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Center for Clinical Standards and Quality/ Survey & Certification Group

Ref: S&C: 12-41-ESRD

DATE: **July 27, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Pilot Surveys Begin for the Survey & Certification (S&C) Quality Assurance Efficiency & Effectiveness (QAEE) Initiative #1: The End Stage Renal Disease (ESRD) Core Survey Process

Memorandum Summary

- The S&C QAEE Initiative #1, the ESRD Core Survey process began a three-month Pilot Test phase on July 1, 2012.
- For 3 months (July through September 2012), 11 States will Pilot Test the new ESRD Core Survey process.
- Following the Pilot Test phase and subsequent updating of Core Survey Process and Materials, the ESRD Core Survey process will be implemented nationally in FY 2013.
- A sample of draft Core Survey materials are attached for your information.

Background on the new ESRD Core Survey Process

The Pilot Test of the first S&C QAEE Initiative, a new ESRD Core Survey process, began on July 1, 2012. The purpose of this QAEE Initiative is to increase the efficiency of the traditional ESRD survey process while maintaining a highly-effective survey process. The new survey process was developed using data from ESRD survey results, as well as data from clinical and technical research. In addition, the information from these data searches was combined with information from experienced ESRD surveyors, technical and clinical subject-matter experts, and ESRD patient leaders. Based upon these sources, a new draft ESRD Core Survey process was developed.

Pilot States Selected

Eleven States were selected to pilot test this new survey process. The pilot States are Arizona, California, Delaware, Florida, Maryland, Michigan, New Jersey, North Carolina, Pennsylvania, Tennessee, and Texas. During a three-month test phase from the beginning of July through the end of September, some surveys in each of these States will be conducted using the new Core Survey process.

New Draft Core Survey Materials

The new Core Survey process is designed to facilitate nationwide consistency and tailor the depth of inquiry into specific areas depending on information pertinent to the degree of health care risk.

Samples of some of the new survey materials are attached for your information. These Core Survey materials and tools place a stronger emphasis on the use of ESRD data in the survey process; on the use of ESRD infection control checklists; and on Quality Assessment and Performance Improvement (QAPI) internal reviews. In addition, the new survey process includes a focus on each facility's approach to safety/openness in dealing with problems; listening to the patients' voices; and risk-adjusting the review of all technical and clinical areas.

Implementation of the New Core Survey Process

You will receive further information and updated materials when the new ESRD Core Survey process is implemented nationally in FY2013. The ESRD automated survey software, Surveyor Technical Assistant for Renal (STAR), will be updated as we obtain results from the pilot-tests of the core survey.

If you have comments or questions regarding the new ESRD Core Survey process, feel free to contact us at our CMS Core mailbox: ESRDCoreSurvey@cms.hhs.gov or contact Judith Kari at Judith.Kari@cms.hhs.gov. Thank you for your interest.

Effective Date: Immediately. This information should be communicated to all pertinent State certification staff and their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachments: ESRD-Core-survey Process
Core-ESRD-Core-survey-Grid
ESRD-Core-Survey-Worksheet-Conference-Materials-List
ESRD-Survey-Worksheet-Entrance-Conference-Questions
ESRD-Survey-Worksheet-Personnel-File-Review

cc: Survey and Certification Regional Office Management

Key Concepts of the ESRD Core Survey Process

The ESRD Core Survey Process is intended to increase the efficiency and effectiveness of the ESRD survey process. Key concepts of the ESRD Core Survey process include the following:

***Content*:**

- **Using Data:** Facility-specific and patient-specific data are central to the ESRD Core Survey for focusing the survey process reviews and monitoring the facility practices/outcomes. When available, patient-specific data are used to develop risk-adjusted rates for the comparative review of facilities.

- **QAPI:** The ESRD Core Survey enhances the importance of a functional and robust facility-based QAPI program to continually protect patients and assure quality of care. The QAPI review task in the ESRD Core Survey Process is extended from the current survey process, and serves as a model for ESRD providers. Throughout the ESRD Core Survey process, documentation of the facility oversight of its own operations, such as audits of staff practices and technical areas, are used in lieu of the more time-consuming tasks in the current survey process.

- **Culture of Safety:** The importance of a systemic facility culture that supports open communication, reporting without fear of retribution, and self-examination is emphasized in the ESRD Core Survey process. The ESRD Core Survey uses interviews with patients and all levels of staff and QAPI review to monitor a facility's culture of safety.

- **Safety of Dialysis Delivery and Infection Prevention:** The highly technical nature of dialysis treatment places the patients at significant risk if there is isolated or systemic failure to follow precise procedures**.** The combination of the configuration of the hemodialysis patient treatment area (no physical separation between patients), one staff member delivering care to multiple patients, and the significant potential for blood exposure during hemodialysis place the patients at increased risk for transmission of blood-borne infections. The ESRD Core Survey Process takes a more focused approach to review of the critical elements of technical dialysis delivery systems, including the use of infection control checklists.

- **Patient Voice:** The ESRD Core Survey process places more emphasis on listening to the individual patient's point of view and to collective patients' voices regarding care received and presence (or absence) of an environment where patient input is sought and welcomed.

Presentation:

- **Detailed Step-by-step Instructions:** To promote consistency the ESRD Core Survey process is described in detailed steps for each task of the survey process. Regulatory references are provided for surveyors to obtain additional information.

- **Survey Tools:** Many of the survey tasks will be accompanied by survey tools which aid in the administration of that task. The existence of survey tools is designated with a ▲ on the ESRD Core Survey.

- **Triggers:** Each survey task includes a list of "triggers" which, if identified during administration of that core survey task, indicate that additional and more comprehensive investigation into that area is warranted to assure patient safety and quality of care.

Draft ESRD Core Survey Process

Purposes:

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

Using the ESRD Core Survey Process: The ESRD Core Survey process is organized by the survey review areas (tasks) of the Full ESRD Survey Process. 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 which, if identified by the surveyor during the ESRD Core Survey activity, denote that more comprehensive investigation into that area must be conducted and/or citation may be warranted. The additional investigation may be limited to the specific issue or may include administration of that entire survey task per the Full ESRD Survey process. This is referred to as "extending" that ESRD Core Survey task.

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

Task 1 ▲Presurvey Preparation:

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

Review the most current Dialysis Facility Report: *At a minimum, review the facility and comparative outcomes for the following indicators. If the facility outcomes are listed as worse than expected, plan to include that area as a* ***data-driven focus area****:*

- **Mortality**: Standardized mortality ratio (SMR), first year SMR, cardiac death
- **Hospitalization**: Standardized hospitalization ratio (SHR); for congestive heart failure - *Focus on fluid management*
- **Infection**: Hospitalizations for septicemia; deaths due to infection; HD and PD access-related infection rates; central venous catheters (CVC) in place >90 days - *Focus on infection control practices and vascular access program, including patient and staff education*
- **Dialysis adequacy**: URR and Kt/V for HD; Kt/V for PD - *Focus on dialysis adequacy*
- **Transplantation**: Standardized Transplantation Ratio (STR); % of eligible patients on waitlist - *Focus on patients fully informed about all options and system for transplant referral/follow up*
- **Vaccination for influenza:** *Focus on the facility's immunization program*
- PLACEHOLDER for other data as available.

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

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

Task 2 Introductions:

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

Contact the person in charge, *introduce the survey team; give that person a copy of the "ESRD Core Survey Worksheet Entrance Conference Materials List." Explain that these are the items the survey team will need to conduct the survey and the facility should provide the materials on pages 1-4, including its most current outcomes data as requested on the Materials List within 3 hours (or as soon as possible) for discussion during the Entrance Conference (Task 4).*

Task 3a Environmental ("Flash") Tour:

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

Observe these areas of the facility: *This is a "flash" look at the 4 patient care-related areas listed below, looking for observable indicators of patient safety concerns. Triggers for additional investigation are listed under each area.*

Ask staff about the facility "culture of safety" *in all of the 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. Learning if a facility is engaged at the direct care level in identifying and effectively addressing risks and errors in its operations is important to evaluating the strength of the QAPI program and how patients are protected from recurring medical errors. To help understand the role the caregivers/staff really play in this process some questions to technicians and nurses asking about when errors or "near misses" occur can demonstrate an active program.* ***Ask*****:** Can you tell me how a technician (nurse) in this unit, like you, helps to reduce treatment errors? How (or to whom) would you report an error or near miss which you made or observed in the unit? Would your responsibility be different if you made the error or near miss or simply observed it? How do you know what errors or near misses require reporting? How would you expect the error or near miss to be addressed? Would you have a role in follow up? Are you aware of the goals and activities of the QAPI team? *It is natural for staff to respond in the way they feel you want them to respond and to compare notes once you have addressed these questions with their coworkers, so asking one or two of these questions early to a number of staff will provide the most useful picture of what actually happens as opposed to what staff thinks the surveyor is looking for.*

