH (consider with other MBD labs, not in isolation)	normal for lab or <10.2 mg/dL[1] (3 mo rolling average) All: 3.5-5.5 mg/dL[2] Under review	[1]NQF #1454 [2]KDIGO CKD-MBD 2009	Chart Interview
V547	(4) Anemia – Hgb **non-ESA** - monitor monthly	Hemoglobin (Adult & pediatric)	No safe upper level established[3] See Hgb **on ESA** (below) for management of anemia[3]	[3]FDA 6/24/11 for more info re CKD 5D recommendation	Chart Interview
V547 V548	(4) Anemia – Hgb **on ESA** – monitor weekly until stable; then monitor monthly; evaluate other anemia causes; educate patients about risks/benefits	Hemoglobin (Adult & pediatric) Blood transfusion	Initiate ESAs <10 g/dL; interrupt/ ↓ dose near or >11 g/dL[3] Give lowest dose of ESAs to avoid transfusion (especially in transplant candidates); consider patient preference	[3]FDA 6/24/11 for more info re CKD 5D recommendation	Chart Interview
V549	(4) Anemia - Monitor iron stores routinely	Adult & pediatric: transferrin saturation Adult & pediatric: serum ferritin	>20% (HD, PD), or CHr >29 pg/cell HD: >200 ng/mL; PD: >100 ng/mL HD/PD: <500 ng/mL or evaluate if indicated	KDOQI Anemia 2006	Chart Interview

Sources: **DFR**=Dialysis Facility Reports; **CW**=CROWNWeb; **Chart**=Patient Chart; **Records**=Facility Records; **Interview**=Patient/Staff Interview; **Abbreviations:** **BCG/BCP**=bromcresol green/purple **BMI**=Body mass index; **CAHPS**=Consumer Assessment of Healthcare Providers & Services; **CFU**=colony forming units; **CHr**=reticulocyte hemoglobin; **CMS CPM**=CMS Clinical Performance Measure; **DOPPS**=Dialysis Outcomes & Practice Patterns Study; **ESA**=erythropoiesis stimulating agent; **KDIGO**=Kidney Disease Improving Global Outcomes; **KDOQI**=Kidney Disease Outcomes Quality Initiative, **nPCR**=normalized protein catabolic rate; **NQF**=National Quality Forum; **RKF**=residual kidney function; **SD**=standard deviation; **spKt/V**=single pool Kt/V

