



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-37

DATE: July 8, 2004

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Addendum I to S&C Letter 04-24 on the Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services

Letter Summary

- S&C Letter 04-24, issued March 19, 2004, clarified certification requirements and coordination of care expectations for residents of LTC facilities who receive ESRD services.
- This addendum to that letter includes as an attachment follow-up Questions and Answers (Qs &As) regarding the scope of the guidance and the responsibilities of the providers.

On March 19, 2004, we issued S&C Letter 04-24. This letter was developed to provide clarification regarding the expectations and approval process for facilities that intend to offer care for residents in a LTC facility. The issuance of S&C Letter 04-24 stimulated questions about the scope of the guidance, responsibilities for service and care, and survey procedures related to this service. In this addendum, we provide answers to the questions that have emerged. The Qs and As follow as an attachment.

Effective Date: Immediately

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers, and the state/RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

Follow-up Questions and Answers to S&C Letter 04-24 on the Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services

Basis for Guidance:

- Q1. What is the basis for the guidance for ESRD facilities and LTC facilities detailed in S&C Letter #04-24?
- A1. The guidance specified in S&C Letter #04-24 reflects current requirements specified ESRD regulations at 42 CFR §405.2100 and LTC facility regulations at 42 CFR §483. ESRD facilities are required to meet the Conditions at §405.2130 through §405.2163 unless otherwise specified by the regulations. LTC facilities are required to meet the regulations at §483.

Relationship to Rules:

- Q2. What is the relationship between the policy memo guidance and current rules?
- A2. S&C Letter # 04-24 provides guidance to state and federal surveyors in applying existing regulations. There are no new regulations in the letter. S&C Letter #04-24 organizes existing regulations in a single document for added convenience. The letter then provides guidance to surveyors in the application of those regulations.

Locating Form CMS-3427A:

- Q3. Where do we locate Form CMS-3427A that is to be used for applicants seeking approval to provide ESRD services in a LTC facility?
- A3. Applicants should use Form CMS-3427 found on the CMS website at www.cms.hhs.gov/forms. Form 3427A is no longer in print.

Application to Hospital-based Nursing Homes:

- Q4. Do the ESRD and LTC survey protocols in this letter apply to hospital-based nursing homes that offer outpatient dialysis services to residents with ESRD?
- A4. Yes. The survey protocols apply to all nursing home facilities that offer home dialysis to residents whose dialysis services are paid under the Medicare ESRD Part B benefit. If the dialysis care is not covered under the Medicare ESRD program, then care may be reviewed in a different manner.

Agreement between Durable Medical Equipment (DME) Supplier and a Nursing Facility:

- Q5. For patients using Method II, is a written coordination agreement required to specify respective responsibilities between the DME supplier and the nursing facility?
- A5. No, an agreement is required between an ESRD facility and a LTC facility, and between the DME supplier and the ESRD facility. The DME supplier is responsible to and reports to the ESRD facility regarding the provision of supplies and equipment in the LTC facility. The DME supplier does not need to have a formal relationship with the LTC facility.

Types of Facilities Covered by Guidance:

- Q6. What facilities are covered by S&C Letter #04-24? Are intermediate care facilities for persons with mental retardation or related conditions (ICF/MR) facilities covered?
- A6. This guidance is directed to dialysis in nursing homes only. In the future, we will describe requirements and expectations regarding dialysis in other types of care facilities. In this guidance we used the terminology “long-term care facility” because the regulations at 42 CFR §483, Subpart B, Requirements for Long Term Care Facilities use this terminology in referring to nursing homes. In §483.5 a facility is defined as "a skilled nursing facility (SNF) that meets the requirements of sections 1819 (a), (b), (c), and (d) of the ACT, or a nursing facility (NF) that meets the requirements of sections 1919 (a), (b), (c), and (d) of the ACT...." but does not include an institution for persons with mental retardation or with related conditions described in §440.150 [Intermediate Care Facility (ICF/MR) services] of this chapter.

States Allowing Dialysis in LTC Facilities:

- Q7. Are states required to allow home dialysis in LTC facilities?
- A7. No, states may have requirements that prohibit the introduction of home dialysis into LTC facilities in their states. According to §405.2135, the ESRD facility must be in compliance with applicable Federal, State, and local laws, and regulations.

One Patient per Machine:

- Q8. What actions should be taken if more than one home dialysis patient is using a single machine in a LTC facility?
- A8. Reimbursement for home dialysis therapies is based upon one machine per patient. If more than one home dialysis patient is using a single machine, the respective CMS Regional Office should report this to the appropriate Fiscal Intermediary.

Monitoring of and by Licensed Health Professionals:

- Q9. What are the responsibilities for monitoring the capabilities of the licensed health professionals? What is the expectation of the ESRD-experienced licensed health care professional?
- A9. Facilities, including their governing bodies and physician directors, are responsible for ensuring that appropriate and adequate staff are hired, trained, and supervised. ESRD regulations at §405.2136 and §405.2161 define the staff monitoring relationships of the governing body and the physician-director. ESRD regulations require that whenever patients are undergoing dialysis, one currently licensed health professional (e.g. physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care. The preamble language for this section recognizes that “this regulation is a minimum requirement.” Therefore, CMS expects that at least one of the above-mentioned professionals is on duty during dialysis.

Licensed health professionals also have responsibilities that are defined by state licensure requirements, state practice acts, state pharmaceutical acts, and other state laws that impact on professional practice, such as education laws.

Responsibilities of the Physician Director of the ESRD facility:

Q10. Does the Physician Director of the ESRD facility have any responsibility for patients being dialyzed in the nursing home?