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

***Triggers for more review and/or citation**:*

- Dummy drip chambers present in the patient treatment area (V400, 403)
- Patients' vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Clear evidence of poor staffing, e.g., machine alarms not answered, patients not regularly monitored, no dietitian or social worker currently on staff (V757)
- Blood spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood (V122)
- HD machine transducer protectors wetted with blood not changed - *observe/interview staff regarding the practice of inspecting the internal transducer for blood prior to machine use for another patient* (V120)
- Functional emergency resuscitation equipment (i.e., AED/defibrillator, oxygen, suction, emergency medications) not present (V413)
- Hemodialysis machines in obvious poor repair (e.g., alarms not functional, missing components) (V403)
- If dialyzer reuse, strong germicide odors noticeable in patient treatment area (V318)
- Disrespectful communication (rude, demeaning, harassing, name calling, loudly calling out weight) or actions toward patients (physical or chemical restraints, involuntary seclusion)(V452)
- Failure to offer patients confidentiality when discussing their condition/treatment; failure to prevent 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's chlorine test results. Also look at the alarm/monitoring systems for reverse osmosis (RO) and/or deionization (DI) components, and dialysate concentrate proportioning ratios (listed on the packaging)*

***Triggers for more review and/or citation**:*

- Carbon system: 2 or more carbon tanks not present, with sampling port between (V192), current chlorine/chloramines test not done, testing reagents not sensitive to 0.1mg/L total chlorine, expired or don't match testing equipment (V196)
- RO: no or non-functioning water quality monitor and/or alarm inaudible in patient treatment area (V200)
- If DI: no or non-functioning resistivity monitor and/or alarm inaudible or not visible in patient treatment area (V203), DI not monitored twice/day (V202)
- Water distribution equipment in obvious disrepair or contaminated state (e.g., algae, discoloration of water present) (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 same* (V249)
- Acid and bicarbonate dialysate concentrate mixing and distribution equipment in obvious disrepair or contaminated state, e.g., algae (V403)

Reuse room - *Briefly look at the condition of the reprocessing equipment and dialyzer storage, including the dialyzer refrigerator, if applicable.*

***Triggers for more review and/or citation*:**

- Stored dialyzers aesthetically unacceptable (e.g., header caps full of blood, leaking, port caps off) (V343)
- Reprocessing room or equipment in obvious disrepair (V316, 403)
- Dirty dialyzers kept at room temperature >2 hrs. (V331)
- Dialyzer refrigerator temperature not between 2-8º C or temperature not monitored (V331)

Home dialysis training area - *Look at the physical layout, infection control and availability of emergency equipment*

Triggers for more review and/or citation:

- Insufficient space in home dialysis patient training area to prevent cross-contamination between patients if >1 patient trained at a time (V404)
- Insufficient methods to provide home dialysis patient privacy (V406)
- Blood or PD effluent spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood or PD effluent (V122)
- No functional emergency resuscitation equipment present or method for summoning immediate help & equipment (in lieu of equipment immediately present in home training area) (V413)

***Triggers for extending the tour to other areas of the facility and/or citation* -** *Consider looking at all of the areas of the facility listed in the Full ESRD Survey process in Task 3a 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 treatment area; uneven/broken floor surfaces creating multiple trip hazards where patients ambulate) (V401, 402)

Task 3b ▲Observations of Hemodialysis Care and Infection Control Practices:

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

1. Observe the direct care staff delivering care - *Observations should be conducted on different days, if possible and of different staff. Watch for infection control practices, dialysis machine and dialyzer use per manufacturer's directions, reprocessed dialyzer safety checks, and patient assessment and monitoring during treatment.* ***Observe the following activities****:*

Sequence of care at one dialysis station: Attempt to capture at least **2 separate observations** of the patient care and dialysis equipment procedures listed below. Include observation of the care for at least one patient with a central venous catheter (CVC), and one patient with an AV fistula/graft (AVF/G)]: ***Continuously observe:***

- Discontinuation of a patient's hemodialysis treatment and post-dialysis vascular access care
- Cleaning and disinfection of the dialysis station
- Preparation of the dialysis machine and extracorporeal circuit
- Pre-dialysis vascular access care and initiation of hemodialysis
- For facilities with poor infection outcomes, observe 1-2 additional vascular access care opportunities each for patients with a CVC and an AVF/G
- Dialysis Supply Management: While conducting the above observations, note the supply management practices in the hemodialysis patient treatment area during the observation period(s). Supplies used for dialysis must be kept/maintained in a manner to prevent contamination.

Triggers for more observation/investigation of hemodialysis care and/or citation:

- Observed trends/multiple breaches in infection control patient care practices:
  - Hand hygiene and glove use (V113)
  - Supplies taken to station not disposed, disinfected or dedicated to that patient (V116)
  - Clean dialysis supplies not protected from potential contamination (V119)
  - Breaches in aseptic practices for CVC (V147) or vascular access care (V550)
- Failure to adequately disinfect the HD station/equipment between patients (V122)
- Failure to test hemodialysis machine alarms (V403); failure to check dialysate pH/conductivity with independent method or lack of staff knowledge of acceptable parameters(V250)
- Failure to perform reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Failure to prime reprocessed or dry pack dialyzers according to manufacturer's DFU (V352, 403)
- Failure to assess patients before and after treatment or monitor during treatment according to facility policy (V504, 543, 550, 551, 715)

Medication preparation and administration: Attempt to capture 2 observations of different staff (if possible) preparing and administering medications to 1-2 patients.

Triggers for more observation/investigation of medication preparation/administration and/or citation:

- 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/needle (V143)
- Poor aseptic technique (V143)
- Medications for multiple patients taken to a patient station (V117)
- Medications prepared and administered by unqualified personnel (V681)

2. Review Facility Isolation practices: If hepatitis B positive (HBV+) patients are being dialyzed at the facility:

- ***Observe*** *the isolation room/area, and the equipment and supplies contained within it. If possible,* ***observe*** *the care delivery to an HBV+ patient as one of your "Sequence of care at one dialysis station" above, looking for separation of care practices from the HBV susceptible patients.*
- ***Review*** *staff/patient assignment for that shift/day for staff simultaneously caring for HBV positive and susceptible patients.* ***Note:*** The exceptions to this requirement are when there is a patient emergency, and when there is 1 RN on duty who may be required to deliver care to an HBV+ patient and HBV susceptible patients on the same shift (e.g. medication administration, CVC access)
- ***Ask*** *staff on duty about how the staff assignments are made when an HBV+ patient is scheduled.*

Triggers for more observation/investigation of isolation practices and/or citation:

- HBV+ patient(s) not isolated (V110, 128, 129)
- Observed trends/multiple breaches in infection control practices HBV+ patients(V113, 116, 117, 119, 121)
- Staff assigned/delivering care to HBV+ patient and susceptible patients - *Look into the extent of the practice* (V110, 131)
- When 1 RN on duty, poor infection control separation between care to HBV+ and susceptible patients (V131)
- Isolation equipment not dedicated for use on HBV+ patients (V130)
- Non-HBV+ patient(s) dialyzing in the isolation room/area when an HBV positive patient is on in-center HD census (V110,128, 130)

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

Triggers for more investigation and/or citation:

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

Task 4 ▲Entrance Conference:

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

Explain purpose and timeline for survey

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

Obtain documentation of current patient outcomes data as requested during Task 2 Introductions (from the *ESRD Core Survey Worksheet Entrance Conference Materials List* pages 1-4)

Review and discuss with the administrative person:

- The current patient outcomes data submitted by the facility on the *ESRD Core Survey Worksheet Entrance Conference Materials List* pages 1-4. *Look at the current outcomes listed in the **"% Met Goal"** column and compare to the outcome thresholds in the table below. **Ask** about actions being taken for improvement in the areas where these thresholds are not currently achieved. (**Note:** **These are the outcome threshold values to be used for the FY 2012**):*

HD Measure	Threshold for % Met Goal	PD Measure	Threshold for % Met Goal
Single pool Kt/V ≥1.2 Standardized Kt/V ≥2.0 for ≥4x/week URR	**≥94.5% Kt/V*** **≥96.6% URR***	Kt/V≥1.7	**≥88.7%***
Calcium corrected for albumin (BCG) <10.0 Phosphorus 3.5-5.5 mg/dL	**≥90%**** **≥70%****	Calcium corrected for albumin (BCG) <10.0 Phosphorus 3.5-5.5 mg/dL	**≥90%** **≥70%**
Albumin ≥4.0	**≥70%****	Albumin ≥4.0	**≥70%**
Intradialytic weight loss <5%	**≥90%**	N/A	N/A
Vascular access cuffed CVC > 90 days	**<10%** CVC ≥90days **≤2.85** HD vascular access infections/100 patient months*	PD access	**≤4.16** PD catheter infection rate per 100 patient months*
Transplant waitlist	**≥23.8%***	Transplant waitlist	**≥23.8%***

*2011 DFR National Average, **NOTE:** average of monthly facility lab results will likely show more variation and a higher percentage of patients above the threshold for any given month
**2012 DOPPS Practice Monitor

Determine the data-driven focus areas for the survey (clinical areas for review) using the following: *Discuss the selection of the data-driven focus areas for the survey with the administrative staff, to engage them in the process:*

- Preliminary focus areas from the DFR that are not improved/reaching thresholds in the current data: ***Note** if the facility has attained improvements and are currently meeting the thresholds in the table above in an area where the DFR showed problems; DO NOT include that as a data-driven focus area for review.*
- Current facility patient outcomes data shows outcomes areas in need of improvement, or an area which was "as expected" on the DFR but is currently not within the threshold listed in the table above.