Tag	Condition/Standard ➡	Measure ➡	Values ➡	Reference ➡	Source
V550 V551	(5) Vascular access (HD)	Fistula Graft Central Venous Catheter	Preferred, if appropriate[4,5,7,8] Acceptable if fistula not possible or appropriate[5,6] Acceptable if evaluated for fistula/graft [6,8], if transplant soon, or if AVF/AVG not possible in small adult or peds pt[5]	[4]NQF #0257 [5]KDOQI Vascular Access 2006 [6]NQF #0251 [7]NQF #0256; [8]Fistula First	Chart Interview
V552	(6) Psychosocial status	Survey physical & mental functioning by standardized tool, e.g.KDQOL-36 survey or age appropriate survey	Documentation of action in response to results	Conditions for Coverage	Chart Interview
V553 V554	(7) Modality	Home dialysis referral Transplantation referral	Candidacy or reason for non-referral	Conditions for Coverage	Chart Interview
V555	(8) Rehabilitation status	Productive activity desired by patient Pediatric: formal education needs met Vocational & physical rehab referrals as indicated	Achieve & sustain appropriate level, unspecified	Conditions for Coverage	Chart Interview
V562	(d) Patient education & training	Dialysis experience, treatment options, self-care, QOL, infection prevention, rehabilitation	Documentation of education in record	Conditions for Coverage	Chart Interview
494.110 Quality assessment & performance improvement (QAPI): The dialysis facility must develop, implement, maintain, & evaluate an effective, data-driven QAPI program with participation by the professional members of the IDT. The program must reflect the complexity of the organization & services (including those under arrangement), & must focus on indicators related to improved health outcomes & the prevention & reduction of medical errors. The dialysis facility must maintain & demonstrate evidence of its QAPI program including continuous monitoring for CMS review. Refer to your ESRD Network's goals for targets for aggregate patient outcomes.					
V628	Health outcomes: Physical & mental functioning	Survey adult/pediatric patients by standardized tool, e.g. KDQOL-36 survey or age appropriate survey	Achieve & sustain appropriate status ↑ % of eligible patients completing survey	Conditions for Coverage	Records
V628	Health outcomes: Patient hospitalization	Standardized hospitalization ratio (1.0 is average, >1.0 is worse than average, <1.0 is better than average)	↓ unplanned hospitalizations	Conditions for Coverage	DFR Records
V628	Health outcomes: Patient survival	Standardized mortality ratio (1.0 is average, >1.0 is worse than average, <1.0 is better than average)	↓ mortality	Conditions for Coverage	DFR Records
V629	(i) HD adequacy (monthly)	HD: Adult (patient with ESRD ≥3 mo)	↑ % with spKt/V ≥1.2 or URR ≥65% if 3 times/week dialysis and stdKt/V ≥2.0/week if 2 or 4-6 times/week dialysis	Conditions for Coverage NQF #0249 (adult) NQF #1423 (peds)	DFR Records
V629	(i) PD adequacy (rolling average, each patient tested ≤4 months)	PD: Adult	↑ % with weekly Kt/V_{urea} ≥1.7 (dialysis+RKF)	Conditions for Coverage NQF #0318	DFR Records
V630	(ii) Nutritional status	Facility set goals; refer to parameters listed in V509	↑ % of patients within lab target range on albumin and other nutritional parameters set by the facility	Conditions for Coverage; KDOQI Nutrition 2000 KDOQI CKD 2002	Records
V631	(iii) Mineral metabolism/renal bone disease	Calcium, phosphorus, & PTH	↑ % in target range on all measures monthly	Conditions for Coverage	Records
V632	(iv) Anemia management Monitor patients on ESAs &/or patients not taking ESAs	Anemia symptoms Blood transfusion Serum ferritin & transferrin saturation or CHr Patient education on ESAs	↓% of patients with anemia symptoms ↓ % of patients (esp. transplant candidates) transfused Evaluate if indicated ↑% of patients educated about potential risks/benefits	FDA 6/24/11 for more info re CKD 5D recommendation	DFR Records Interview
V633	(v) Vascular access (VA) Evaluation of VA problems, causes, solutions	Cuffed catheters > 90 days AV fistulas for dialysis using 2 needles, if appropriate Thrombosis episodes Infections per use-life of access VA patency	↓ to <10%[6] ↑ to ≥65%[6] or ≥66%[7] ↓ to <0.25/pt-yr at risk forfistulas; 0.50/pt-yr at risk for (grafts ↓ to <1% (fistula); <10% (graft) ↑ % with fistula >3 yrs & graft >2 yrs	[5]KDOQI Vascular Access2006 [8]Fistula First	DFR Records
V634	(vi) Medical injuries & medical errors identification	Medical injuries & medical errors reporting	↓ frequency through prevention, early identification & root cause analysis	Conditions for Coverage	Records
V635	(vii) Reuse	Evaluation of reuse program including evaluation & reporting of adverse outcomes	↓ adverse outcomes	Conditions for Coverage	Records
V636	(viii) Patient satisfaction & grievances	Report & analyze grievances for trends CAHPS In-Center Hemodialysis Survey or other survey	Prompt resolution of patient grievances ↑ % of patients satisfied with care	Conditions for Coverage	Records Interview
V637	(ix) Infection control	Analyze & document incidence for baselines & trends	Minimize infections & transmission of same Promote immunizations	Conditions for Coverage	DFR Records
V637	Vaccinations	Hepatitis B, influenza, & pneumococcal vaccines Influenza vaccination by facility or other provider	Documentation of education in record ↑ % of patients vaccinated on schedule ↑ % of patients receiving flu shots 10/1-3/31	Conditions for Coverage NQF #0226	Records DFR

Sources: *DFR*=Dialysis Facility Reports; *CW*=CROWNWeb; *Chart*=Patient Chart; *Records*=Facility Records; *Interview*=Patient/Staff Interview; **Abbreviations:** *BCG/BCP*=bromcresol green/purple *BMI*=Body mass index; *CAHPS*=Consumer Assessment of Healthcare Providers & Services; *CFU*=colony forming units; *CHr*=reticulocyte hemoglobin; *CMS CPM*=CMS Clinical Performance Measure; *DOPPS*=Dialysis Outcomes & Practice Patterns Study; *ESA*=erythropoiesis stimulating agent; *KDIGO*=Kidney Disease Improving Global Outcomes; *KDOQI*=Kidney Disease Outcomes Quality Initiative, *nPCR*=normalized protein catabolic rate; *NQF*=National Quality Forum; *RKF*=residual kidney function; *SD*=standard deviation; *spKt/V*=single pool Kt/V

