ESRD CORE SURVEY QAPI REVIEW WORKSHEET

Facility_____**CCN**_____**Date**_____

Surveyor_____**Facility-based Responsible Person**_____

Preparation for QAPI Review: Although portions of the QAPI review may occur throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey to enable focus of the review during Segment II on the QAPI activities for recognizing and addressing areas you have identified as problems during the survey. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and list below the areas, in addition to the three critical priority areas, you will focus on during Segment II.*

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

The QAPI review is divided into 3 General Segments of review:

Segment I. Monitoring care and facility operations to verify that the facility QAPI program has sufficient infrastructure, and continuously monitors all areas as expected, including technical areas
- ➢ **Clinical and operational indicators**
- ➢ **Oversight of technical operations and practice audits**

Segment II. Review of Quality Assessment and Performance Improvement in three critical priority areas, and in the data-driven focus and survey findings areas specific to this facility survey; A detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and addressing the critical priority and problematic areas to attain and sustain improvements
- ➢ **Mortality review**
- ➢ **Infection prevention and control**
- ➢ **Medical error/adverse occurrence/clinical variance tracking and investigation system**
- ➢ **Data-driven focus and survey findings areas** for this facility survey

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

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

Segment I: Monitoring Care and Facility Operations
- ➢ **Clinical and operational indicators monitored**

*Review the QAPI documentation to verify that the facility's QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI Team monitors at a minimum all the expected areas of patient clinical management and facility operations. Refer to table of indicators in the "ESRD Core Survey QAPI Review Worksheet." **Note** that not all areas listed in the table are expected to be monitored monthly. This is not a detailed review, but a brief look at the facility's QAPI dashboard or other summarizing documentation. **You will review the facility QAPI performance improvement activities in the critical priority areas, survey data-driven focus areas and survey findings/concerns areas in more detail during Segment II.***

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Areas to be routinely monitored: Note that not all areas are required to be monitored monthly

☐ Water & dialysate quality (separate in-center & home) (V628):
- Chemical analysis of product water *annual & as needed*
- Monthly water & dialysate microbial content (CFU and LAL)
- Total chlorine testing *prior to each HD shift or approx q 4 hrs*
- RO daily monitoring

☐ Dialysis equipment repair and maintenance (V628)

☐ Physical plant safety "rounds," audits (V628)

☐ Reuse QA audits & adverse events (V635)

☐ Staff issues (V628)	☐ ESRD Network relationship/communication (V772)
• Staff qualifications	• Data submission
• Medical staff appointments	• Refusal of admission
• Staffing-turnover	• Involuntary transfer and discharge

☐ Patient modality choice & transplant referral (V628)	☐ Health outcomes-physical and mental functioning (V628)
• % patients/modality	• KDQOL-36 (or other age appropriate survey/tool)
• % patients potential transplant candidates	
• Transplant referral, status and follow up	

☐ Mortality-expirations & cause (separate HD & PD, home & in-center) (V628)	☐ Morbidity-hospitalizations, admitting diagnoses & readmissions w/in 30days (separate HD & PD) (V628)

☐ Fluid & BP management-HD (V628)	☐ Fluid and BP management-PD (V628)
• % intradialytic weight loss	• Weight variances
• BP variances pre and post dialysis	• BP variances
• Intradialytic symptoms of depletion	• Symptoms of fluid overload, dehydration

☐ Dialysis adequacy-hemodialysis (V629)	☐ Dialysis adequacy-peritoneal dialysis (V629)
• Separate conventional, nocturnal and >4x/wk	• Residual kidney function monitoring
• Residual kidney function monitoring	

☐ Nutritional status (separate HD & PD) (V630)	☐ Mineral, bone management (separate HD & PD) (V631)
• Albumin	• Calcium, phosphorus, iPTH
• Variance from usual body weight	

☐ Anemia management (HD) (V632)	☐ Anemia management (PD) (V632)
• Hgb	• Hgb
• Ferritin & TSAT% or CHr	• Ferritin & TSAT% or CHr
• Symptoms of anemia	• Symptoms of anemia
• Transfusions	• Transfusions

☐ Vascular access-HD (V633)	☐ Dialysis access-PD (V633)
• % CVC, AVF, AVG (AVF non-functional)	• Tunnel & exit site infections
• Efficacy monitoring	• Reduced function/flow impairments
• Adverse events-clotting, infiltration, infection	• Repositioning/removal/replacements