***Triggers to extend the survey or individual survey tasks*:**

- Based on current data and other information learned during the entrance conference, the survey team may consider extending one or more survey tasks to the Full Survey Process for that task.

Task 5 Patient Sample Selection:

(Purpose - To select a core patient sample that represents the facility systems for patient care and management in the data-driven focus areas i.e., clinical areas where facility data indicates

improvements are needed, and areas pertinent to quality patient care/management and patients' rights that are not represented by available data)

Review the patient–specific information submitted by facility - *on the ESRD Core Survey Worksheet Entrance Conference Materials List*

Select 10% of patients (minimum 4; maximum 10) *representing all dialysis modalities offered at the facility. Attempt to include in-center hemodialysis patients from different days/shifts. Select patients using the criteria below:*

Minimum patient sample: If there are fewer than 10% of patients who fit into any of the criteria listed below and the facility data shows there are no clinical areas in need of improvement (no data-driven focus areas indicated), the survey team should select for patient interview (Task 10) and treatment record review (Task 11) at least 10% of patients (minimum of 4; maximum of 10) representing every modality provided.

Criteria for patient selection:

- **On all surveys**: To enable review of various aspects of care which are not represented by available data, *select patients listed as*:
  - **Unstable** - *To review the facility process for interdisciplinary team (IDT) functionality in the comprehensive patient assessment and plan of care process for the most fragile patients*
  - **New admission <90 days** - *To review facility processes for assuring timely evaluation and appropriate care of patients new to the facility during their first treatment and first weeks at the facility.*
  - **Involuntarily discharged** (IVD) **in the past 12 months, if applicable** - *To review facility actions taken in attempt to avert the IVD and processes prior to the patient's discharge.* ***An IVD of a dialysis patient is a grave situation, because the patient has no reliable means for obtaining their dialysis treatments, and may expire as a result.*** *(**Note:** Do not include patients who voluntarily or involuntarily transferred to other facilities.)*
  - **Long Term Care (LTC) residents receiving home dialysis within the LTC facility** - *If the dialysis facility supports long term care (LTC) residents who receive home dialysis within their LTC facility, select at least one to sample and follow the Full survey process as outlined in the current guidance for review of the care of the home dialysis LTC resident.*
- **Based on the data-driven focus areas** you selected during the Entrance Conference. *Using the patient-specific information submitted from the Entrance Conference Materials list (i.e. the lists of patients' names in the tables on pages 2-4; lists of patients' labs hospitalization logs, infection logs , select patients with trends of not meeting outcome goals in the data-driven focus areas for the survey.*
- **Based on observations and complaints** - *You may sample patients with concerns you identified during Tour and Observations of HD Care (Task 3) or from a complaint investigation being conducted during the survey.*

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

Task 6 ▲Water Treatment and Dialysate Review:

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

Review critical water treatment components with staff responsible for daily chlorine/chloramines testing and system monitoring:

- **Observe chlorine/chloramines test and interview** *regarding maximum allowable level of 0.1mg/L total chlorine and chlorine/chloramines "breakthrough" procedures*
- **Observe reverse osmosis (RO) unit and quality monitor/alarm and interview** *regarding monitoring % rejection and/or total dissolved solids (TDS)*
- **Observe deionization(DI) and resistivity monitor/alarm**, if present; *verify presence of automatic divert-to-drain, UF post DI (or in-line UF for each machine) and* ***interview*** *regarding allowable levels, how monitoring is conducted, and what actions are taken when resistivity falls <1 megohm*

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

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

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

- **Review facility chemical and microbiological monitoring documentation**
  - 2 months of chlorine/chloramines testing
  - 2 months of RO monitoring (% rejection/TDS, GPM/function only, **NOT** all gauge and component readings)
  - If DI present: 2 months of resistivity readings at least 2x/day
  - 12 months of product water chemical analysis
  - 6 months microbiological monitoring of water (including reuse room) and dialysate (colony forming units, endotoxin units)
- **Review practice audits of the operator's compliance with procedures** - *Look at 6 months of facility documentation of observations of staff conducting water testing, dialysate mixing, pH/conductivity testing, etc.* (V260)

Triggers to extend water and dialysate quality review and/or citation:

- Chlorine removal/carbon system
  - 2 or more carbon tanks with sample port between **not** present (V192)
  - Observed chlorine/chloramines test result greater than maximum allowable level; test done incorrectly or with incorrect reagents/equipment (V196)

- Staff with knowledge deficit of maximum allowable level of 0.1mg/L total chlorine and/or breakthrough procedures (V260)

- RO
  - RO % rejection/TDS monitor/alarm non-functional, not audible and visible in patient treatment area, or not monitored daily (V200)
- DI, if present
  - Resistivity monitor/alarm non-functional, not audible in patient treatment area or not monitored 2x/day (V202, 203)
  - Automatic divert-to-drain not present or non-functional (V203)
  - Staff knowledge deficit 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 or in-line to each HD machine (V204)
- Log reviews
  - Chlorine/chloramines exceeding maximum level without documentation of appropriate actions taken (V197)
  - Chemical analysis of product water not done at least annually (V201)
  - Irregularities, trends of omitted tests (V178,196, 199, 213, 252, 253)
  - Microbiological results exceeding action/maximum levels without documentation of appropriate actions taken (V178, 180)
- Interviews
  - Water/dialysate sampling method irregularities - not drawn before disinfection (V254); each HD machine not cultured at least annually (V253)
  - Staff lack of knowledge about dialysate concentrate mixing, testing of acid concentrate batches, etc. (V260)

Task 7 ▲Dialyzer Reprocessing/Reuse Review:

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

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

Transportation of used/dirty dialyzers *to the reprocessing area - if immediately reprocessed and refrigerated, ask about procedures for refrigeration temperature and maximum refrigeration time.*

Pre-cleaning procedures - *if manual pre-cleaning, header removal/cleaning and/or reverse ultrafiltration are conducted, observe practice for 1-2 dialyzers and interview regarding the procedures, the water source for pre-cleaning and the maximum allowable water pressures.*

Focused interview with reuse technician - *regarding dialyzer labeling/similar names warnings; pre-processing prior to first use; maximum number of uses; germicide tests/contact time; germicide storage and mixing.*

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

QA audits - *Look at facility documentation of the following reuse observational audits for the past 12 months:*

- Observations of reprocessing procedures (each reuse technician observed semi-annually)
- Observations of preparation for clinical use of reprocessed dialyzers (i.e. germicide tests, priming, 2 persons identification of patient/dialyzer quarterly)
- Dialyzer labeling (including similar names labeling)

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) ***for 12 months*** - *Look for actions taken in response to issues related to reprocessing*

Triggers to extend reuse review and/or citation:

- Centralized reprocessing is conducted with the dialyzers transported to an off-site location for reprocessing - *if this is the case, extend to the Task 8 Reuse review in the Full ESRD Survey Process*
- Observations of improperly performed pre-cleaning, 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 per manufacturer's DFU (V339)
- Knowledge deficit of reuse tech regarding key patient safety areas (per interview guide) (V309)
- Observations of dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
- QA audits listed above not done or incomplete - *Extend to look for all of the required QA audits for reuse* (V362-368)
- Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355, 356, 635)

Task 8 Machine Operation/Preventative Maintenance:

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

Interview machine maintenance personnel - ***Ask*** *about the hemodialysis machine manufacturer's directions for PM and repair; intervals of PM per operating hours or calendar*

Review PM documentation for 10% of hemodialysis machines (minimum 3) *for 12 months: include 10% of the home hemodialysis machines maintained by facility; 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 prior to this review; this may be obtained in the machine operator's manual.*

Review documentation of reference meter calibration and maintenance: *Briefly look at 2 months of logs for pH and conductivity meters and equipment calibration meters.*

Triggers to extend equipment review to more hemodialysis machine PM documentation or ancillary equipment and/or citation:

- Trends of failure to adhere to hemodialysis machine manufacturer's directions for PM (V403)
- Failure to calibrate pH and conductivity meters or equipment calibration meters (V403)
- Observations of serious lack of maintenance of ancillary equipment (scales, chairs, infusion pumps, oxygen concentrators, etc) that has the potential to impact patient safety (V403, 626)

Task 9 ▲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)