Centers for Medicare & Medicaid Services - Version 2.5   Page 2 of 2

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

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

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

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

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

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

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

Record the current dialysis treatment and medication orders:
Treatment Orders: Date:_____ EDW:_____ Frequency:_____days/week
Dialyzer:_____ Dialysate:_____ BFR:_____ DFR:_____
Treatment duration:_____hours_____minutes Heparin/anticoagulant:_____
ESA dose:_____ Frequency:_____ Iron:_____ Vitamin D:_____
Other meds/treatments:_____
_____

Review 2-3 consecutive weeks of HD treatment records. RECORD EXCEPTIONS and VARIANCES ONLY. Check if no exceptions. ☐
(Number)_____ treatment records reviewed between _____and _____

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

Patient Name:_____ ID #:_____

Facility:_____Surveyor: _____

EXCEPTIONS	DATES/COMMENTS
Adequacy plan not implemented (V544):	
☐ BFR, DFR, time, dialyzer type	
Meds/treatments not administered as ordered:	
☐ Anemia management (V547)	
☐ Mineral metabolism (V546)	
☐ Incorrect dialysate(V541)	
☐ Antihypertensives (V543)	
☐ Other	
BP/fluid management (V543):	
☐ Hypertension	
☐ Hypotension	
☐ Dry/target weight not achieved	
☐ Ultrafiltration Rate >13mL.kg/hr *(review for trends)*	
Patient monitoring:	
☐ No assessment pre and/or post dialysis (V543)	
☐ Not monitored per policy (V543)	
☐ Access function and/or care not documented (V550):	
☐ Unusual or adverse events (V634)	

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

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

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

If yes: Is there evidence that facility staff recognized the trend as a problem, acted with interventions aimed at resolution/improvement, and changed strategies when interventions were unsuccessful?
   o **If yes-**no citation is indicated*
   o **If no-**citation at V543 may be indicated*

Patient Name:_____ID #:_____
Facility:_____Surveyor: _____

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

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

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

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

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

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

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

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

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members (physician, RN, registered dietitian, master's prepared social worker at a minimum)?
  ☐ **Yes** ☐ **No** (V501, 509, 510, 541, 552)

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

Notes:_____
_____
_____
_____
_____
_____
_____

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

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

- Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated? ☐ **Yes** ☐ **No** (V124, 125, 126, 506)

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

Notes:_____
_____
_____
_____
_____
_____
_____

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

Admit Date: _____ Review Date: _____

DOB: _____ Age: _____ ☐ Peritoneal catheter ☐ Fistula ☐ Graft ☐ CVC

Diagnosis: _____

Criteria for Sampling: _____ Sections of this worksheet completed _____

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

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

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

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

Record the current treatment and medication orders:

Treatment Orders: Date: _____ EDW: _____ ☐ APD ☐ CAPD

APD cycles/day: _____ Dialysate: _____ Volume: _____ Dwell: _____

CAPD exchanges/day: _____ Dialysate: _____ Volume: _____ Dwell: _____

ESA dose: _____ ESA frequency: _____ Other meds/treatments: _____

_____

_____

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

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

EXCEPTIONS	DATES/COMMENTS
Treatment delivered different from ordered:	
☐ # of CAPD exchanges, volume (V544)	
☐ # of APD cycles, volume (V544)	
☐ Dialysate (V544)	

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

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

- Is there evidence that the facility home training/support staff monitored the patient's home dialysis through routine review of their PD flowsheets? ☐ **Yes** ☐ **No**-(V587) Explain_____
  _____

- Did you identify trends in the patient or caregiver not following their dialysis prescription or parenteral medication orders? ☐ **Yes** ☐ **No**-Explain_____
  _____

- Did you identify trends in problems with the patient's blood pressure, fluid or weight management? ☐ **Yes** ☐ **No**-Explain_____

  If yes to either of the above 2 questions: Is there evidence that the home training/support staff recognized that there was a problem, acted with interventions aimed at resolution/improvement, and changed strategies when interventions were unsuccessful?
  - o **If yes-**no citation is indicated
  - o **If no-**citation at the applicable V-tag listed in the table above may be indicated

Notes:_____
_____
_____
_____
_____
_____

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS

Patient Name:_____ ID #:_____

Facility:_____Surveyor:_____

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

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

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

Notes:_____

_____

_____

_____

_____

_____

_____

_____

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

- Is there evidence that the patient's outcome in the data driven focus area(s) used for sampling them has improved and their goal(s) currently met?

