



**ESRD Update:
Transitioning to New ESRD Conditions for Coverage
Student Manual**

Lesson #12: Survey and Certification Issues

Learning Objectives

At the conclusion of this lesson, you will be able to:

- Discuss the legal authorities and guidance documents that govern ESRD S&C
- Describe components of ESRD surveys
- Discuss relationship with ESRD Networks
- Delineate survey tools
- Review waivers

Quality Assurance for the Medicare & Medicaid Programs

FY2009 Mission & Priority Document (MPD)

Survey and Certification

End Stage Renal Disease (ESRD) Facilities

Overall Responsibilities: States are responsible for conducting initial, recertification, complaint and associated revisits of ESRD dialysis facilities (whether independent or hospital-based). We continue to maintain a goal of surveying ESRD facilities once every three years on average, but distribute ESRD surveys over multiple Tiers:

- (a) Tier 2: Survey 10% of ESRD facilities (the CMS-generated Outcomes List targets 20% of State facilities, with States selecting half of the facilities from the CMS list to yield the final 10%);
- (b) Tier 3: The Tier 3 priority is an interval measure identifying a maximum period of time between surveys for any one particular facility (see Appendix 1);
- (c) Tier 4: Conduct additional surveys sufficient to achieve a once-every 3.0-year average as a Tier 4 priority.

Tier 2 Targeted Sample: The FY2009 Tier 2 targeted sampling requirement for ESRD is 10% of the facilities (the same as for FY2008). Each State selects its Tier 2 facilities from a rank-ordered Outcomes List that CMS distributes to each State at the beginning of the FY. The Outcomes Lists identify those facilities that are in the lowest 20th percentile ranking for each State. For targeted ESRD surveys in Tier 2, each State will then select half of the CMS-designated facilities to arrive at the final list equal to 10% or more of all ESRD facilities in the State. The Outcomes List is a confidential list for use only within the specific State survey agency. This list is distributed directly to the ESRD contact persons within each State. Targeted sample requirements do not apply to States with fewer than 7 ESRD facilities.

High Safety Risk: ESRD surveys are conducted to protect the health and safety of ESRD beneficiaries because of the extraordinary health and safety risks associated with dialysis treatments. The treatments provided in ESRD facilities involve high safety risks because: (1) the complex and varied nature of the dialysis and reuse equipment requires operation by knowledgeable staff; (2) the need for water to be treated onsite because it can only contain a minimal level of bacteria, endotoxins, or chemicals (since during treatment, the water is separated from the patient's blood only by a thin, porous membrane); and (3) the extracorporeal circulation of blood that occurs in the ESRD facility has a higher risk for transmission of infections than in the hospital setting. Many of the potentially life-threatening procedures associated with dialysis treatments have

resulted in individual or multiple patient deaths.

State Specialization for a Complex, Technical Survey: States must be prepared to survey ESRD facilities for such technically and clinically complex areas as water treatment safety, dialyzer reuse safety, specialized infection control and prevention precautions, equipment operation and maintenance, and staffing qualifications and abilities. While the average lifespan of the ESRD beneficiary is 6 years, the ESRD data show that taking into account the difference among patients, the practice patterns of facilities can affect that lifespan by 20% on average – almost a one-year gain in life expectancy directly attributable to better quality of care. The emphasis of the ESRD survey process focuses on those practice patterns that are known to affect mortality and to provide potential safety risks to patients. When a State invests in specialization of their surveyors responsible for ESRD surveys, it allows the State to build higher levels of expertise in this complex survey process and focus training on that smaller group.

Data Reports: CMS has implemented a system of providing facility-specific and State-specific ESRD Data Reports for use by States as a guide for ESRD surveys. Each State must:

- (a) Use the data profiles to (1) select facilities for survey; and (2) as part of the pre-survey activity for every ESRD survey.
- (b) Use these data reports to better understand and monitor the performance of renal facilities.
- (c) Coordinate activities with ESRD networks and provide results of surveys to the appropriate network.

Beginning in February 2009, the ESRD Program will initiate a new web-based ESRD data system titled CROWNWeb. During 2009, data from the CROWNWeb system will be integrated into the facility-specific and State-specific Data Reports by CMS. These data will be used to address specific areas of the new regulations, including Quality Assessment and Performance Improvement, Patient Assessment, and Plan of Care.

Fistula First: Each State should have an identified person who can report on the State's activities regarding the Department's Breakthrough Initiative on Vascular Access Improvement (i.e., "Fistula First"). This State representative should remain current regarding the goals and materials available as part of this Breakthrough Initiative. One of the sources of information is the Web site, www.fistulafirst.org. The representative should also ensure that State data regarding fistula rates are reviewed, and focused surveying occurs in facilities that have low fistula rates. CMS will provide additional information to SAs with regard to specific roles they can play. We do not expect this to represent a substantial workload, nor require a full-time position. The basic requirement is for a point person who can maintain key communications, become knowledgeable about fistulas and the national initiative, train others in-house, and design internal procedures that will advance fistula implementation.

