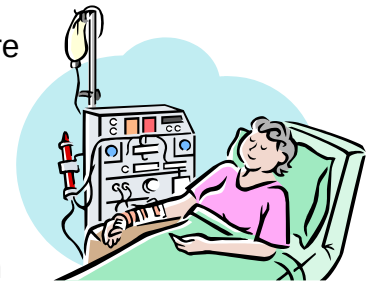
End Stage Renal Disease (ESRD) Survey Process



Survey protocols and Interpretive Guidelines were established by the Centers for Medicare and Medicaid Services (CMS) to provide guidance to personnel conducting surveys. They serve to clarify, and/or explain, the intent of the federal regulations. All surveyors are required to use this protocol in assessing compliance with requirements. The ESRD facility survey protocols, and federal regulation set, are contained within 42 Code of Federal Regulations (CFR) Part 494, Appendix H, of the CMS State Operations Manual (SOM).

The regulatory requirements are made up of sixteen Conditions for Coverage (CfC) and each of these Conditions is made up of specific standards. The ESRD facility must be in compliance with all CfC requirements, at all times. Below is a brief description of the ESRD facility survey. Please refer to Appendix H for detailed information regarding the ESRD facility survey process.

In accordance with the **ESRD Core Survey process**, surveyors will request required documents and outcome data when the survey is initiated and during the entrance conference. The last pages of this document include the information which will be requested. For complete information on the Core Survey process, please visit the CMS website: **https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html**. Scroll to the Downloads heading and click on the ESRD Core Survey Field Manual Version 1.6.

Initial Surveys

Providers seeking initial Medicare certification as an ESRD facility must have their application materials approved, by the State Agency and CMS, prior to an initial survey. Once the State Agency receives notification from the Medicare Fiscal Intermediary that the application has been approved, we will contact you to discuss when an initial survey may be done. However, due to limited staffing resources and funding, as well as the requirement to accomplish higher priority work to meet our contractual agreement with CMS, this office is unable to complete initial certification

surveys, now or in the foreseeable future. Please refer to CMS letter, S&C 08-03 *Initial Surveys*, November 5, 2007, for additional information.

Recertification Surveys

CMS directs the frequency and priority status of ESRD recertification surveys. CMS established priorities and frequencies for the current FFY are as follows:

- Priority One: There currently are no Priority One designations for ESRD facilities.
- Priority Two: 10% targeted sample - the State surveys 10% of the providers in the state selected from a list provided by CMS. Surveys based on an ESRD relocating are also Priority Two work.
- Priority Three: 3.5 year interval - additional surveys are done (beyond Priority Two surveys) to ensure that no more than 3.5 years elapse between surveys for any one particular ESRD facility.
- Priority Four: 3.0 year average - additional surveys are done (beyond Priority Two and Priority Three surveys) such that all providers in the state are surveyed on average, every 3.0 years.

Follow-up Surveys

The purpose of the follow-up survey is to determine that systemic corrective action has been implemented for the deficiencies cited during the previous survey. A follow-up survey may be conducted at the facility or by phone/mail. An unannounced on-site revisit is mandated when deficiencies are cited at the CfC level; but may be optional when cited at the standard level.

Complaint Surveys

Anyone may file allegations of provider non-compliance with regulatory requirements. The State Agency is required to investigate all such allegations. When a complaint which alleges regulatory non-compliance is received, an unannounced complaint survey is conducted which focuses on the allegations of the complaint. Please refer to SOM Chapter 5 for more specific information regarding the complaint survey process.