  ☐ **Yes** - **no further review is needed,** *no citation in that area is indicated*

    ☐ **No** - is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement/resolution; and changed strategies if no improvement?

      o ☐ **Yes** - *no citation is indicated.*
      o ☐ **No** - *citation in that outcome area at the applicable Patient assessment or Plan of care V-tag is indicated.*

Notes:_____

_____

_____

_____

_____

_____

_____

_____

_____

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
PERITONEAL DIALYSIS

Patient Name: _____ ID #: _____

Facility: _____ Surveyor: _____

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

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

_____

_____

_____

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members (physician, RN, registered dietitian, master's prepared social worker at a minimum)?
  ☐ **Yes** ☐ N**o** (V501, 509, 510, 541, 552)
- Was an assessment of the patient conducted and the clinical and psychosocial issues related to the patient's instability addressed through revised care interventions?
  ☐ **Yes** ☐ **No** - *citation at the applicable Patient assessment or Plan of care V-tag may be indicated.*

Notes: _____

_____

_____

_____

_____

_____

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

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

- Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated? ☐ **Yes** ☐ **No** (V124, 125, 126, 506)

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

Notes: _____

_____

_____

_____

_____

_____

_____

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (ICHD)

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

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

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

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

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

Record the current dialysis treatment and medication orders:
Treatment Orders: Date:_____ EDW:_____ Frequency:_____ days/week
Dialyzer:_____ Dialysate:_____ BFR:_____ DFR:_____
Treatment duration:_____ HD Machine Type_____
Heparin/anticoagulant:_____ ESA dose:_____ Other meds/treatments:_____
_____

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

(Number)_____ treatment records reviewed between _____ and _____

EXCEPTIONS	DATES/COMMENTS
Safety checks not documented (V585):	
☐ Independent pH/ conductivity(V250)	
☐ Machine alarm check (V403)	
☐ Water total chlorine testing (V595)	
Treatment delivered different from ordered:	

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (ICHD)

Patient Name:_____ ID #:_____

Facility:_____ Surveyor:_____

EXCEPTIONS	DATES/COMMENTS
☐ BFR/DFR/dialyzer/time, dialysate (V544) (i.e. clearance/adequacy)	
☐ Heparin/anticoagulant (V544)	
☐ Anemia management (V547)	
☐ Other medications	
BP/fluid management (V543):	
☐ Hypertension	
☐ Hypotension	
☐ Estimated dry weight not achieved	
☐ Patient not recording weight/BP	
☐ Ultrafiltration rate >13mL.kg/hr *(review for trends)*	
Staff monitoring:	
☐ Tx records not reviewed (V587)	
☐ No treatment records in chart (V587)	
☐ Unusual or adverse events (V634)	
Other concerns Identified	

- Is there evidence that the facility home training/support staff monitored the patient's home hemodialysis through routine review of their HD treatment records? ☐ **No** ☐ **Yes**-(V587) Explain__

- Did you identify trends in the patient or caregiver not following the dialysis prescription and parenteral medication orders? ☐ **No** ☐ **Yes**-Explain_____

- Did you identify trends in problems with the patient's blood pressure, fluid or weight management? ☐ **No** ☐ **Yes**-(V543) Explain_____

- Did you identify trends in the patient or caregiver not operating the HD machine and equipment or performing the safety checks as expected? ☐ **No** ☐ **Yes**-Explain_____

  If yes to the any of the above 3 questions: Is there evidence that the home training/support staff recognized that there was a problem, acted with interventions aimed at resolution/improvement, and changed strategies when interventions were unsuccessful?
  - o **If yes**-*no citation is indicated*
  - o **If no**-*citation at the applicable V-tag listed in the table above may be indicated*