☐ Medical errors/adverse occurrences/clinical variances-in-center hemodialysis & home dialysis (V634)
- Cardiac arrest at facility
- Deaths during dialysis
- Errors in dialysis prescription delivery
- Medication errors, omissions, adverse reactions
- Transfusion reactions
- Incorrect reprocessed dialyzer set up or used
- Blood loss>100cc
- Chlorine/chloramine/fluoride breakthrough
- Machine malfunction w/treatment interruption
- Patient transfers to hospital from dialysis
- Patient falls; Patient injuries
- Vascular access infiltration, excessive bleeding
- Intradialytic symptoms
  - Hypotension w/loss of consciousness
  - Chest pain
  - Severe cramping; nausea/vomiting
  - Pyrogenic reactions
- Staff incidents and injuries:
  - Needle sticks
  - Blood/body fluid exposures
  - Non-adherence to procedures
  - Patient abuse/disrespect

☐ Patient satisfaction & grievance/complaints (V636)
- Patient satisfaction survey
- Complaints/grievances/suggestions **voiced** or submitted by patients

☐ Infection prevention and control (separate HD & PD, home & in-center) (V637)
- Infection occurrence surveillance & recording/antibiotic starts
- HBV, TB surveillance
- Vaccinations-HBV, influenza, pneumococcal
- Staff education & visual practice audits
- Patient education

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Is the facility routinely monitoring and trending all of the expected areas? ☐ **Yes** ☐ **No** (V626, 628)-Explain _____

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

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

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

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

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

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

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

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

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Additional notes: _____

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

Review *the facility Quality Assessment and Performance Improvement activities in three critical priority areas (mortality, infection prevention and control, medical error/adverse occurrence investigation system) for ALL facilities, and in the data-driven focus and survey findings areas specific to this facility survey* (identified areas of patient risk). *In all areas, conduct a sufficiently detailed review to determine the quality and effectiveness of the facility QAPI Team actions for addressing problematic areas and attaining and sustaining improvements in outcomes.*

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

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

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

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

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

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> ➢ **Infection prevention and control**

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

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

Infection occurrence tracking/trending/surveillance:
Ask: What types of infections do you record? What information do you record about each infection?
Review: *The infection tracking logs.*

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Are all positive culture results, dialysis access infections, blood stream infections (BSI), and peritonitis episodes, if applicable recorded with sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic susceptibility)? ☐ **Yes** ☐ **No** (V637)-Explain_____

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

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

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

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

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

_____

Staff education and visual practice audits for infection control:
Ask: What are staff taught about the prevention of infections in dialysis? How often are they re-educated in infection prevention? How often do you visually audit personnel infection control practices? If you identify a problem when auditing staff, how do you involve the staff in the development and implementation of the solution?
Review: The documentation of visual audits of personnel infection control practices while delivering care to patients.

Is there evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff member? When lapses in practices were observed, were actions taken toward improvement, i.e., applicable staff involved in the investigation into issues surrounding the practices such as low staffing, and development and implementation of improvement plans, rather than not just counseling or reeducating? ☐ **Yes** ☐ **No** (V637, V142, V147)-Explain_____

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

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

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

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

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

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

Review the facility error/occurrence log for the past 6 months: Select one error/occurrence to "follow" along with the responsible person. You may randomly select the error or select one pertinent to concerns identified during the survey (e.g., you observed staff not identifying patients' reprocessed dialyzers as required, and select an error to follow when a patient was dialyzed on another patient's dialyzer). Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI Team actions to prevent future similar occurrences.

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

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

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

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

Focus Area_____

Is there evidence that the QAPI Team prioritized performance improvement activities to assure areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner? ☐ **Yes** ☐ **No** (V639)-Explain_____
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Did the facility routinely monitor the focus area, and **identify the issue or recognize that a problem** or opportunity for improvement existed? ☐ **Yes** ☐ **No**-Explain_____
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Did the facility thoroughly **investigate root/multiple causes** of the issue and develop, implement, and monitor performance improvement plans? ☐ **Yes** ☐ **No**-Explain_____
_____

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

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

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

Culture of Safety: In healthcare, lessons show that true patient safety is only achieved through the implementation of a facility-wide "culture of safety." The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and clear expectations of staff practices. A culture of safety supports complete staff and patient engagement and assures that everyone at the facility is committed to identifying and mitigating any risks to patients. This segment includes reviews of the following 3 areas:

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

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

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

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

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

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

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

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

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

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➢ **Patient Engagement Review**

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

Ask: How do you track and trend eligible patients' scores in an age-appropriate standardized physical and mental functioning survey, e.g., KDQOL-36? What is your facility's threshold for patients completing and refusing the survey annually? *Note: Although it is expected that a few patients may refuse to participate in the assessment of their physical and mental functioning, high refusal rates, e.g., >20% would indicate a problem which should be recognized and addressed by the QAPI Team.*

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

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

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

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

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

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

Review the patient suggestion/complaint/grievance log with the responsible person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient.

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

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

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

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

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

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

Additional notes: