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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Admin Info: 19-06-ESRD

DATE: **January 22, 2019**

TO: State Survey Agency Directors

FROM: Director
             Quality, Safety & Oversight Group

SUBJECT: Release of Fiscal Year (FY) 2019 End Stage Renal Disease (ESRD) Core Survey
             Data Worksheet, Notice of Quarterly Dialysis Facility Report (DFR) Updates and
             Revisions to the Tier 2 Outcomes List Methodology

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Memorandum Summary

- **Release of FY 2019 ESRD Core Survey Data Worksheet:** The ESRD Core Survey Data Worksheet is updated annually to reflect clinical indicators, outcome goals, and outcome thresholds based on current national data. The Worksheet is used as a surveyor tool while conducting an on-site dialysis facility survey. The worksheet has been updated to reflect current national thresholds for the data elements used to evaluate a facility's performance. The updates align with information contained in the FY 2019 DFR.

- **Notice of Quarterly DFR updates:** Select measures of the DFR will be updated on a quarterly basis as of December 2018. The comprehensive DFR will continue to be updated annually along with three quarterly updates throughout the FY. Surveyors should review the most recent DFR to appropriately evaluate current data elements included in the ESRD Core Survey.

- **Revisions to FY 2019 Tier 2 Outcomes List Methodology:** The FY 2019 Tier 2 Outcomes List has been revised to identify the top 5% of ESRD facilities with poor clinical outcomes across four defined clinical measures. States are expected to survey all facilities on the outcomes list from their State. The annual process for releasing and reviewing the Outcomes List will remain the same.

Background

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

Historically, the DFR has been updated on an annual basis with comprehensive facility information including data on select clinical measures used to determine data driven focus areas during an ESRD survey. These data elements may be up to 9 months old at the time of surveyor review. As of December 2018, select measures of the DFR will be updated on a quarterly basis throughout the FY along with the comprehensive annual DFR.

The Outcomes List remains a confidential list for use within the State survey agency to assist in determining annual survey priorities. The Outcomes list may be accessed through a secure website at: https://www.dialysisdata.org by the Master Account Holder for each state and other designated users.

Discussion
The ESRD Core Data Worksheet has been updated to align with the data contained in the FY 2019 DFR. Surveyors should use the most recent FY worksheet to ensure appropriate evaluation of current data elements included in the ESRD Core Survey Process. The current FY 2019 ESRD Core Survey Data worksheet may be found on the CMS ESRD Quality, Safety and Oversight page on www.cms.gov.

The quarterly DFR reports will be utilized by State Agencies as a surveyor resource when conducting a survey of an ESRD facility. These reports will provide more recent data on select measures including infection, fluid management, anemia, adequacy, nutrition and mineral metabolism. The comprehensive DFR will continue to be updated annually along with three quarterly updates throughout the FY. Surveyors should review the most recent DFR available to appropriately evaluate the current data elements contained in the ESRD Core Survey.

In order to reduce Tier 2 workload and increase the focus on ESRD facilities with poor clinical outcomes, the FY 2019 Tier 2 Outcomes List has been updated to identify the top 5% of ESRD facilities with poor clinical outcomes across four defined clinical measures using calendar year 2017 data. These measures were chosen based upon their potential to significantly impact patient outcomes and include:

- Mortality
- Hospitalizations
- Hospitalizations related to septicemia
- Catheter use greater than 90 days

The new methodology of the Outcomes list is expected to reduce the Tier 2 outcomes list by an estimated 350 surveys nationally in FY 2019. While this reduction varies by State, the vast majority of States will see reductions in their Tier 2 workload with a few states seeing only a slight increase in Tier 2 workload from previous years. States are expected to survey all identified facilities on the Outcomes list. The annual process for releasing and reviewing the Outcomes List will remain the same.

Contact: For questions, please contact ESRDQuestions@cms.hhs.gov

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

/s/
Karen Tritz
Acting Director

Attachment – FY 2019 ESRD Core Survey Data Worksheet

cc: Survey and Certification Regional Office Management

Facility: _____   **Date:**_____

CCN:_____   **Surveyor:**_____

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

Contents: There are 3 sections of this worksheet:
   I.   **Presurvey Preparation and Dialysis Facility Report (DFR) Review** (pages 1-2)**:** To review and evaluate the facility outcomes data from the FY 2019 DFR, as well as facility survey history review, and ESRD Network contact
   II. **Entrance Conference Materials List** (pages 3-4)**:** To be copied and given to the facility
   III. **Clinical Outcomes Thresholds Table** (page 5)**:** To compare the current facility clinical outcomes against current national benchmarks and determine the finalized **data-driven focus areas** for the survey

I.   PRESURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW:

Download and Review the FY 2019 DFR for the facility. The DFR and the partially pre-populated "FY 2019 Pre-survey DFR Extract" for each facility, as well as the Region and State Profiles may be accessed at http://www.DialysisData.org. Enter your Username and Password then click "Log in" to log onto the Secure DialysisData.org web site. The *DFR* tab (at the top of the page) is where you may obtain the current DFR for all facilities in your State or Region. The *Profiles* tab (at the top of the page) contains the partially pre-populated FY 2019 Pre-survey DFR Extract for each facility, as well as the Region and State profiles, which contain the Outcomes list.