ESRD Core Survey
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? _____

_____

II. ENTRANCE CONFERENCE MATERIALS LIST /CLINICAL OUTCOMES TABLES

Guidance to surveyors: *Make a copy of pages 3-6 to give to the facility person in charge during "Introductions." You will be reviewing the patient-specific outcomes, and facility information submitted during "Entrance Conference." Attach the completed facility-submitted copy to this worksheet.*

Facility: _____ **Date:** _____

Documents/items needed for the survey: Please return this form to the survey team leader after completion of facility current iuformation 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 listing by days & shifts with any isolation patients identified (seating chart or assignment sheet)
4. ☐ Patients admitted to this facility within the past 90 days and currently on census (do not include visiting patients)
5. ☐ Patients who have been designated as "unstable" for any month in the past 3 months
6. ☐ All patients involuntarily discharged (not transferred to another outpatient dialysis facility) from the facility in the past 12 months
7. ☐ All patients transferred or discharged from the facility as "lost to follow up" (i.e., no outpatient dialysis facility identified as patient's destination) for the past 12 months
8. ☐ Residents of long term care facilities receiving dialysis at the LTC facility and the name of the LTC where they are receiving dialysis
9. ☐ Hospitalization logs with admitting diagnoses listed for 6 months
10. ☐ Infection logs for past 6 months
11. ☐ Patient individual laboratory results for hemoglobin, Kt/V, URR, corrected calcium, phosphorus and albumin for the current 3 months; separated by modality

Materials needed by the end of Day 1 of survey:

12. ☐ Vaccination information:
    - # of patients administered complete series of hepatitis B vaccine _____
    - # of patients administered influenza vaccine between September 1 and March 31 _____
    - # of patients administered pneumococcal vaccine _____

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

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

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

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

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

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

19. ☐ 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

20. ☐ For Equipment Maintenance Review: 12 months documentation of preventative maintenance and repair of hemodialysis machines

21. ☐ 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 QA audits-12 months

Materials needed by noon on Day 2 of survey

22. ☐ Completed "Personnel File Review" Worksheet

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

For Fiscal Year 2014 (10/01/13-9/30/14)
ESRD CORE SURVEY DATA TOOLS

Signature of person completing this form_____**Date:**_____
Needed within 3 hours: Please fill in the table below with yonr facility data based on yonr most current QAPI information. Provide the average for the number of months listed next to each measure. List additional patients' names on a separate sheet of paper, if needed.

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

Measure	MAT Goal Unless Other Specified	% Met Goal or Other Specified	Current Patients Who Did Not Meet Goal (or as listed) in ≥2 of Last 3 Mo
Adequacy (3 months) Single pool Kt/V Standardized Kt/V URR	 ≥1.2 for 3tx/week ≥2.0 weekly for ≥4 tx/week ≥65%	 _____ _____ _____	1._____ 2._____ 3._____ 4._____ 5._____ 6._____
Anemia (3 months) Hemoglobin-patients' last value of month	Refer to MAT	<10 g/dL _____	HD Patients with Hgb <10 in ≥2 months 1._____ 2._____ 3._____ 4._____ 5._____
Mineral & bone(3 mo) Calcium corrected for albumin Phosphorus	Normal for lab; preferred <10.2mg/dL 3.5-5.5 mg/dL	_____ _____	Patients w/ either goal not met in ≥2 mos 1._____ 2._____ 3._____ 4._____ 5._____
Nutrition Albumin (3 mo)	≥4 g/dL for BCG; lab normal for BCP	_____	Patients w/ Alb.<3.5 in ≥2 mos.(if none, list patients w/Alb. 3.6-3.9 in ≥2mos) 1._____ 2._____ 3._____ 4._____ 5._____
Fluid management (3 mo) Intradialytic (average) weight loss in treatment length ≤4 hours	Average intradialytic weight loss <5% target weight	_____	1._____ 2._____ 3._____ 4._____ 5._____
Vascular access(VA) (12 mo) CVCs in use VA infection rate/100 patient months	 ↓ CVC rates ↓ VA infection rate	CVC in use % _____ _____	Patients with CVC only ≥90 days 1._____ 2._____ 3._____ 4._____ 5._____
Hospital readmissions within 30 days of discharge (12 mo)	Minimize hospital readmissions	Readmissiou rate _____	HD patients readmitted to hospital within 30 days of discharge in past 3 months 1._____ 2._____ 3._____ 4._____
Transplant waitlist for patients <70 years old (12 mo)	Interested patients are referred for transplant nnless excluded by area transplant criteria	Transplant waitlist rate _____	Patients <70 not active on a Transplant list 1._____ 2._____ 3._____ 4._____ 5._____

