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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-03-ESRD

DATE: **November 20, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Release of Fiscal Year (FY) 2016 End Stage Renal Disease (ESRD) Core Survey
Data Worksheet

Memorandum Summary

ESRD Core Survey Data Worksheet: The worksheet has been updated for FY 2016 with current clinical indicators and corresponding national thresholds for facility comparison. The Centers for Medicare & Medicaid Services (CMS) is providing the revised worksheet to ensure consistent administration of a standardized ESRD survey process and is requiring surveyor's use of the ESRD Core Survey Data Worksheet for all recertification surveys of ESRD facilities.

Background

The ESRD Core Survey Data Worksheet is the primary surveyor tool for effectively focusing survey activities on clinical areas where an individual facility's data indicates improvements are needed. The Data Worksheet corresponds to the key data elements from the Dialysis Facility Report, and guides the surveyor in determining which clinical areas will be reviewed for a survey.

It is important for the survey process to remain current with the quickly evolving clinical aspects of dialysis care, including changes in data elements, emerging clinical indicators and national averages to use as thresholds for facility comparison. The ESRD Core Survey Data Worksheet is updated each fiscal year to assure the standardized survey process remains current.

Highlights of Changes for FY 2016

- Fluid management: hemodialysis clinical indicator has been changed to Average Ultrafiltration Rate (UFR) >13 ml/kg/hr (page 5 of Data Worksheet)
- Uncorrected Calcium: changed to uncorrected calcium from corrected calcium as clinical indicator (pages 5 and 6)
- Hospital Readmissions: added to materials needed to conduct survey (page 3)
- National Averages: all of the national averages for the clinical indicators have been updated to current data (page 7)

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All State Surveyors who conduct ESRD surveys, State Agency ESRD Supervisors, and Regional Office ESRD personnel should be aware of the changes to the Data Worksheet to assure consistent administration of a standardized ESRD survey process. To assure the administration of a standardized ESRD Core Survey process nationally, the FY 2016 ESRD Core Survey Data Worksheet should be used for all recertification surveys of ESRD facilities.

Contact: Please email any questions to the ESRD mailbox at 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/
Thomas E. Hamilton

Attachment- FY2016 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 2016 DFR, as well as facility survey history review, and ESRD Network contact
  II. **Entrance Conference Materials List with Clinical Outcomes Tables** (pages 3-6)**:** To be copied and given to the facility
  III. **Clinical Outcomes Thresholds Table** (page 7)**:** To compare the current facility clinical outcomes against current national benchmarks and determine the **data-driven focus areas** for the survey

I.   PRESURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW:

Download and Review the FY 2016 DFR for the facility. The DFR and the partially pre-populated "FY 2016 Pre-survey DFR Extract" for each facility, as well as the Region and State Profiles may be accessed at 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 2016 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 1-4 of the DFR. To guide your review of the DFR data tables, you may use STAR or download the FY 2016 Pre-survey DFR Extract for the facility.

STAR Users: You do not need to download the pre-populated FY 2016 Pre-survey DFR Extract for the facility. STAR 3.7 and later versions display the key DFR data elements for each facility, automatically uploaded from ASPEN with the survey shell. Follow the guidance on STAR screen [3] in the Presurvey Preparation task.

Non STAR users: Review the FY 2016 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 2016 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 2016 Pre-survey DFR Extract document to this worksheet.

Preliminary data-driven focus areas based on DFR review:

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

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

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

_____
_____
_____
_____

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

Network person contacted_____**Position:**_____

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

_____
_____
_____

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

_____
_____
_____

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

_____
_____
_____

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

_____
_____
_____

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

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

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

Facility: _____   **Date:** _____

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

Needed within 3 hours:

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

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

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

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

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

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

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

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

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

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

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

12. ☐ Infection logs for past 6 months

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

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

Materials needed by the end of Day 1 of survey:

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

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

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

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

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

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

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

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

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

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

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

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

Materials needed by noon on Day 2 of survey

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

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

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

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

Indicator	MAT Goal Unless Other Specified	% of HD Pts with	List Current HD Patients as Stated
Adequacy (3 mo) Single pool Kt/V Standardized Kt/V	≥1.2 for 3 tx/week ≥2.0 weekly for ≥4 tx/week	Kt/V <1.2 _____% Kt/V <2.0 _____%	HD pts **not** meeting goal ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Anemia (3 mo) Hemoglobin – pts' last value of month	For Hgb. <10, focus on symptoms, diagnosis and treatment of anemia	Hgb <10 g/dL _____%	HD pts with Hgb <10 in ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Mineral/bone (3 mo) Calcium (uncorrected) Phosphorus (PO4)	<10.2mg/dL 3.5-5.5 mg/dL	Ca >10.2 _____% PO4 >7.0 _____%	HD pts w/Ca >10.2 &/or PO4 >7.0 in ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Nutrition Albumin (3 mo)	≥4 g/dL for BCG; Lab normal for BCP	Alb <4.0 _____%	HD pts w/ Alb <3.5 in ≥2 mos 1._____ 2._____ 3._____ 4._____ 5._____
Fluid management (3 mo) Avg ultrafiltration rate (UFR)	Avg UFR <13ml/kg/hr	Avg UFR >13 ml/kg/hr _____%	HD pts w/avg UFR>13 ml/kg/hr in ≥2 mo 1._____ 2._____ 3._____ 4._____ 5._____
Vascular access (VA) (12 mo) CVCs >90 days/3 mo VA infection rate/100 pt mo [# events ÷ total mo pts on HD in 12 mo] x 100	↓ CVC rate ↓ VA infection rate	CVCs >90 days _____% VA infection rate _____ per 100 pt mo	HD pts with CVC >90 days/3 mo 1._____ 2._____ 3._____ 4._____ 5._____
Transplant waitlist (12 mo) % of all pts age <70 on waitlist any time during last 12 mo	Interested pts are referred for transplant unless excluded by evaluation or listed exclusion criteria	Transplant waitlist rate % _____	Provide a copy of the transplant waitlist, transplant program(s) exclusion criteria, and procedure for candidacy evaluation and referral of patients.