Minimum Requirements for ESRD surveyors: The basic requirements for new ESRD

surveyors were specifically communicated in policy letter S&C-03-05, which clarified the intent of Section 4009C of the SOM. CMS expects States to continue to fulfill these requirements for FY2009. Specifically, before any State or Federal surveyor may serve on a survey team (except as a trainee) for an ESRD survey, he/she must attend one of the ESRD technical courses, i.e., the ESRD Basic Technical Course, or the ESRD Advanced Technical Course. Surveyors may choose the courses that best fulfill their needs.

Because of the complicated, technical nature of the ESRD survey process and because of changes in technology, CMS expects that specialized ESRD surveyors who do ESRD surveys will keep their skills updated and learn about new ESRD equipment and technologies by attending the ESRD Annual Update Course or an ESRD Technical Course at least every other year.

New ESRD Conditions for Coverage & New Survey Protocol: Effective October 14, 2008, new ESRD regulations will be used to certify and survey ESRD facilities. Two identical courses, taught in September, 2008, will summarize the new regulations, identify major changes from the current regulations, and describe a new survey protocol for ESRD facilities. All surveyors who are ESRD specialists are expected to attend one of these courses. There are a number of notable changes in the new ESRD regulations, including:

- **New - ESRD Life Safety Code Surveys:** Effective February 9, 2009, ESRD facilities must comply with applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association. Beginning on October 14, 2008, applicable ESRD facilities must be in sprinkled buildings according to the requirements of the LSC cited above. Surveys for the LSC requirements may occur any time after October 14, 2008 at State discretion. However, the State may elect to phase in the LSC component according to the following schedule, provided that complaint investigations occur when the complaint is made:
 1. **New Providers:** LSC surveys should occur at the time of their initial certification if the survey is done on or after February 9, 2009;
 2. **Existing Providers:** LSC surveys must be accomplished as part of ESRD recertifications beginning on a date after February 9, 2009 that is specified by CMS. We expect this date will coincide with the date of an ASPEN release that accommodates the new LSC requirement. We will issue more specific instructions before December 31, 2008 regarding the phase-in of LSC surveys for existing ESRD suppliers
- **Mostly New - QAPI System:** The previous requirement for a “quality assessment and performance improvement” system has been substantially strengthened and modernized to reflect the current state of program improvement science. The regulation obliges facilities to have an ongoing, data-driven system to measure and track quality indicators so as to achieve measurement improvement in outcomes and

error reduction. The facility must immediately correct any identified problems that threaten the health and safety of patients, and use the QAPI system to take actions that reduce future incidents. This is an important Condition for Coverage in its own right, as well as functioning as an “independent but associated” finding that is identified in concert with deficiencies in a variety of other Conditions.

STAR software, PC Tablet Technology, and Training: STAR is an automated software program for the ESRD survey process, which is utilized on PC Tablets. We expect ESRD surveyors will benefit from attending the STAR training course, which includes an introduction to PC Tablet technology. STAR training focuses on ESRD-trained surveyors who are the ESRD specialists in their respective States.


Initial ESRD Surveys: We encourage initial surveys of ESRD facilities to occur as early as possible on the survey schedule because of a combination of unique characteristics of ESRD facilities:

1. Approximately 95% of the beneficiaries in ESRD facilities are supported by Medicare insurance.
2. The statute prevents ESRD facilities from being deemed for certification by any accrediting organization.
3. ESRD beneficiaries represent one of the fastest growing Medicare sub-populations.
4. Capital construction costs for ESRD facilities are significant, and the staff required to operate a dialysis treatment facility is specialized.

For these reasons initial ESRD surveys are prioritized at a higher level than most other initial surveys (see row 15 of Appendix 1).


ESRD FACILITIES			
Tier 1	Tier 2	Tier 3	Tier 4
	<p>10% Targeted Sample: States survey a 10% targeted sample of ESRD facilities, selected from a CMS list that identifies those facilities most at risk of providing poor care. Targeted surveys may count toward the requirements in Tiers 3 and 4. Not applicable for states with fewer than 7 ESRD facilities.</p>	<ul style="list-style-type: none"> ▪ 4.0-Year Interval: Additional surveys are done to ensure that no more than 4.0 years elapses between surveys for any <u>one</u> particular ESRD facility. ▪ State Option: States may elect to substitute an interval between 3 and 4 years. ▪ Support “Fistula First” 	<p>3.0-Year Avg: Additional surveys are done (beyond Tiers 2-3) sufficient to ensure that ESRD facilities are surveyed with an <u>average frequency</u> of 3.0 years or less.</p>