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

Interviews and medical record reviews with/of home dialysis patients are addressed *Patient Interviews (Task 10)* and *Medical Record Review (Task 11*)

Note: If there are long term care (LTC) residents supported by the facility who are receiving home dialysis within their LTC facility, the surveyor is expected to follow the Full survey process as outlined in the current guidance for review of the care of the home dialysis LTC resident

Triggers to extend review of Home Dialysis and Support and/or citation:

- Home training nurse(s) interview identifies concerns about his/her knowledge or aspects of the home training and support program, including training materials and patient access to registered dietitian and/or master's prepared social worker
- Patient/caregiver interviews identify concerns about the adequacy of training and IDT support (V581, 585, 586, 592)
- Medical record reviews of home dialysis patients identify concerns related to training and monitoring of home dialysis patients, including monitoring water/dialysate quality for HHD patients, if applicable (V585, 586, 593-595)
- The facility is not evaluating home program outcomes separately in QAPI (V626)

Task 10 ▲Patient Interviews:

(Purpose - To listen to the patients' voices as recipients of the care provided at the facility to evaluate patients' knowledge of and freedom to assert their rights, understanding of their responsibilities, and their satisfaction with and quality of care concerns where there is little or no data to demonstrate desirable outcomes)

Interview the sampled patients selected during Task 5: *To ensure the survey process includes sufficient attention to the point of view and care experience of the patients, you should attempt to interview as many of the "interviewable" (i.e., alert, oriented, and not mentally impaired to the point that the interview would yield unreliable results) sampled patients as possible.*

After offering to interview them in person or by phone, if fewer than 50% of the sampled patients are interviewable or willing to be interviewed, ***interview at least 2 additional alert and oriented patients.*** *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 as they are not part of the core patient sample.*

You may individualize patient interviews to focus on each patient's issues, however ***ask*** *at least the "core" questions listed on the applicable Patient Interview Worksheet.*

Triggers to extend the number of patients interviewed and/or citation:
Patients express concerns regarding:

- Patients' rights and receipt of understandable information, including education including information on transplant options and all dialysis modalities and settings including those not offered at the facility (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- Lack of knowledge of how to prevent infections and protect their dialysis access (V562)
- The safety and comfort of the physical environment of the facility (V401, 402)
- Lack of knowledge of emergency evacuation and disaster preparedness (V409, 412)
- Lack of meaningful involvement of IDT in communication with and support of patient in planning their care (V501, 541)
- The proficiency of staff in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff (nursing, dietitian, social worker, patient care technicians) (V757-759)
- Knowledge about and freedom to report care concerns, ask questions, or file a grievance/complaint without fear of reprisal (V465-467)
- Adequate training and IDT support of home dialysis patients and caregivers to facilitate successful home dialysis (V585, 592)

Task 11 ▲Medical Record Review:

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

Review the medical records for all patients selected for sampling *at Task 5 -* ***All of the medical record reviews are focused reviews****, looking at the care provided to each sampled patient in the area/rationale used to select them. You will review each sampled patient's dialysis/medication orders, and the documentation of their dialysis treatments, however the remainder of each medical record review should be focused on the components of the record related to the sampling rationale, using the following guidelines:*

All sampled patients (except closed records of patients involuntarily discharged) ***review*** *the patient's current dialysis and medication orders and compare to the documentation of the dialysis process on their recent treatment records:*

- **In-center HD patients** - Look at 2-3 weeks of hemodialysis treatment records *for safety checks, implementation of dialysis prescription & medications, blood pressure/fluid management and patient monitoring*
- **Home HD patients** - Look at 2-3 weeks of hemodialysis treatment records *for staff monitoring of the patient's adherence to dialysis prescription & medications, safety checks, blood pressure/fluid management and recognizing and addressing issues*
- **PD patients** - Look at 8-12 weeks of PD documentation (e.g., flowsheets) *for staff monitoring of the patient's adherence to dialysis prescription & medications, blood pressure/fluid management, and recognizing and addressing issues*

Patients sampled because of - *Review the components of the record pertinent to the sampling rationale:*

- **Poor outcomes (not meeting goals) in the data-driven focus areas for the survey** – *as determined during Task 4 (Entrance Conference): **Review** the patient's trend in outcomes in **that** data-driven focus area, e.g., 3 months of labs for outcomes, etc. Then look at the physician's orders, interdisciplinary progress notes, patient care plans, and other applicable medical record components to assess the facility's actions for monitoring the patient's outcome(s), recognizing that there is a problem, and taking action to address it.*
    - Is there evidence that the patient's outcome in that data-driven focus area has improved and their goal is currently met?
        - **If yes, no further review is needed**
        - **If no,** is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; and took actions toward improvement/resolution? *If "no," citation in that outcome area at the applicable Patient Assessment or Plan of Care V-tag may be indicated.*

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

- **"Unstable" patients** - *Review the IDT documentation in progress notes, physician's orders, assessments, results of physical and mental functioning surveys (KDQOL-36 or other age-appropriate survey), plans of care, etc. pertaining to the two most recent comprehensive 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.*
    - Was a comprehensive assessment of the patient conducted and the clinical and psychosocial issues which contributed to the patient's instability addressed through revised plan of care interventions?

- Is there evidence of a functional IDT process, including substantive contributions from all required IDT members?

- **Newly admitted patients (<90 days)** - *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.* ***Review*** *the admission orders, labs 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?
  - Was the patient evaluated for hepatitis B and tuberculosis and offered hepatitis B vaccine and pneumococcal vaccine, if indicated?
  - Is there evidence facility staff evaluated and addressed 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, were their training needs evaluated and addressed?

- **Home HD and PD dialysis patients** - *If an interview (patient or staff) indicates a possible issue related to inadequate training for the patient and/or caregiver, review documentation of training*
  - **Home HD patients:** *In addition to the above areas applicable to a sampled home HD patient, review documentation of water/dialysate chemical and microbiological quality, for the dialysis equipment in use, if applicable*
  - **LTC residents receiving home dialysis at the LTC facility:** *If there are long term care (LTC) residents supported by the ESRD facility who receive home dialysis within their LTC facility, follow the Full survey process as outlined in the current guidance for review of the care of the home dialysis LTC resident*

- **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 after a patient has been IVD'd 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 **only** patients who may be involuntarily discharged under the Conditions for Coverage (i.e., without transfer of their care to another outpatient dialysis facility) are those patients whose behavior is abusive and disruptive to the extent that the delivery of care to the patient or the ability of the facility to effectively operate is seriously impaired (V767). For more information, refer to the current Survey and Certification guidance on "Dialysis Admission, Transfer and Discharge Practices" *Patients' rights protect a patient's right to refuse treatment. Therefore, skipping or shortening treatments and/or failing to meet facility set goals for clinical outcomes, as well as verbal outbursts that do not express a credible threat are not acceptable reasons for involuntary discharge.* The only exception to the requirements for IVD at V766-767 when the facility may utilize an

abbreviated IVD procedure is in the case of an immediate severe threat to the health and safety of others.

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

- Is there evidence that the patient was IVD'd due to seriously disruptive behavior, and NOT for the reasons listed at V766? *The reasons listed at V766 are allowable ONLY for involuntarily* ***transferring*** *a patient to another outpatient dialysis provider and are NOT allowable reasons for IVD.*
- Is there evidence that the IDT took meaningful actions in attempt to avert the IVD? *At a minimum, these efforts must include a full 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).*
- Is there evidence that the facility contacted and worked in conjunction with the applicable ESRD Network in an attempt to resolve the problems, avert the discharge, and, if unsuccessful, facilitate a transfer to another facility?
- Is there documented evidence that the facility staff contacted other dialysis facilities including those outside their corporation to attempt to transfer the patient before considering IVD? Is there evidence that "sister" facilities did not deny the patient admission ("lock out")?
- Is there evidence that the facility fully implemented/conducted ALL of the above actions **before** proceeding with the procedures for IVD?
- Once the decision for IVD was made: Is there documentation that the facility notified the patient at least 30 days before the IVD? Did the facility notify the applicable ESRD Network? Is there a written physician's order for the IVD, signed by the medical director and the patient's attending physician? Was the State survey agency notified of the IVD?
  - If **yes to all** of the above questions: *no citation is indicated*
  - If **no to one or more** of the above questions: *deficient practice under V766 or V767, as applicable, is indicated*

Triggers to extend medical record reviews to more patients' records or to additional areas of review in the sampled patients' records and/or citation:

- Trends of failure to demonstrate a functional IDT process to monitor, recognize and address barriers to attainment of identified outcome goals in one or more clinical areas

- Patient or caregiver interviews indicate lack of functional patient education program and patients' rights concerns - *Extend review to documentation of patient education and patients' rights*
- Incomplete, inaccurate, inaccessible or insecure medical records - *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

Task 12 ▲Personnel Interviews:

(Purpose - To assess staff knowledge, competence, and their awareness of expectations for safe and effective care aimed at achievement of optimum patient outcomes; to clarify/verify potential survey findings; and to give staff an avenue for voicing concerns)

Interview the following staff in-person (or offer to interview by phone) on all surveys - *You may individualize the staff interviews according to the survey issues and concerns, however* ***ask*** *the questions listed as "core" in the corresponding interview worksheets:*

- Medical director
- Water treatment personnel - *during Task 6*
- Reuse technician - *during Task 7*
- Home training nurse(s) - *during Task 9*
- Machine technician - *during Task 8*
- Master's prepared social worker
- Registered dietitian
- 2-3 direct patient care staff (RN, LPN/LVN, or PCT)

Triggers to extend 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.