ESRD CORE SURVEY MEDICAL RECORD REVIEW:
HOME HEMODIALYSIS (ICHD)

Patient Name:‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗ ID #:‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗

Facility:‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗ Surveyor: ‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗‗

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

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

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

Notes:‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

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

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

Notes:‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

‗‗

Patient Name:_____ ID #:_____

Facility:_____ Surveyor: _____

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

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

_____

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members (physician, RN, registered dietitian, master's prepared social worker at a minimum)? ☐ **Yes** ☐ **No** (V501, 509, 510, 541, 552)
- Was an assessment of the patient conducted and the issues related to the patient's instability addressed through revised care interventions? ☐ **Yes** ☐ **No** - *citation at the applicable Patient assessment or Plan of care V-tag may be indicated.*

Notes:_____

_____

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

- Is there evidence that the patient had orders by a physician or non-physician practitioner if allowed by state law, and was evaluated by an RN prior to their first dialysis treatment at the facility? ☐ **Yes** ☐ **No** (V715)
- Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated? ☐ **Yes** ☐ **No** (V124, 125, 126, 506)
- Is there evidence facility staff evaluated and addressed issues related to the patient's training needs, labs, fluid management, dialysis-related & other clinical and psychosocial problems? ☐**Yes** ☐ **No**- *citation at the applicable Patient assessment or Plan of care V-tag may be indicated.*

Notes:_____

_____

Section "D": Complete for ALL HHD patients SAMPLED:
Monitoring of home hemodialysis water and dialysate quality: RECORD EXCEPTIONS ONLY.
Check if no exceptions. ☐

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

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

_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Facility_____CCN_____Date_____

Surveyor_____Facility-based Responsible Person_____

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

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. 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 list the areas for Segment II review.*

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

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.
  ➢ **Clinical and operational indicators** (pg. 2)
  ➢ **Oversight of technical operations and practice audits** (pg. 3)

Segment II. Review of QAPI activities in three critical priority areas for ALL facilities, and in the data-driven focus and survey findings areas specific to this facility survey: A detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and responding in the critical priority and problematic areas to attain and sustain improvements
  ➢ **Mortality review** (pg.4)
  ➢ **Infection prevention and control** (pgs. 4-7)
  ➢ **Medical error/adverse occurrence/clinical variance tracking and investigation system** (pg. 7)
  ➢ **Data-driven focus and survey findings areas** for this facility survey (pg. 8)

Segment III. Culture of Safety Review: Verifying the presence of a facility-wide culture that promotes and protects patient safety. The primary components are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated.
  ➢ **Risk identification and reporting** (pg. 9)
  ➢ **Staff engagement** (pg. 9)
  ➢ **Patient engagement** (pg. 10-11)

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

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Segment I: Monitoring Care and Facility Operations

> ### Clinical and operational indicators monitored

*Review (briefly) the facility-based QAPI documentation to verify that the facility's QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI program monitors at a minimum all the expected areas of patient clinical management and facility operations. Refer to table of indicators below. **This is not a detailed review**, but a brief look at the facility's QAPI summarizing documentation. **Review of the facility QAPI performance improvement activities is conducted in more detail during Segment II.***

Indicators to be routinely monitored: Data must be segregated by dialysis modality and setting (e.g. HD, PD, nocturnal, in-center, home) Note that not all areas are required to be monitored monthly.

Indicator	Indicator
☐ Water & dialysate quality (V628)	☐ Physical plant safety "rounds," audits (V628)
☐ Dialysis equipment repair and maintenance (V628)	☐ Dialyzer Reuse QA audits & adverse events (V635)
☐ Personnel qualifications and issues (V628)	☐ ESRD Network relationship/communication (including IVDs) (V772)
☐ Patient modality choice & transplant referral (V628)	☐ Health outcomes-physical and mental functioning (HRQOL results) (V628)
☐ Infection prevention & control (V637)	☐ Patient satisfaction & grievance/complaints (V636)
☐ Mortality-(expirations & causes) (V628)	☐ Morbidity-(hospitalizations, admitting diagnoses & readmissions w/in 30days) (V628)
☐ Fluid & BP management) (V628)	☐ Dialysis adequacy (V629)
☐ Nutritional status (V630)	☐ Mineral and bone management (V631)
☐ Anemia management (Hgb, transfusions, TSAT%, ferritin) (V632)	☐ Vascular access-HD (V633) ☐ PD access-PD (V633)