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

Peritoneal Dialysis Clinical Outcomes Table

Indicator	MAT Goal Unless Other Specified	% of PD Pts with	List PD Pts as Stated
Adequacy (6 mo) Kt/V	≥1.7 weekly	Kt/V <1.7 _____%	PD pts **not** meeting goal in last 6 mo 1._____ 2._____ 3._____ 4._____ 5.
Anemia (3 mo) Hemoglobin – pts' last value of month	For Hgb. <10, focus on symptoms, diagnosis and treatment of anemia	Hgb <10 g/dL _____%	PD pts w/Hgb <10g/dL for ≥2 mo 1._____ 2._____ 3._____ 4._____ 5.
Mineral/bone (3 mo) Calcium (uncorrected) Phosphorus (PO4)	<10.2 mg/dL 3.5-5.5 mg/dL	Ca >10.2 _____% PO4 >7.0 _____%	Pts w/ Ca >10.2 &/or PO4 >7.0 for ≥2 mo 1._____ 2._____ 3._____ 4._____ 5.
Nutrition (3 mo) Albumin	≥4g/dL BCG Lab normal for BCP	Alb <4.0 _____%	PD pts w/Alb <3.5 in ≥2mos 1._____ 2._____ 3._____ 4._____ 5.
Peritonitis rate (12 mo) *May be expressed as:* • Episodes per pt. year at risk *[episodes ÷ (total PD pt mo ÷ 12 mo)]*; **OR** • Episodes per 100 pt mo *[episodes ÷ total PD pt mo] x 100*	Minimize peritonitis episodes	Peritonitis infection rate _____ Check how calculated: ☐ episodes per pt. year at risk OR ☐ episodes per 100 pt. mo	Current pts w/ peritonitis in past 6 mo 1._____ 2._____ 3._____ 4._____ 5._____
Transplant waitlist (12 mo) % of all pts age <70 on waitlist any time during last 12 mo	Interested patients are referred for transplant unless excluded by evaluation or listed exclusion criteria	Transplant waitlist rate % _____	Provide a copy of the transplant waitlist, transplant program(s) exclusion criteria, and procedure for candidacy evaluation and referral of patients

III. CLINICAL OUTCOMES THRESHOLDS TABLE
Prior to the Entrance Conference review the current patient outcomes data submitted. *Compare the current facility outcomes listed in the* **"% of (HD or PD) Pts with"** *columns of the HD and PD Clinical Outcomes Tables to the applicable entry in the* **"US Threshold"** *columns from the table below, where available. Check "Yes" if facility outcomes are ABOVE the US Threshold, except for transplant waitlist, check "Yes" if BELOW the US Threshold.*

Clinical Outcomes Thresholds Table for FY 2016

HD Indicators	US Threshold	Above Threshold?	PD Indicators	US Threshold	Above Threshold?
Adequacy: Single pool Kt/V <1.2 Standardized Kt/V <2.0 if ≥4x/week or nocturnal	**2.5%*** **Not reported***	☐ **Yes** ☐ **No**	**Adequacy:** Kt/V <1.7	**7.9%***	☐ **Yes** ☐ **No**
Anemia: Hemoglobin <10 g/dL	**14.1%***	☐ **Yes** ☐ **No**	**Anemia:** Hemoglobin <10 g/dL	**25.7%***	☐ **Yes** ☐ **No**
Mineral/bone: Calcium uncorrected >10.2 mg/dL Phosphorus >7.0 mg/dL	**4.2%*** **11.0%***	☐ **Yes** ☐ **No** ☐ **Yes** ☐ **No**	**Mineral/bone:** Calcium uncorrected >10.2 mg/dL Phosphorus >7.0 mg/dL	**4.2%*** **11.0%***	☐ **Yes** ☐ **No** ☐ **Yes** ☐ **No**
Nutrition: Albumin <4.0 g/dL BCG; lab normal BCP	**Albumin 62%****	☐ **Yes** ☐ **No**	**Nutrition:** Albumin <4.0 g/dL BCG; lab normal BCP	**Albumin 62%****	☐ **Yes** ☐ **No**
Fluid management: Avg UFR >13 ml/kg/hr.	**8.9%***	☐ **Yes** ☐ **No**	N/A	N/A	N/A
Vascular access (VA): CVCs >90 days/3 mo HD VA infection rate /100 pt mo	**10.2%*** **1.68***	☐ **Yes** ☐ **No** ☐ **Yes** ☐ **No**	**Peritonitis rate** Peritonitis episodes per patient year at risk **OR** Peritonitis episodes per 100 patient mo	**.36*** **3.00***	☐ **Yes** ☐ **No**
HD Indicators	**US Threshold**	**Below Threshold?**	**PD Indicators**	**US Threshold**	**Below Threshold?**
Transplant waitlist <age 70	**24.1%*** See Note	☐ **Yes** ☐ **No**	**Transplant waitlist** <age 70	**24.1%*** See Note	☐ **Yes** ☐ **No**

*FY2016 DFR National Average **NOTE:** average of monthly facility lab results will likely show more variation and a higher percentage of patients above the threshold for any given month
**DOPPS Practice Monitor, April 2015: patient-level 3 month average through December 2014
***Piraino B et al., ISPD Position Statement on Reducing the Risks of Peritoneal Dialysis-Related Infections, 2011

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. _____

Additional Notes As Needed