Task 13 ▲Personnel Record Review:

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

Review the facility-submitted documentation on the "Personnel File Review" worksheet *given to the facility administrative person during the Entrance Conference*

Review selected personnel files: *Select a minimum of 3 personnel files to review to validate the facility-submitted documentation as accurate. Select the files using the criteria below:*

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

Triggers to extend review to more personnel files and or citation:

- Your validation of 1 or more personnel files indicates inaccurate facility-submitted documentation
- If PCTs have no certification expiration date listed, check for hire date within 18 months (V695)

Task 14 ▲Quality Assessment and Performance Improvement (QAPI) Review:

(Purpose - To verify that the facility's QAPI program is sufficiently pervasive and robust to monitor all facility operations/services, recognize when performance improvement is indicated, and take actions to attain and sustain improvements)

The QAPI review is divided into 6 Segments of review:

1. A quick review of facility summary documentation to ensure the facility is monitoring all the indicators and areas expected; that the infrastructure for QAPI is present; and meaningful efforts to promote a facility-wide "culture of safety" are in place
2. A focused look into the facility's QAPI performance improvement activities in the data-driven focus areas and survey findings to determine what the facility's QAPI actions were in response to problematic areas where there are opportunities for improvement
3. A review of the facility medical error/adverse occurrence/clinical variance reporting system
4. A review of the system for monitoring patient health outcomes in physical and mental functioning and the patient grievance/complaint/suggestion log review system
5. A review of the facility's QAPI oversight for the prevention and control of infections
6. A review of the facility required practice and technical audits

Preparation for QAPI Review: *Although portions (e.g., Segments 1, 5, 6) of the review may be initiated throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey to enable focus of the review during Segment 2 on the facility's QAPI activities in the* ***data-driven focus areas*** *(clinical areas where performance improvement is indicated based on the facility data) and on* ***concerns identified during the survey*** *to determine if the facility has identified the same concerns and what QAPI actions have been taken to address them. Prior to conducting the QAPI review, the survey team should communicate and discuss the survey findings, and make a list of areas you will focus on during Segment 2 of the QAPI review.*

Review the QAPI documentation for current 6 months in the following 6 segments. Interview the responsible facility-based person.

SEGMENT 1:

- **All facility areas monitored** (V626-637): ***Review*** *the QAPI documentation to verify that the facility's QAPI team monitors at a minimum all the expected areas of patient clinical management and facility operations (refer to table on page 2 of the ESRD Worksheet for QAPI Review). This is not a detailed review, but a quick look at the facility's QAPI dashboard or other summarizing documentation.* ***Note*** *that not all areas are expected to be monitored monthly.*
- **Facility efforts to promote a "culture of safety:" Note:** The provision of a facility culture of open, blame-free communication between all levels of staff and patients, that

encourages liberal reporting of all errors/occurrences, "near misses," and suggestions for improvements has been demonstrated to improve patient safety and reduce healthcare associated conditions.

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" or "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 quality assessment and performance improvement 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 a system in place for written or verbal submission and recording of staff suggestions for improvement, communication of concerns about their work environment, and complaints. Is there evidence that the facility administration encourages and responds to staff suggestions, concerns and complaints?

Ask: How are patients encouraged to voice questions, suggestions, concerns and complaints freely and without fear of retaliation? How are patient suggestions, concerns and complaints recorded and addressed? How are patients informed about the outcome of their suggestions, concerns, and complaints? **Note:** The Patient grievance/complaint/suggestion log and system is reviewed during SEGMENT 4 of this QAPI Review.

SEGMENT 2: Performance improvement activities in the data driven focus areas and **survey concerns/findings** (areas of patient risk) - *Using your list of QAPI focus areas, look at the documentation of outcome tracking and QAPI discussion in all of those areas for the previous 6 months. You may wish to ask the responsible person to show this documentation to you. For each focus area you listed:*

- Is there evidence the facility's QAPI team routinely monitored the focus area, recognized that a problem/opportunity for improvement existed, investigated root/multiple causes of the issues, developed and implemented performance improvement plans, and attained and sustained improvements?
  - **If yes:** no further review is needed for those focus areas and survey concerns/findings, *,no citation at QAPI is indicated in those areas*
  - **If no:** or the QAPI documentation indicates incomplete/ineffective actions were taken and no improvement has been attained - ***Review*** *those data-driven focus areas and survey concerns in more detail with the responsible facility-based person;* ***Ask*** *them to show you how the QAPI team recognized the problem/issue, investigated the root/multiple cause(s), took actions for improvement, and how the actions/outcomes were monitored to assure sustained improvement.*
    - Is there evidence that the facility's QAPI team investigated the root/multiple causes of the problem/issue and is currently taking actions to address the problem/issue to achieve improvements, although current outcomes are not yet within goals?

- **If yes:** No further review is necessary in that area. Effective QAPI activity is in process, *no citation in QAPI is indicated*
- **If no** (V626-637)**:** Facility's QAPI actions in that focus area are ineffective, *citation in QAPI is indicated for that focus area*

SEGMENT 3: Medical error/adverse occurrence/clinical variance reporting system: *The intent of this review is to ensure that there is an effective QAPI system in place for reporting and investigating errors/occurrences and "near misses" or "close calls."* ***The error/occurrence log is not intended as a source for survey citations****. Tell the responsible person that you will be reviewing the facility error/occurrence log with them.*

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" of the table on page 2 of the ESRD QAPI Review Work Tool 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 or close calls? ***Note:*** *The evaluation of near misses or close calls has been shown to be a rich source of error/adverse occurrence prevention and highly effective for improving patient safety.*

Review the facility error/occurrence log for the past 6 months*: Select one error/occurrence to "follow" along with the responsible person. Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI team actions to prevent future similar occurrences.*

- Is there evidence that the facility investigated the error/occurrence to determine what circumstances surrounded it, and possible causes? Did the QAPI team take meaningful actions in response to prevent recurrence?
  - **If yes:** No further review is necessary in this area. Effective QAPI activity is in process, *no citation in QAPI is indicated*
  - **If no** (V634)**:** Facility's QAPI actions may be ineffective, *citation in QAPI may be indicated.*

SEGMENT 4: Patient health outcomes-physical and mental functioning and grievance/complaint/suggestion log review: *The intent of this review is:*

- *To verify that the facility QAPI team is focused on patients' psychosocial status by regular monitoring by using a standardized survey that assesses the patients' physical and mental functioning; and*
- *To verify that the facility QAPI Team is "listening" to the patients, and that a patient grievance/complaint submission system is in place which allows patients to feel free to express concerns without fear of reprisal. If the patient interviews indicated trends of concerns about reluctance to speak up, plan to spend more time reviewing this area with*

the responsible person. Tell the responsible person you will be reviewing the patient grievance/complaint suggestion log with them.

Patient physical and mental functioning:
Ask: How do you track and trend eligible adults' scale scores on the KDQOL-36 or other age appropriate physical and mental functioning 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 by the QAPI Team.*

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

- Does the facility's QAPI team track and trend the % of eligible patients who complete and refuse the KDQOL-36 or other age appropriate physical and mental functioning survey? Does the facility's QAPI team track and trend the case mix adjusted scale scores? Does the facility's QAPI team investigate if above average risk is associated with negative behaviors and/or poor outcomes?
- If the trends of scale scores show a decline or the refusal rate has increased, is there evidence that the facility's QAPI team recognized a problem existed, investigated the root causes, and took meaningful actions to address the issue(s) and attain improvements?
    - **If yes** to the above questions-No further review is necessary in that area. *No citation in QAPI is indicated*
    - **If no** to one or more of the above questions- *citation may be indicated* (V627)

Patient grievance/complaint/suggestion system:
Ask: What types of patient concerns do you expect staff to report and record? *Expect to see that the facility encourages patients to verbalize suggestions and concerns, in addition to written complaints/grievances, and that staff are aware they should report verbalized suggestions and concerns to their supervisor for recording and follow up.*

Ask: How are patient concerns, verbal or written suggestions, complaints, and grievances recorded? How does your facility respond to these? 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: *Ask the responsible person to show you an example of one patient suggestion/complaint/grievance, how it was investigated, resolved, and the result communicated to the patient.*

- Is there evidence that the patient's concern was recorded, the circumstances investigated, and mutually acceptable resolution reached? Was the result communicated to the patient?
    - **If yes:** No further review is necessary in that area. Effective QAPI activity is in process, *no citation in QAPI is indicated*
    - **If no** (V636, 465, 765)**:** Facility's QAPI actions may be ineffective, *citation in QAPI may be indicated*

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 an indication of a facility's 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.

SEGMENT 5: Facility infection prevention and control: *Infections are the second 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 effective facility-wide processes for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare associated infections (HAI) acquired at the facility.*

Review 6 months of QAPI documentation in these areas:

Infection occurrence surveillance:

Ask: What types of infections do you record? What information do you record about each infection?

Review: The infection surveillance logs. *Expect to see that all positive culture results, all dialysis access and blood stream infections (BSI), and all peritonitis episodes, if applicable, are recorded with sufficient information for each (i.e. patient, date, infecting organism, culture site, and antibiotic use), and that trends in infections were recognized and evaluated/investigated.*

High risk disease-specific management: *Refer to the facility vaccination information obtained from the Entrance Conference Materials List, page 5.*

Ask*:* The responsible person to show you the QAPI documentation of oversight for surveillance and vaccinations including:

- Hepatitis B patient surveillance and susceptible patients and staff offered vaccination
- Tuberculosis surveillance of patients on admission or exposure
- Influenza vaccinations offered to patients and staff annually
- Pneumococcal pneumonia vaccination offered to patients on recommended schedule

*There should be evidence of active QAPI oversight of the above high risk disease surveillance and vaccination programs, and meaningful actions taken to investigate and implement performance improvement plans **if** trends of lapses in surveillance or vaccination were identified.*

Staff infection control education and visual practice audits: *Look at the documentation of staff infection control education and visual practice audits.*

Ask: What are staff taught about the prevention of infections in dialysis? How often are they re-educated in infection prevention? How often do you visually audit staff infection control practices?

Patient education in infection prevention:

Ask: How are patients educated in infection prevention? How are they encouraged to be engaged in knowing what infection prevention actions (e.g., cleaning and disinfecting the access site, changing gloves, performing hand hygiene) they and staff should follow (V562, 585))?

- Is there evidence that the facility's QAPI team monitored their infection prevention and control program, and, if applicable, recognized the existence of and investigated the root/multiple causes of infection control problems and has or is currently taking actions to address the problem/issue to achieve improvements?
- Is there evidence that staff caring for patients were visually audited for infection control practices, and, if lapses/breaches in expected practices were identified, actions taken to improve practices?
    - **If yes to the above questions:** No further review is necessary in that area. Effective QAPI activity is in process. *no citation in QAPI is indicated.*
    - **If no to one or both** (V637)**:** Facility's QAPI actions for infection prevention and control may be ineffective, *citation in QAPI may be indicated.*

SEGMENT 6: Oversight of technical and facility operations and required practice audits: ***Review*** *6 months of the facility's QAPI documentation to ensure routine audits are conducted in these areas, as required in the Conditions for Coverage:*

Water and dialysate quality

- Review of monthly cultures/endotoxin results, annual product water chemical analysis, and other microbial monitoring as indicated for the equipment in use (V626)
- Audits of staff mixing dialysate concentrates; testing dialysate ph/conductivity; water testing for chlorine/chloramines and microbial sample collection (V260)

Dialysis equipment

- Review of dialysis machine, equipment and ancillary equipment maintenance and repair (V626)

Reuse

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

Triggers for extension of QAPI review and/or citation:

The QAPI program does not:

- Recognize and address risk areas where performance improvement is needed/indicated (V625-640)
- Follow up on performance improvement plans, resulting in improvements not attained or sustained (V638)
- Promote a culture of quality and safety - *This would be indicated if staff or patient interviews indicated lack of knowledge about how to report or reluctance or fear to report errors, occurrences or suggestions for improvements, and/or the review of the patient and/or staff suggestion/grievance/complaint systems demonstrated concerns*
- Administer oversight of all facility operations: monitor all areas required by CfC; conduct practices audits as required in the CfC (V132, 260, 362-368, 403)

Task 15 Decision Making:

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

- Meet with the survey team
- Refer to laminates (ESRD: Condition vs. Standard Decision Tool and Immediate Jeopardy Decision Making Tool: Components of IJ)
- Make copies of evidence as needed to document survey findings

Task 16 Exit Conference:

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

- Verbally present findings in order of severity; do not provide specific V-tags
- Follow relevant SOM & State procedures
- Explain: When the facility may expect to receive the CMS 2567; when the plan for correction is due; what should be included in the plan for correction; the requirements for a dated signature on the first page, one date of correction for each V-tag & the potential for a revisit

Survey & Certification Quality Assurance Efficiency & Effectiveness (QAEE)

Purpose: The QAEE Project has been tasked with increasing the focus of the ESRD survey process on those findings which link to mortality, hospitalization, and infections as evidenced by currently available and prospective data. In developing the core survey for QAEE, the overarching goal is to improve patient outcomes and improve the efficiency of the survey process through use of data-driven survey algorithms. We anticipate that successful completion of this initiative will require 1) development of a more focused core survey process, 2) surveyor education, and 3) implementation of a change management strategy.

Red (italic) text reflects areas of core survey incorporating Patient Activation/Voice in dialysis care.

Infection Control		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Access-related bacteremia
  ○ Facility QI data
  ○ DFR
• Hospitalizations for septicemia
• Peritonitis
• Inadequate immunizations
  ○ Facility QI data
	• Direct care practices
	  ○ Hand hygiene
	  ○ Gloves/ masks
	  ○ HBV+ isolation
	  ○ Disinfection
	  ○ Supply mgmt
	  ○ Med prep/admin
	  ○ Put on/take off care
	  ○ Exit site care
	• Vaccinations program
	• Surveillance program
	• Sufficient space between stations
	• Isolation station/area
	• Physical separation of clean & dirty
	• Clean supply area
	• Medication prep area
		• Observation of care practices
		  ○ If bacteremia /septicemia rates are low, observation should focus on hand hygiene, glove/mask use, HBV isolation, disinfection, supply management with less focus on initiation and termination of dialysis and exit site care.
		• Review of infection control audits
		• Disinfection of machine and station
		• If HBV+ pt., then observe specifics of Isolation Practices
		• Validation of vaccine /surveillance data (in med record)
		• *Patient Interview questions (including patient education/ engagement)*

Survey Expansion Triggers
• Problems identified during observations on tour and care delivery
  ○ blood spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood
  ○ poor isolation practices; staff delivering care to HBV+ patient and susceptible patients (this would be to look into the extent of the practice-is it the "normal" assignment); when 1 RN on duty-poor infection control separation b/t care to HBV+ and susceptible patients
  ○ trends/multiple breaches in infection control
• Inadequate IC audits
• Multiple complaint allegations about poor infection control practices		

Water & Dialysate Quality		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**
AAMI quality water & dialysate not met • Chlorine/ chloramine breakthrough • Elevated microbial growth >200 cfu, >2 EU • Fluoride breakthrough • Chemical contaminates exceeding AAMI Table 2	• Chemical analysis of product water yearly or as indicated • Test water for total chlorine post-primary carbon prior to every ICHD shift or ~4 hrs during treatment day • RO monitored 1x/day; • IF DI, **DI monitored 2x/day** • Water bacteriology monitoring before loop disinfection • Point of use pH & conductivity testing • Practice audits review • Carbon tanks (2) • Purification unit (RO) • Purification unit (DI) o Auto divert to drain o UF filter post • Continuous water quality monitor/alarm (observe) • Water distribution loop • Central delivery vs. individual jugs • Appropriate concentrate available	• Observe /interview chlorine/chloramine testing • Observe carbon system o Tour- review current test log and any additional sheets on clipboard, reagents, testing equipment • Observe RO o Observe/Interview o Functioning Water Quality Monitor/Alarm in Use? (no forced test) • IF DI, Observe DI o Observe/**Interview** o **Observe resistivity monitor** o **Automatic divert to drain** o Observe presence of UF filter post DI (individual in-line UF filters acceptable) o Functioning Water Quality Monitor/Alarm in Use? (no forced test) • Interview- microbial sampling plan for product water and dialysate to cover sample sites, collection methodology, and timing relative to water loop disinfection and machine sampling. • Observe/Interview- pH and Conductivity testing • QAPI link- Practice Audits for Water and Dialysate are maintained • Log Reviews o One month chlorine/chloramine logs o RO Log- one month RO logs; % rejection or TDS checked daily o If DI- resistivity checked twice daily; review 1 mo. of data; resistance threshold > 1 megohm o Most recent product water chemical analysis o Water/Dialysate microbial monitoring- 4 mo.: compare with culture plan

Water & Dialysate Quality (continued)

Survey Expansion Triggers

Chlorine removal/carbon system:

- 2 or more carbon tanks with sample port between not present; current chlorine/chloramines test not done; testing reagents expired or don't match testing equipment
- Chlorine/chloramines test done incorrectly or with incorrect reagents/equipment; staff knowledge deficit of max allowable level and/or breakthrough procedures