Note how the facility is ranked on the State Profile/Outcomes List. Review the information about the facility on pages 1-3 of the DFR. To guide your review of the DFR data tables, you may use STAR or download the FY 2019 Pre-survey DFR Extract for the facility.

STAR Users: You do not need to download the pre-populated FY 2019 Pre-survey DFR Extract for the facility. STAR 4.1 and later versions display the key DFR data elements for each facility, automatically uploaded from ASPEN with the survey shell. Follow the guidance on STAR screen [3] in the Presurvey Preparation task.

Non STAR users: Review the FY 2019 Pre-survey DFR Extract in conjunction with the facility DFR. Review each pre-populated data element on the DFR Extract, which are key aspects of facility performance. Note trends in outcomes over the 4 year period. For standardized mortality (SMR) and transplant ratios (STR), the 4-year average is a more consistent measure of facility performance. For standardized hospitalization ratio (SHR) and standardized readmission ratio (SRR) the most recent 1-year statistic is most meaningful.

Record in the "Outcome and Trend Conclusions" column of the FY 2019 Pre-survey DFR Extract how the facility compares with U.S. Averages. Note declining or improving trends and flag which elements are worse than the U.S. Average. Consider those clinical areas for **preliminary data-driven focus areas** for the survey. Attach the completed FY 2019 Pre-survey DFR Extract document to this worksheet.

Preliminary data-driven focus areas based on DFR review:

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

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

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

_____
_____
_____
_____

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

Network person contacted_____**Position:**_____

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

_____
_____
_____

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

_____
_____
_____

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

_____
_____
_____

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

_____
_____
_____

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

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

II. **ENTRANCE CONFERENCE MATERIALS LIST/CLINICAL OUTCOMES TABLES**
Guidance to surveyors: Make a copy of the Entrance Conference Materials List (pages 3-4) to give to the facility person in charge during Introductions. Attach the completed copy to this worksheet.

Facility: _____ **Date:** _____

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

Needed within 3 hours:

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

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

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

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

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

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

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

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

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

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

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

12. ☐ Infection logs for past 6 months

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

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

Materials needed by the end of Day 1 of survey:

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

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

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

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

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

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

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

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

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

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

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

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

Materials needed by noon on Day 2 of survey

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

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

III. CLINICAL OUTCOMES THRESHOLDS TABLE

During the entrance conference, review and confirm the preliminary data-driven focus areas by reviewing more recent facility data. Once validated, determine declining or improving trends and flag data elements which continue to be worse than the US Threshold. *When "Yes" is checked in the "Above/Below Threshold" column, include those data elements as the final data-driven focus areas for review throughout the survey.*

Clinical Outcomes Thresholds Table for FY 2019

HD Indicators	US Threshold	Above Threshold?
Adequacy: Single pool Kt/V <1.2	**2.1%***	☐ Yes ☐ No
Standardized Kt/V <2.0 if ≥4x/week or nocturnal	**Not reported***	
Anemia: Hemoglobin <10 g/dL	**16.8%***	☐ Yes ☐ No
Mineral/bone: Calcium uncorrected >10.2 mg/dL	**1.3%***	☐ Yes ☐ No
Phosphorus >7.0 mg/dL	**12.6 %***	☐ Yes ☐ No
Nutrition: Albumin <4.0 g/dl BCG; lab normal BCP	**67.7****	☐ Yes ☐ No
Fluid management: Avg UFR >13 ml/kg/hr.	**9.4%***	☐ Yes ☐ No
Vascular access (VA): CVCs only >90 days/3 mo	**10.7%***	☐ Yes ☐ No
Transplant waitlist <age 70	**20.1%*** See Note	**Below Threshold?** ☐ Yes ☐ No
PD Indicators	US Threshold	Above Threshold?
Adequacy: Kt/V <1.7	**5.2%***	☐ Yes ☐ No
Anemia: Hemoglobin <10 g/dL	**26.2%***	☐ Yes ☐ No
Mineral/bone: Calcium uncorrected >10.2 mg/dL	**1.3%***	☐ Yes ☐ No
Phosphorus >7.0 mg/dL	**12.6%***	☐ Yes ☐ No
Nutrition: Albumin <4.0 g/dL BCG; lab normal BCP	**67.7%****	☐ Yes ☐ No
Transplant waitlist <age 70	**20.1%*** See Note	**Below Threshold?** ☐ Yes ☐ No

*FY2019 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
**Serum albumin values were obtained from DFR reporting of national CROWNWeb data and averaged among all eligible HD and PD patient –months.

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

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

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

Record the final data-driven focus areas for survey

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

Additional Notes As Needed