A10. The ESRD Physician Director is responsible for oversight of care including responsibility for patients dialyzed in center and for all home patients. These specific responsibilities are found at §405.2136(f)(2), §405.2161(b)(3), and §405.2161(b)(5).

Home Training Nurses Responsibilities:

Q11. Who is responsible for training the staff performing the dialysis treatments?

A11. The qualified home training nurse of the approved ESRD facility must be in charge of all home training both for home patients and for individuals who assist patients in home dialysis. The expectation of CMS is that the qualified home training nurse is directly responsible for all home training.

Nursing Home Social Worker and Dietitian:

Q12. Can the nursing home's staff social worker (MSW) and dietitian (RD) substitute for staff from the DME or the ESRD provider?

A12. No, the ESRD benefit includes support services from a "qualified" social worker (MSW) and a "qualified" dietitian (RD) provided by the ESRD facility.

Responsibilities for Medications:

Q13. Who is responsible for providing medications for the dialysis patient/resident?

A13. The ESRD and LTC facilities should delineate the responsibilities for the patients' medications in the written agreement. The LTC facility provides routine and emergency drugs for its residents. If dialysis drugs are maintained in the LTC facility pharmacy, applicable regulatory requirements for LTC apply. Erythropoietin (EPO) is provided to the patient by the ESRD facility. The safe and effective use of EPO by patients at home requires that the patient's dialysis facility or physician responsible for all dialysis-related services make a comprehensive assessment of the patient and the patient's needs at the time of selection for EPO therapy according to ESRD regulations at §405.2163(g).

Care in an Emergency:

Q14. In the event of an emergency, who is responsible for the patient while the patient is undergoing dialysis?

A14. The ESRD facility and LTC facility are expected to define responsibilities for emergencies in the written agreement. The ESRD facility is required to have specific policies and procedures for handling medical and nonmedical emergencies that threaten patient health or safety related to the patient's dialysis treatments. ESRD facilities are governed by regulations at §405.2136(f)(1)(v), 405.2136(g), and 405.2160(b) that require the facilities to have policies governing the care of patients in emergencies and to arrange for physician services and hospital services for emergency care.

Patient's Right to Select Treatment:

Q15. Do patients/residents continue to have the right to select a treatment method for dialysis?

A15. S&C Letter #04-24 reaffirms the patient's right to choose a modality and setting. These rights are regulated in both the care planning and patients' rights sections of the respective ESRD and LTC regulations.

Adequacy of Caregiver/Technician Training:

Q16. How will the adequacy of caregiver/technician training be assessed?

A16. Responsibility for oversight of caregiver/technician training for home dialysis in LTC settings rests primarily with the governing body and the physician director of the ESRD facility. The governing body of the ESRD facility [§405.2136(f)] must approve patient care policies concerning the provision of home dialysis support services. The physician director [§405.2161(b)(3)] is responsible for assuring adequate monitoring of the patient and the home dialysis process with periodic assessment of the performance of dialysis tasks.

ESRD Networks and Home Dialysis in LTC Facilities:

Q17. What responsibilities will ESRD Networks have for home dialysis in LTC facilities?

A17. Since these patients receive care through an ESRD facility that is under the purview of an ESRD Network whose role is defined by statute, these beneficiaries will be treated like other ESRD beneficiaries. ESRD Networks will undertake their statutory role with respect to quality improvement activities, data management, and grievance/appeals processing just as they do for other ESRD beneficiaries.

Role of LTC Surveyor regarding Appropriate Dialysis:

Q18. What are the expectations for LTC surveyors, many of whom do not have ESRD survey experience?

A18. The LTC surveyors are not expected to survey for appropriate dialysis treatments. ESRD surveyors will conduct the dialysis survey. The LTC surveyors are surveying the nursing home under current regulatory requirements as stated in the protocols. The LTC surveyors will observe care. If a LTC surveyor feels that there may be a potential problem, the surveyor will generate a complaint and referral to an ESRD surveyor.

Responsibilities of the LTC Medical Director:

Q19. Does the LTC medical director have to know anything about dialysis?

A19. Currently, residents with diagnoses of ESRD reside in LTC facilities. The LTC Medical Director is required to be in compliance with current regulations at 483.40 Physician Services and 483.75 (i) Medical Director. The regulatory requirement at 483.20(k)(2)(ii)- F280 states “A comprehensive care plan must be prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and *other appropriate staff* in disciplines as determined by the resident’s needs, and, to the extent practicable, the participation of the resident, the resident’s family or the resident’s legal representative.”

Since the resident has a diagnosis of ESRD and is receiving dialysis treatments, CMS expects that “other appropriate staff” includes the ESRD physician, ESRD nurse, ESRD social worker, and ESRD dietitian. It is expected that this coordination is outlined in the agreement between the ESRD facility and the nursing home.

Citation for LTC Medical Director:

Q20. Which LTC regulation is cited if there is a lack of compliance in areas of medical responsibility for the LTC Medical Director?

A20. The LTC survey team will cite F501 if the team has evidence that the facility is not in compliance with the regulatory requirement for the Medical Director. F501 Medical Director. (2) The medical director is responsible for –(i) Implementation of resident care policies; and (ii) the coordination of medical care in the facility.

Coordination of ESRD and LTC citations:

Q21. How do States with multiple survey agencies (separate agencies for LTC and ESRD) coordinate citations?

A21. Citations are not coordinated. Non-compliance with LTC requirements is cited at 42 CFR 483, Requirements for LTC Facilities. Non-compliance with ESRD Conditions of Coverage is cited at 42 CFR 405.2100. Since there are no alternative sanctions for ESRD regulations, LTC must be processed separately, using LTC guidelines and timelines.