Reverse Osmosis:

- RO % rejection/TDS monitor non-functional or not monitored daily
- No or non-functioning water quality alarm audible in patient treatment area

DI, if present:

- Resistivity monitor/alarm non-functional or not monitored 2x day
- Automatic divert-to-drain not present or non-functional
- Resistivity alarm not audible and visible in patient treatment area
- Staff knowledge deficit of minimum allowable resistivity and actions for DI tank exhaustion; no ultrafilter post DI or in-line to each HD machine

Dialysate

- Dialysate pH and conductivity not done at each HD machine prior to each treatment or per manufacturer DFU
- Multiple dialysate proportioning ratios present
- Dialysate mixing and distribution equipment in obvious disrepair or contaminated state

Log reviews:

- Irregularities, trends of omitted tests
- Chlorine/chloramines exceeding maximum level (breakthrough) without documentation of appropriate actions taken
- Microbial results exceeding action/maximum levels without documentation of appropriate actions taken
- Product water chemical analysis shows level(s) exceeding AAMI Table 2
- Practice audits not done

Reuse of Hemodialyzers		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Patient adverse events related to dialyzer reprocessing/reuse
  ○ QAPI logs
	• Reuse/reprocessing practices
	  ○ Appropriate transport of dirty dialyzer
	  ○ Pre-rinse (including appropriate header removal & cleaning)
	  ○ Appropriate germicide dwell time
	  ○ Tests for germicide at point of care
	  ○ 2 checks of patient & dialyzer ID
	• QA audits
	• Reuse room
	• Reprocessing equipment designed, constructed, tested
	• Trained personnel
		• Observe/Interview:
		  ○ Appropriate transport of dirty dialyzer
		  ○ Pre-rinse (including appropriate header removal & cleaning)
		  ○ Appropriate germicide dwell time
		  ○ Tests for germicide at point of care
		  ○ 2 checks of patient & dialyzer ID
		• Review Medical Records- reprocessed dialyzer checks
		• Review QA Audits for 12 months to ensure facility adherence with this requirement.
		• Review PM logs for reprocessing equipment
		• *Patient Interview regarding informed consent, participation in safety checks*

Survey Expansion Triggers:

Observations:

- Noticeable strong odors of germicide in patient treatment area
- Reprocessing equipment in obvious disrepair
- Dirty dialyzers kept at room temperature > 2 hours
- Failure to perform reprocessed dialyzer germicide tests or patient/dialyzer id
- Improperly performed pre-rinse procedures (i.e. Header cleaning)
- Knowledge deficit of reuse tech regarding key question areas

Log reviews:

- QA audits not done
- Trends of adverse occurrences related to dialyzer reprocessing not addressed

Physical Environment and Patient Care in the Facility		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Safe & comfortable environment
• Systems impacting patient safety & comfort are functional
• Educated staff & patients
	• Dialysis equipment are operated & maintained per DFU
	• Patients' faces & accesses can be seen at all times
	• Staff & patients trained in emergency procedures
	• Emergency equipment/meds available & ready for use
	• Facility hazard free
		• *Patient/Staff Interviews*
		  ○ *Safe/Comfortable Environment*
		  ○ *Knowledge of Emergency Plans*
		• Tour Facility-
		  ○ Failure to maintain safe and comfortable environment
		  ○ Observe/Interview to ensure functional Emergency Equipment
		• Observe Care
		  ○ HD Machines operated per DFU
		• QAPI Link- Review Adverse Incident Logs
		• Review HD Machine Maintenance Logs 10% selection (min 2 machines)

Survey Expansion Triggers:

Observations in patient treatment area:

- Dummy drip chambers present
- Patients' vascular accesses covered, not uncovered/corrected by staff
- No emergency resuscitation equipment present or non-functional
- Hemodialysis machines in obvious poor repair-alarms not functional, missing components
- Failure to test HD machine alarms
- Evidence of serious lack of maintenance of ancillary equipment that has the potential to impact patient safety

Observations in other patient-related areas:

- Evidence of serious lack of environmental maintenance that has the potential to impact patient safety

Interviews:

- Lack of staff knowledge in the use of emergency equipment and/or emergency procedures
- Lack of patient knowledge in emergency evacuation procedures and disaster preparedness

Log reviews:

- HD machine preventative maintenance logs show trends of failure to adhere to HD machine manufacturers' DFU
- No emergency evacuation drills conducted

Patients' Rights		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Patients' rights are protected
• Patients' choice of modality is adhered to unless contraindicated
	• Patients treated with dignity & respect
	• Patients informed in manner they can understand:
	  o Grievance process & right to file w/o retribution
	  o Rights & responsibilities
	  o Discharge/ transfer policies
	• Access to & resources about modalities & settings
	  o Posted State & Network phone numbers
		• *Interview all core sampled patients (if possible)*
		• *Observe care*
		• *QAPI Link-Review Grievance Log, patient satisfaction*
		• *Link to Tour- Observe postings for Patient Rights/Responsibilities and contact info.*

Survey Expansion Triggers • Observation of disrespectful treatment of patients • Patient(s) verbalize concerns on interview in all areas of patient information and rights		

Patient Assessment & Patient Plan of Care		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Hospitalization for CHF, HTN
• Average IDWL < 5%
• Kt/V > 1.2
• IDT activated for unstable patients
• Adequate nutrition
• Target calcium met
• Target phosphorus met
• Hgb, asymptomatic
• Catheter rate
• KDQOL scores, 10 point drop
	• IDT identifies unstable patients
	• IDT uses the community accepted goals (MAT) to develop POC
	• IDT develops POC based on comprehensive IDT PA
	• Monitor, Recognize, Address
	• All IDT members Community accepted goals available (MAT)
		• Review DFR, unstable patient list, and QAPI Patient Outcomes
		  ○ If all outcomes "good" and patient stable, no further review required
		  ○ If specific outcomes "bad", proceed
		  ▪ Focus selection of patient sample on those with "bad" outcomes over last 12 months
		  ▪ Focused Medical Record Review-MRA
		• Unstable patient- Review IDT care
		• *Patient Interview for meaningful involvement in IDT (follow the outcome)*

Survey Expansion Triggers • Trends of failure to demonstrate a functional IDT process to monitor, recognize and address in aiming at achievement of identified outcome goals		

Care at Home		
Refer also to Patients' Rights, Patient Assessment & Patient Plan of Care Conditions		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Successful dialysis at home
• Services at least equivalent to in-center patients
	• Fact-based education & appropriate candidate selection
	• Training includes comprehension & testing of competency (patient &/or care partner)
	• Support/monitoring
	  ○ Home visit
	  ○ Interval review of home treatments
	  ○ Water/dialysate (HD)
	  ○ IDT consultation
	• Qualified RN
	• Support (personnel, supplies, equipment)
	• Training room(s)
	• Training curriculum
	• Plan for emergency back-up dialysis
		• Observe Home Training area
		• Interview the Home Training Nurse (both HD and PD)- pare down
		• *Interview the Home Dialysis Patients*
		• Medical Record Review
		  ○ Interval review of home treatments
		  ○ Water/dialysate (HD)
		  ○ Machine maintenance
		• QAPI Link- Evaluate Home and In-center Programs separately

Quality Assessment & Performance Improvement		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**

• Culture of safety is present
• Measures of water/ dialysate quality, reuse practices, and equipment maintenance assure patient safety
• Ongoing improvements in health outcomes are attained & sustained
• Medical errors & injuries are accurately reported and reduced
	• Medical director/QAPI team that includes IDT & facility management
	• Effective two-way communication exists among medical director, QAPI team, facility staff, & governing body
	• Data is collected, trended, & cause analysis performed
	  ○ Clinical
	  ○ Operational
	  ○ Patient satisfaction
	  ○ Adverse events (e.g., infections, errors/ omissions, transports from dialysis to hospital, complaints & grievances, IVD/IVT, etc.)
	• Plan(s) for performance improvement are developed, implemented, & revised periodically, & as needed
	• Facility has process for QAPI
	• Resources are allocated to facilitate effective QAPI
	• Data available to review
		• Culture of Safety
		  ○ *Interview Patients and Staff (What is your responsibility/role in reporting errors (for patients 'care concerns')? Have you seen any errors? Have you reported? What happened? If you haven't reported, why?)*
		  ○ Review 'Error' Log (basket) and system for reporting adverse events
		  ○ Following the event- How does reporting activate the QAPI team to prevent future events?
		• Practice Audits from the other Conditions
		• Focus QAPI review on substandard facility outcomes and survey findings (basket)

Survey Expansion Triggers QAPI program does not: • Address areas where performance improvement is indicated • Follow up on performance improvement plans, resulting in improvements not achieved or sustained • Promote a culture of safety • Administer oversight of all facility operations through practice audits as required in the CfC		