For Fiscal Year 2014 (10/01/13-9/30/14)
ESRD CORE SURVEY DATA TOOLS

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

Peritoneal Dialysis Clinical Outcomes Table

Measure	MAT Goal Unless Other Specified	% Met Goal or Other Specified	Names of Current Patients Who Did Not Meet Goal as listed
Adequacy (6 mo) Kt/V	≥1.7 weekly	_____	Not met in last 6 months 1._____ 2._____ 3._____ 4._____
Anemia (3 mo) Hemoglobin – patients' last value of month	Refer to MAT	<10 g/dL _____	Patients w/Hgb <10g/dL for ≥2 months 1._____ 2._____ 3._____ 4._____
Mineral/bone (3 mo) Calcium corrected for albumin Phosphorus	WNL for lab; <10.2 mg/dL 3.5-5.5 mg/dL	_____ _____	Patients with either goal not met for ≥2mos 1._____ 2._____ 3._____ 4._____
Nutrition (3 mo) Albumin	≥4g/dL BCG; lab normal for BCP	_____	Patients w/ Alb.<3.5 in ≥2mos. (if none, list patients w/Alb. 3.6-3.9 in ≥2mos.) 1._____ 2._____ 3._____ 4._____
PD infections Peritonitis rate/100 patient months (12 mo)	Minimize peritonitis episodes	Peritonitis infection rate _____	Current Patients with peritonitis in past 6 months 1._____ 2._____ 3._____ 4._____
Hospital readmissions within 30 days of discharge (12 mo)	Minimize hospital readmissions	Readmission rate _____	Current PD patients readmitted to hospital within 30 days of discharge in past 3 months 1._____ 2._____ 3._____ 4._____
Transplant waitlist For patients <70 years old (12 mo)	Interested patients referred for transplant unless excluded by area transplant exclusion criteria	Transplant waitlist rate _____	Patients <70 not active on a Transplant list 1._____ 2._____ 3._____ 4._____ 5._____ 6._____

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

PART 1 – APPLICATION – TO BE COMPLETED BY FACILITY

1. Type of Application/Notification (check all that apply; if "Other," specify in "Remarks" section [Item 33]): (V1)
☐ 1. Initial ☐ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services ☐ 5. Change of ownership
☐ 6. Other, specify:

2. Name of Facility		3. CCN
4. Street Address		5. NPI
6. City	7. County	8. Fiscal Year End Date
9. State	10. Zip Code:	11. Administrator's Email Address
12. Telephone No.	13. Facsimile No.	14. Medicare Enrollment (CMS 855A) completed? ☐ Yes ☐ No ☐ NA

15. Facility Administrator Name:
Address:
City: State: Zip Code: Telephone No:

16. Ownership (V2) ☐ 1. For Profit ☐ 2. Not for Profit ☐ 3. Public

17. Is this facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? (V3) ☐ 1. Yes ☐ 2. No
Is this facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? (V4) ☐ 1. Yes ☐ 2. No
Is this facility not owned or managed by a hospital (i.e., independent)? (V5) ☐ 1. Yes ☐ 2. No
If owned and managed by a hospital: hospital name: (V6) CCN: (V7)

18. Is this facility located in a SNF/NF (check one): (V8) ☐ 1. Yes ☐ 2. No
If Yes, SNF/NF name: (V9) CCN: (V10)

19. Is this facility owned &/or managed by a multi-facility organization? (V11) ☐ 1. No ☐ 2. Yes, Owned ☐ 3. Yes, Managed
If Yes, name of multi-facility organization: (V12)
Multi-facility organization's address:

20. Current Services (check all that apply): (V13)
☐ 1. In-center Hemodialysis (HD) ☐ 2. In-center Peritoneal Dialysis (PD) ☐ 3. In-center Nocturnal HD ☐ 4. Reuse
☐ 5. Home HD Training & Support ☐ 6. Home PD Training & Support ☐ 7. Home Training & Support **only**

