DATE: November 17, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Release of Fiscal Year (FY) 2018 End Stage Renal Disease (ESRD) Core Survey Data Worksheet

Memorandum Summary

- **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.

- **Worksheet Revision**: The instructions for the completion of Section II of the Worksheet, *Clinical Outcomes Thresholds Table*, are revised to no longer require that ESRD staff complete this portion of the Worksheet. Surveyors will complete this section of the Worksheet according to the data contained in the most recent Dialysis Facility Report (DRF) for the ESRD facility being surveyed, and will use these data to inform the survey process.

Background

Each fiscal year, the Centers for Medicare & Medicaid Services (CMS) forwards to the Regional Offices (ROs) and State Survey Agencies (SAs) a revised Core Survey Data Worksheet. These revised Worksheets include the most current national benchmarks, based on DFR data, for each of the data fields contained within the Clinical Outcomes and Thresholds Table. Historically, the ESRD facility was asked to provide a list of all patients that fell below the national benchmark for any given data field. This information assisted with the identification of focused areas for the survey and the selection of the patient sample.

Discussion

CMS has revised the ESRD survey protocol to eliminate the requirement that ESRD staff complete Section II of the Core Survey Data Worksheet, including the identification of patient names associated with poor clinical indicators for the purpose of patient sample selection.
Surveyors will continue to use the facility DFR during the pre-survey preparation to identify those clinical areas at the ESRD that are below the national benchmark. This information will inform the survey in the identification of data-driven focus areas during the random sample selection. In addition, surveyors will also continue to target the patient sample based on the various areas of care, e.g. dialysis modality, recent hospitalization, voluntary withdrawal, and recurrent infections.

No changes are currently being made to Sections I and III of the Core Survey Data Worksheet.

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

Effective Date: Immediately. This memo 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/
David R. Wright

Attachments: FY18 Core Data Worksheet

cc: Survey and Certification Regional Office Management
Fiscal Year 2018 (10/01/17-9/30/18)
ESRD CORE SURVEY DATA WORKSHEET

Facility: ______________________________ Date: ______________________________

CCN: ___________________________ Surveyor: ______________________________

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

Contents: There are 3 sections of this worksheet:

I. Pre-survey Preparation and Dialysis Facility Report (DFR) Review (pages 1-2): To review and evaluate the facility outcomes data from the FY 2018 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 data-driven focus areas for the survey

I. PRE-SURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW:

Download and Review the FY 2018 DFR for the facility. The DFR and the partially pre-populated “FY 2018 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 2018 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 2018 Pre-survey DFR Extract for the facility.

STAR Users: You do not need to download the pre-populated FY 2018 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 2018 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 2018 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 2018 Pre-survey DFR Extract document to this worksheet.
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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

Guidance to surveyors: Make a copy of the Entrance Conference Materials List (pages 3-5) 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) from this facility in 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
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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

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-12 months
   • 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 THRESHOLD TABLE

Prior to the Entrance Conference review the current Dialysis Facility Report. Compare the facility-level indicator from the current Dialysis Facility Report to the applicable entry in the “US Threshold” column from the table below to determine whether or not the facility’s performance “exceeded” the threshold indicator. When “Yes” is checked in the “Above/Below Threshold” column, consider including that clinical area as a data-driven focus for the survey.

**Clinical Outcomes Thresholds Table for FY 2018**

<table>
<thead>
<tr>
<th>HD Indicators</th>
<th>US Threshold</th>
<th>Above Threshold?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adequacy:</strong> Single pool Kt/V &lt;1.2 Standardized Kt/V &lt;2.0 if ≥4x/week or nocturnal</td>
<td>2.1%*</td>
<td>Yes No</td>
</tr>
<tr>
<td>Anemia: Hemoglobin &lt;10 g/dL</td>
<td>16.6%*</td>
<td>Yes No</td>
</tr>
<tr>
<td>Mineral/bone: Calcium uncorrected ≥10.2 mg/dL Phosphorus &gt;7.0 mg/dL</td>
<td>1.5%* Yes No 12.1%* Yes No</td>
<td></td>
</tr>
<tr>
<td>Nutrition: Albumin &lt;4.0 g/dL BCG; lab normal BCP</td>
<td>65.8%*</td>
<td>Yes No</td>
</tr>
<tr>
<td>Fluid management: Avg UFR &gt;13 ml/kg/hr.</td>
<td>10.1%*</td>
<td>Yes No</td>
</tr>
<tr>
<td>Vascular access (VA): CVCs only &gt;90 days/3 mo</td>
<td>10.3%*</td>
<td>Yes No</td>
</tr>
<tr>
<td><strong>Transplant waitlist &lt;age 70</strong></td>
<td>21.4%* See Note</td>
<td>Below Threshold? Yes No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PD Indicators</th>
<th>US Threshold</th>
<th>Above Threshold?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adequacy:</strong> Kt/V &lt;1.7</td>
<td>5.6%*</td>
<td>Yes No</td>
</tr>
<tr>
<td>Anemia: Hemoglobin &lt;10 g/dL</td>
<td>26.7%*</td>
<td>Yes No</td>
</tr>
<tr>
<td>Mineral/bone: Calcium uncorrected ≥10.2 mg/dL Phosphorus &gt;7.0 mg/dL</td>
<td>1.5%* Yes No 12.1%* Yes No</td>
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<td>21.4%* See Note</td>
<td>Below Threshold? Yes No</td>
</tr>
</tbody>
</table>

*FY2018 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 data-driven focus areas for this survey:**

1. 
2. 
3. 
4. 
5. 
6.
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Additional Notes As Needed

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