Personnel Qualifications		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**
• Patients receive safe and effective care	• Qualified personnel • Certified PCTs • Qualified water tech	• Review- Facility attestation of Staff Qualifications • Observe care • *Interview patients & staff*
Survey Expansion Triggers • Observations of breaches in patient care and staff performance o Infection Control o Equipment use, maintenance and testing o Chlorine/chloramine testing o Dialyzer Reprocessing o Working outside scope of practice • Interview demonstrated inadequate training or knowledge		

Responsibilities of the Medical Director		
Drill down to this Condition if findings in other Conditions indicate.		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**
• Patients receive appropriate clinical care • Timely initial MD orders & RN assessment of new admission	• Medical director actively participating in oversight of dialysis facility operations • Facility has one medical director	• Interview the Medical Director o Questions based on DFR, facility QAPI data and survey findings • Link to Medical Record (add incident patient to selection for Medical Record review)

Medical Records		
Medical Record review is reflected in survey of other Conditions (e.g. Water/Dialysate, Reuse, PA/POC, Patients' Rights.)		
Target Outcome	**Outcome Drivers**	**Core Survey Actions**

Complete, accurate and centralized records	• System of medical records	• Review for sampled patients
		  ○ In-Center and Home HD treatment records for last 3-4 weeks
		  ○ PD home treatment records for last 2 months

Survey Expansion Triggers • Incomplete, inaccurate, inaccessible or non-secure medical records • Concerns identified in other survey tasks, investigated further through medical record review to support/dispel findings		

Governance		
Drill down to this Condition if findings in other Conditions indicate.		
Target Outcomes	**Outcome Drivers**	**Core Survey Actions**
• Facility provides sufficient resources for patients to receive safe and effective care • Patients have equal access to care ○ List of patients with IVD/T in last 12 months	• Facility submits data as required • Admission, discharge, transfer policies assure protection of patients' rights • RN on duty when patients present • Adequate number of qualified/trained staff based on acuity	• Pre-survey contact with the ESRD Network • Observation of RN present and staffing • *Patient and Staff Interviews regarding staffing/resource availability, including Social Worker and Renal Dietitian* • *IVD/T patients in Medical Record review sample (focus on discharge /transfer circumstances)*
Survey Expansion Triggers: • RN not present when patients are dialyzing • Medical record review shows irregularities with involuntary transfer or discharge • Evidence of insufficient staffing to meet patients' needs (observation and/or interview) • ESRD Network communicates serious concerns regarding quality of care		

ESRD CORE SURVEY ENTRANCE CONFERENCE MATERIALS LIST

Facility: _____ **Date:** _____

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

Needed as soon as possible (within 3 hours):

- ☐ List of current patients by name, separated into modalities
- ☐ List of facility key personnel: medical director, administrator, nurse manager, social worker, dietitian, chief technician, home training nurse(s)
- ☐ Current in-center hemodialysis patient listing by days & shifts with any isolation patients identified (seating chart or assignment sheet)
- ☐ Patients admitted to this facility within the past 90 days (do not include visiting patients)
- ☐ Patients who have been designated as "unstable" for any month in the past 3 months
- ☐ All patients involuntarily discharged (no transfer to another outpatient dialysis facility) from the facility in the past 12 months
- ☐ Residents of long term care facilities dialyzing in the LTC facility and the name of the LTC where they are receiving dialysis
- ☐ Hospitalization logs with admitting diagnoses listed for 6 months
- ☐ Infection logs for past 6 months
- ☐ Patient lab results for hemoglobin, Kt/V, URR, corrected calcium, phosphorus and albumin for the current 3 months; separated by modality

ESRD CORE SURVEY ENTRANCE CONFERENCE MATERIALS LIST

Needed as soon possible (within 3 hours):
Please fill in the table below with your facility data based on the last 3 months of your QAPI information. List additional patients' names on a separate sheet of paper.

Hemodialysis (Designate If Patient Is on Home Hemodialysis)

Measure	MAT Goal Unless Other Specified	% Met Goal	Names of Patients Who Did Not Meet Goal in 2 or More of Last 3 months
Single pool Kt/V Standardized Kt/V URR	≥1.2 for 3tx/wk ≥2.0 weekly for ≥4tx/wk ≥65%	_____ _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8.
Calcium corrected for albumin Phosphorus	WNL for lab; <10mg/dL 3.5-5.5 mg/dL	_____ _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8.
Albumin	≥4 g/dL BCG; lab normal for BCP		1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8.
Intradialytic weight loss	Average intradialytic weight loss <5%		1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8.
Vascular access (VA)	CVC ≥90 days <10%	Facility current %CVC ≥90 days _____ HD VA Infection rate____	Patients with CVC ≥90 days 1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8.

Measure	MAT Goal Unless Other Specified	% Met Goal	Names of Patients Who Did Not Meet Goal in 2 or More of Last 3 months
Transplant waitlist	Interested patients are referred for transplant unless excluded by area transplant exclusion criteria	Facility current TP waitlist rate _____	Interested HD patients not referred for transplant 1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8.

Peritoneal Dialysis

Measure	MAT Goal Unless Other Specified	% Met Goal	Names of Patients Who Did Not Meet Goal in 2 or More of Last 3 months
Kt/V	≥1.7 weekly		1. _____ 2. _____ 3. _____ 4.
Calcium corrected for albumin Phosphorus	WNL for lab; <10 mg/dL 3.5-5.5 mg/dL	_____ _____	1. _____ 2. _____ 3. _____ 4.
Albumin	>4g/dL BCG; lab normal for BCP		1. _____ 2. _____ 3. _____ 4.
PD access		Current PD catheter infection rate _____	Patients with PD Catheter Infections 1. _____ 2. _____ 3. _____ 4.
Transplant waitlist	Interested patients referred for transplant unless excluded by area transplant exclusion criteria	Current TP waitlist rate_____	Interested PD Patients Not Referred for Transplant 1. _____ 2. _____ 3. _____ 4.

ESRD CORE SURVEY ENTRANCE CONFERENCE MATERIALS LIST

Materials Needed by 8 a.m. on Day 2 of Survey:

☐ Vaccination information as reported in section "C Vaccines" of the CDC NHSN "Outpatient Dialysis Center Practices Survey":
- # of patients administered at least 3 doses of hepatitis B vaccine _____
- # of patients administered influenza vaccine during most recent flu season (September or later) _____
- # of patients administered pneumococcal vaccine _____

☐ Completed "Personnel File Review" Worksheet

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

☐ Patient care staff schedule for the current time period (last two weeks)

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

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

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

☐ QAPI committee meeting minutes for past 6 months and any supporting materials

☐ Copy of CMS-approved waivers for medical director, isolation room, as applicable

☐ For Water and Dialysate Review: Logs for:
- Daily water system monitoring-3 months
- Chlorine/chloramines testing-3 months
- Bacterial cultures and endotoxin results-water and dialysate-12 months
- Chemical analysis of product water-12 months
- Staff practice audits for water testing, dialysate mixing & testing and microbiological sampling-12 months

☐ For Equipment Maintenance Review: 12 months documentation of preventative maintenance and repair, including electrical leakage testing of dialysis machines

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

ESRD Core Survey Worksheet
Entrance Conference Questions

Facility: _____ Date: _____

Gather the following information from the facility representative:

Current HD in-center census: _____

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

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

How many patient shifts are there? MWF _____ TThS _____

What hours is the facility open? _____

What time do patient shifts start? _____

What time do staff arrive? _____

When are water tests done? _____

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

If yes: how many isolation stations are available? _____

How many HBV+ patients are on census? _____

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

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

Does the facility reprocess/reuse dialyzers? ☐ Yes ☐ No

If yes, what type of germicide is used?_____

Is the reprocessing off-site/centralized? ☐ Yes ☐ No

Does the facility have any home dialysis programs? ☐ Yes ☐ No

If yes: Number of PD patients_____ Number of HHD patients_____

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

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

_____

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

Are any staff members currently in orientation? ☐ Yes ☐ No

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

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

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

☐ Yes ☐ No

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

_____

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

What are the names of those patients? _____

_____

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

_____

ESRD SURVEY WORKSHEET: PERSONNEL FILE REVIEW

Facility: **Date:**

ID #	Name/Position	Hire Date/ Orientation	License/ Cert Expiration Date	CPR Expiration Date	TB Evaluation Date	Hepatitis Vaccine or Decline	Competencies Documented	Emergency Procedures, Infection Control Training	**Water, Dialysate, Machine, Reuse Training

****Must pass color blindness testing if using colormetric testing methods**

ESRD SURVEY WORKSHEET: PERSONNEL FILE REVIEW

Facility: **Date:**

ID #	Name/Position	Hire Date/ Orientation	License/ Cert Expiration Date	CPR Expiration Date	TB Evaluation Date	Hepatitis Vaccine or Decline	Competencies Documented	Emergency Procedures, Infection Control Training	**Water, Dialysate, Machine, Reuse Training

****Must pass color blindness testing if using colormetric testing methods**