Resources




Survey & Certification Issues

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Objectives

- Discuss the legal authorities and guidance documents that govern ESRD S&C
- Describe components of ESRD surveys
- Discuss relationship with ESRD Networks
- Delineate survey tools
- Review waivers



The ESRD Benefit

- PL 92-603: ESRD Benefit
 - Outpatient dialysis (hospital-based, independent)
 - Home training and support
 - Transplant (separate S&C program)
- Not included in ESRD Benefit
 - Acute/inpatient dialysis (hospital benefit)
 - CKD stages 1-4

ESRD S&C Program

- Initial certification survey
 - ESRD initials have priority
- Survey for change in service
- Recertification survey (focused & random)
- Complaint survey

MPD: Mission & Priority Document

- Published annually
- Guidance for workload for State Agencies
 - Establishes priorities for surveys (tier structure)
 - Failure to meet the priorities outlined may = nonperformance deductions for State Agencies
- Copy of ESRD portion in Student Manual

Initial Approvals

- All requirements must be completed before the RO can recommend certification
 - 855 approval
 - Successful completion of survey
- BE SURE you have an approved 855 before you do the initial survey!

Changes

- Change in # stations: on-site survey not required by CMS; may be required by state; use CMS 3427 to notify CMS
- Change in services:
 - Must file a CMS 3427 for addition of home dialysis (hemodialysis or PD), addition of reuse, or support for dialysis in LTC
 - May require an onsite survey
- Change in location:
 - Must file a CMS 3427
 - Requires an onsite survey

Survey & Certification Issues

Questions?

STAR Survey Software

- Guides the ESRD Survey Process
- CMS expects all states to be moving towards using STAR for all ESRD surveys
- STAR program is being updated to new regs

Clicker Question!!!

o Question: Have you attended a STAR training workshop?

- A. Yes
- B. No
- C. I don't work for a state

Clicker Question!!!

o Question: Have you used STAR for an ESRD survey?

- A. Not yet (but I have attended training..)
- B. Once
- C. More than 5 times
- D. Haven't attended training
- E. I don't work for a state

ESRD Survey Types

Basic Survey

- o Use the outline of the ESRD Survey Process
 - May expand portions if needed to gather more information in specific areas when required by findings

Use Decision Making to Determine if Additional Activities Are Needed

When Condition level deficiencies are suspected:

- Review P&P in areas of concern;
- Interview additional involved staff;
- Review Governing Body minutes / other administrative documents; or
- Expand the patient sample for specific areas of concern.

Focused ESRD Surveys

- Initials
- Complaints
- Relocations
- Change in services

Nursing Home Dialysis

- Current guidance based on previous ESRD CfC
- Will be developing new S&C letter
- Plan to develop additional regulation for Nursing Home Dialysis

Temporary Closure

Why:

- Remodeling: more likely to be planned
- Repair: might be immediate, e.g., post hurricane
- Regrouping: in response to safety issues

Temporary Closure

- Facility must provide notice to State Agency to include:
 - Reason
 - Expected time to be closed (greater than 6 months should be rare)
 - Provision for patient treatment during the closure; patients must be transferred
 - Communication of any change to the timeline
 - Notice of intended reopening date
- State should periodically determine progress
- State should use CMS 3427 "Remarks" to communicate with CMS

Relationship with Networks

- Partnerships
 - QAPI
 - Involuntary discharge
 - Emergency preparedness
- Shared goals
 - Use of data to improve patient outcomes
 - Resolution of complaints & grievances

ESRD Survey Tools

- Interpretive Guidance
- Measures Assessment Tool (MAT)
- Outline of Basic ESRD Survey Process
- STAR software
- Data reports

Data Reports

- Dialysis Facility Reports
 - Will conform to new regulations
 - Will expand to include CROWNWeb data
 - Moving to web-based reports
- Outcomes List
 - Confidential list for State use only
 - Dictates selection of facilities for focused review (Tier 2 workload)

ESRD Life Safety Code Surveys

- LSC: 2000 NFPA rules for ambulatory health facilities, except for the requirement for an essential electrical system (EES)
- May be conducted by State LSC experts or local fire marshals, dependent on state decision
- Beginning Feb 9, 2009, all initials will require a successful completion of a LSC survey prior to certification
- LSC surveys may be done separately from ESRD surveys

Waivers

- Isolation station for Hepatitis B+ (HBV+) patients
- Life Safety Codes (LSCs)
 - Use the State code in lieu of LSCs
 - Facility exceptions for specific requirement(s) that cause "unreasonable hardship"
- Qualifications of the medical director

Survey and Certification Issues

Questions??