☐ Medical errors/adverse occurrences/clinical variances-in-center hemodialysis & home dialysis (V634)
- Cardiac arrest at facility
- Deaths during dialysis
- Errors in dialysis prescription delivery
- Medication errors, omissions, adverse reactions
- Transfusion reactions
- Incorrect reprocessed dialyzer set up or used
- Blood loss
- Chlorine/fluoride breakthrough
- Machine malfunction w/treatment interruption
- Patient transfers to hospital from dialysis
- Patient falls; Patient injuries
- Vascular access events: infiltration, clotting, excessive bleeding, infection
- Intradialytic symptoms
  - Hypotension w/loss of consciousness
  - Chest pain
  - Severe cramping; nausea/vomiting
  - Pyrogenic reactions
- Staff incidents and injuries:
  - Needle sticks
  - Blood/body fluid exposures
  - Non-adherence to procedures
  - Patient abuse/disrespect

Is the facility routinely monitoring and trending all of the expected areas, and segregating data by modality and setting (HD, PD, nocturnal HD, in-center, home)? ☐ **Yes** ☐ **No** (V626, 628)-Explain_____

_____

_____

For the clinical areas, has the facility identified outcome goals which reflect community standards from the current Measures Assessment Tool (MAT)? ☐ **Yes** ☐ **No** (V628)-Explain_____

_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Does the QAPI documentation show the active involvement of all on-site personnel necessary to adequately address and resolve problems/issues, including all members of the interdisciplinary team, i.e., medical director, nurse manager, masters-prepared social worker, registered dietitian, and other personnel such as technical staff and patient care staff? ☐ **Yes** ☐ **No** (V626, 628)-Explain_____

➢ **Oversight of technical operations and practice audits**: *Review the facility QAPI documentation to ensure routine audits in these areas are conducted and discussed, and performance improvement actions taken, when indicated:*

Water and dialysate quality (for in-center and home hemodialysis)
☐ Review of water and dialysate cultures/endotoxin results monthly, 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 dialysis machine, equipment and ancillary equipment maintenance and repair monthly (V628)

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

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

If problems were identified in the reviews and audits above, is there evidence the facility acted to resolve the problem(s) and attain improvements? (*Note that the cycle of elevated water or dialysate cultures "addressed" with disinfection, followed by elevated cultures the following month, "addressed" with disinfection, and repeated for several consecutive months is not effective performance improvement and may be risking patient safety.*) ☐ **Yes** ☐ **N/A** ☐ **No**-Explain_____
_____
_____

Additional notes:_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

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

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

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

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

Is there evidence that the facility reviewed and evaluated all patient deaths, and analyzed trends in causes of patient deaths? ☐ **Yes** ☐ **No** (V628)-Explain_____

_____

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

For identified trends in cause of deaths, did the QAPI Team conduct review focused on the aspects of care related to specific-cause categories? (*Examples are: for high rates of deaths due to **infection causes** the facility should have looked at the CVC rate and CVC reduction efforts, hospitalization patterns, water/dialysate cultures, staff compliance with infection control practices, etc.; for high rates of HD death due to **cardiac causes** the facility should have looked at HD ultrafiltration rates, length of HD treatments, the use of low potassium (0K+ or 1K+) dialysate, patients' serum bicarbonate levels, etc.)* Did the QAPI Team develop, implement and monitor performance improvement actions aimed at addressing contributory factors related to the care received at the facility? ☐ **Yes** ☐ **No** (V628)-Explain

_____

_____

> ➢ **Infection prevention and control**

This review is intended to assure that the facility's QAPI activities facilitate a multi-faceted and effective facility-wide program for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare associated infections (HAI) acquired at the facility. There are 4 areas of this review:

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

Review: *The infection tracking logs.*

Are all positive culture results, dialysis access infections, blood stream infections (BSI), and peritonitis episodes, if applicable recorded with sufficient information for each (i.e., patient name, date, infecting

organism, culture site, antibiotic use)? ☐ **Yes** ☐ **No** (V637)-Explain_____

_____

Is there evidence that trends in infections were recognized, evaluated/investigated, and performance improvement activities implemented and monitored for effectiveness?
☐ **Yes** ☐ **N/A** ☐ **No** (V637)-Explain_____

_____

Review: Documentation of facility dialysis-related infection rates.

Does the facility routinely calculate dialysis-related infection rates as applicable to the modalities offered (i.e. hemodialysis vascular access, peritoneal dialysis catheter, peritonitis) using an accepted formula?
☐ **Yes** ☐ **No** (V637)-Explain_____

_____
(Vascular access and peritoneal dialysis catheter infection rates are generally expressed as events per 100 patient months ([*#events ÷ total months patients on HD/PD in 12 months] x 100).* Peritonitis rates are either expressed as episodes per patient year at risk [*episodes ÷ (total PD patient months ÷ 12 months)]* or episodes per 100 patient months)

Is there evidence that high infection rates and upward trends were recognized, investigated, and performance improvement actions implemented and monitored for effectiveness? ☐ **Yes** ☐ **N/A** ☐ **No** (V637)-Explain_____

_____

Vaccination: high risk disease-specific management: *Refer to the facility vaccination information obtained from the Entrance Conference Materials list.*
Ask: The responsible facility-based person to show you the QAPI documentation of oversight for surveillance and vaccination for:
- Hepatitis B patient surveillance and susceptible patients and personnel offered vaccination
- Tuberculosis surveillance of patients on admission or exposure
- Influenza vaccinations offered to patients and personnel annually
- Pneumococcal pneumonia vaccination offered to patients
- New Hepatitis C (HCV) infections (i.e. antibody elevations for facilities that test for HCV) or unexplained ALT elevations; HCV surveillance/routine testing including testing on admission.

Is there evidence of active QAPI oversight of the above high risk disease surveillance and vaccination programs? ☐ **Yes** ☐ **No** (V637, V125-V127)-Explain_____

_____

If trends of lapses in surveillance or vaccination were identified, did the facility take meaningful actions to investigate the problem, implement performance improvement plans, and monitor them for effectiveness? ☐ **Yes** ☐ **N/A** ☐ **No** (V637)-Explain_____

_____

If HBV conversions, other notifiable diseases or outbreaks were identified, were they reported to the local health department? ☐ **Yes** ☐ **N/A** ☐ **No** (V637)-Explain_____

_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

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

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

Is there evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff providing care to patients (e.g. initiation and discontinuation of hemodialysis, vascular assess care, medication preparation and administration, hand hygiene, etc.)? When lapses in practices were observed, were actions taken toward improvement? Were the involved staff included in the investigation into issues surrounding the practices, and development and implementation of improvement plans, rather than just counseling or reeducating?
☐ **Yes** ☐ **No** (V637, V132, V142, V147)-Explain_____
_____
_____

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

Does the facility's infection prevention and control program include educating patients and their families about strategies for remaining infection-free? ☐ **Yes** ☐ **No** (V637, V562, V585)-Explain_____
_____
_____

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

Is there evidence that the facility recognized and acted upon their poor infection outcomes? (*Examples are: **for high patient infection rates**, fully investigating for trends and causes of the infections, including staff care practices, water/dialysate and dialyzer reprocessing sources, etc. For **high rates of CVC >90 days**, implementing meaningful strategies for reducing CVC rates*) ☐ **Yes** ☐ **No** (V637)-Explain_____
_____
_____

When reductions in infection rates or CVC >90 days rates were not attained, did the QAPI Team revise and change the performance improvement actions until improvements were achieved ?
☐ **Yes** ☐ **N/A** ☐ **No** (V637)-Explain_____
_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

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

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

Did the facility thoroughly investigate the error/occurrence to determine why it happened, including interviews with all applicable staff to understand what circumstances surrounded it, and involved those staff members in the development of the plan for resolution? ☐ **Yes** ☐ **No** (V634)-Explain_____

_____

_____

Did the facility implement a meaningful action plan to mitigate factors that contributed to the error/occurrence, monitor the plan for effectiveness in preventing recurrence, and, if a similar error/occurrence happened, revise and implement the revised plan? ☐ **Yes** ☐ **No** (V634)-Explain_____

_____

_____

Additional notes: _____

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

MAKE ONE COPY OF THIS PAGE FOR EACH FOCUS AREA YOU WILL REVIEW

➢ **Data-driven focus areas and survey findings areas:** *Using your list of QAPI focus areas from page 1 of this worksheet,* **Review** *those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*
Ask*: How do you prioritize facility performance improvement activities? How did the facility-based QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did you take for improvement, and how were the actions and subsequent outcomes monitored to assure improvements were attained and sustained? If improvements were not attained, what actions did you take?*