21. New services being requested (check all that apply): (V14)
☐ 1. N/A ☐ 2. In-center HD ☐ 3. In-center PD ☐ 4. In-center Nocturnal HD ☐ 5. Reuse
☐ 6. Home HD Training & Support ☐ 7. Home PD Training & Support ☐ 8. Home Training & Support **only**

22. Does the facility have any home dialysis (PD/HD) patients receiving dialysis in long-term care (LTC) facilities?
(V15) ☐ 1. Yes ☐ 2. No
LTC (SNF/NF) facility name: (V16) CCN: (V17)
Staffing for home dialysis in LTC provided by: (V18) ☐ 1. This dialysis facility ☐ 2. LTC staff ☐ 3. Other, specify
Type of home dialysis provided in this LTC facility: (V19) ☐ 1. HD ☐ 2. PD
For additional LTC facilities, record this information and attach to the "Remarks" (item 33) section.

23. Number of dialysis patients currently on census:
In-Center HD: (V20) ____ In-Center Nocturnal HD: (V21) ____ In-Center PD: (V22) ____
Home PD: (V23) ____ Home HD <= 3x/week: (V24) ____ Home HD >3x/week: (V25) ____

24. Number of approved in-center dialysis stations: (V26) ____ Onsite home training room(s) provided? (V27) ☐ 1. Yes ☐ 2. N/A

25. Additional stations being requested: (V28) ☐ None In-center HD: (V29) ____ In-center nocturnal HD: (V30) ____
In-center PD: (V31) ____

26. How is isolation provided? (V32)
☐ 1. Room ☐ 2. Area (established facilities only) ☐ 3. CMS Waiver/Agreement (Attach copy)

27. If applicable, number of hemodialysis stations designated for isolation: (V33)

28. Days & time for in-center patient shifts (check all days that apply and complete time field in military time): (V34)

1st shift starts:	M	T	W	Th	F	Sat	Sun
Last shift ends:	M	T	W	Th	F	Sat	Sun

29. Dialyzer reprocessing system: (V35) ☐ 1. Onsite ☐ 2. Centralized/Offsite ☐ 3. N/A

30. Staff (List full-time equivalents): Registered Nurse: (V36) Certified Patient Care Technician: (V37)
LPN/LVN: (V38) Technical Staff (water, machine): (V39)
Registered Dietitian: (V40) Masters Social Worker: (V41)
Others: (V42)

31. State license number (if applicable): (V43)

32. Certificate of Need required? (V44) ☐ 1. Yes ☐ 2. No ☐ 3. NA

33. Remarks (copy if more and attach additional pages if needed):

34. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my knowledge. I understand that incorrect or erroneous statements may cause the request for approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 494.1 and 488.604 respectively.

I have reviewed this form and it is accurate:

Signature of Administrator/Medical Director	Title	Date

PART II TO BE COMPLETED BY STATE AGENCY

35. Medicare Enrollment (CMS 855A approved by the MAC/FI)? (V45) ☐ 1. Yes ☐ 2. No

(Note: approved CMS 855A required prior to certification)

36. Type of Survey: (V46) ☐ 1. Initial ☐ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services
☐ 5. Change of ownership ☐ 6. Complaint ☐ 7. Revisit ☐ 8. Other, specify

37. State Region: (V47)

38. State County Code: (V48)

39. Network Number: (V49)

My signature below indicates that I have reviewed this form and it is complete.

40. Surveyor Team Leader (sign)	41. Name/Number (print)	42. Professional Discipline *(Print)*	43. Survey Exit Date:

ESRD SURVEY WORKSHEET: PERSONNEL FILE REVIEW

Facility Name: **Facility Staff Signature:** **Date:**

ID #	Name/Position *Full-Time (FT)* *Part-time (PT)* *Agency (A)*	Hire Date/ Orientation	License/ Cert Expiration Date	CPR Expiration Date	*TB Evaluation Date	Hepatitis Vaccine or Decline	Competencies Documented Date	Emergency Procedures, Infection Control Training	**Water, Dialysate, Machine, Reuse Training

***If required by State regulation** ****Must pass color blindness testing if using colormetric testing methods**