Focus Area_____

Is there evidence that the facility prioritized performance improvement activities to assure areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner? ☐ **Yes** ☐ **No** (V639)-Explain_____

_____

Did the facility routinely monitor the focus area, and **identify the issue or recognize that a problem** or opportunity for improvement existed? ☐ **Yes** ☐ **No**-Explain_____

_____

Did the facility thoroughly **investigate root/multiple causes** of the issue and develop, implement, and monitor performance improvement plans? ☐ **Yes** ☐ **No**-Explain_____

_____

Does the **current QAPI documentation show improvements** have been attained and sustained?
☐ **Yes** ☐ **No**-Explain_____

- o **If yes to all above questions:** no further review is needed for that focus area or survey concern/finding-the facility QAPI response was effective-*no citation at QAPI is indicated*

If improvements were not attained, and outcome goals in the focus area are not currently reached, is there evidence the facility revised, implemented and monitored the revised QAPI actions*?(note that repeated entries of "will monitor" without active revisions to action plans is not sufficient evidence of effective QAPI)* ☐ **Yes** ☐ **N/A** ☐ **No** (V626, 628-637)-Explain_____

_____

_____

Additional Notes:_____

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

SEGMENT III: Culture of Safety

Culture of Safety: The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients clearly communicated. This segment includes reviews of 3 areas:

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

Ask: How do you define medical errors/adverse occurrences/clinical variances? What occurrences are staff expected to report?

Compare: the answer (list of occurrences) with the list in the section "Medical error/adverse occurrences/clinical variances" from the table on page 2 of this worksheet to ensure that these occurrences, at a minimum are recognized as potentially hazardous and are included in the facility reporting and investigation system.

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

Does the facility medical error/adverse occurrence/clinical variance reporting system include all expected error/occurrences, and staff education for reporting defined occurrences and near misses/close calls?
☐ **Yes** ☐ **No (**V634)-Explain_____

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

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

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

Is there evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment? Do administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues? ☐ **Yes** ☐ **No** (V627) Explain-

_____
_____
_____
_____

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

➢ **Patient Engagement Review**

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

Ask: How do you track and trend eligible patients' scores in an age-appropriate standardized physical and mental functioning survey (HRQOL survey)? What is your facility's threshold for patients completing and refusing the survey annually? *It is expected that some patients may be excluded due to cognitive impairment, dementia, active psychosis, no translation or interpreter for their language, and some may refuse to participate in the assessment of their physical and mental functioning. High refusal rates, e.g., >20% would indicate a problem which should be recognized and addressed with performance improvement actions).*

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

Does the facility track and trend the % of eligible patients who complete and refuse the physical and mental functioning survey? Does the facility track and trend the scores on a facility level? ☐ **Yes** ☐ **No** (V628)-Explain_____

_____

If the trends of facility level scores showed a decline or the refusal rate increased, is there evidence that the facility recognized a problem existed, investigated the possible causes, and took meaningful actions to address the issue(s) and attain improvements? ☐ **Yes** ☐ **N/A** ☐ **No** (V628)-Explain_____

_____

_____

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

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

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

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

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

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

ESRD CORE SURVEY QAPI REVIEW WORKSHEET

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

Is there evidence the facility management and staff educate and encourage patients to verbalize suggestions and concerns in addition to written complaints/grievances? Are staff educated how to respond professionally to patients' verbalized concerns, and report them to their supervisor for recording and follow up? ☐ **Yes** ☐ **No** (V627)-Explain_____

_____

_____

Is there evidence the patient's concern you reviewed was recorded, the circumstances investigated, and mutually acceptable resolution reached? Was the result communicated to the patient? ☐ **Yes** ☐ **No** (V636, 465, 765)-Explain_____

_____

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

Based on your interviews during the survey with staff, patients, and the facility-based QAPI responsible person, and the above reviews in this "Culture of Safety" section, is there evidence that substantial efforts are being made to establish and maintain a facility-wide "culture of safety?" ☐ **Yes** ☐ **No** (V627)-Explain_____

_____

_____

Additional notes: _____

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____