

Center for Medicaid and State Operations/Survey and Certification Group

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TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services.

Letter Summary

- Regardless of the type of ESRD services provided, all Medicare-approved ESRD facilities must meet the Conditions for Coverage (CfCs) at 42 CFR §405.2130 through §405.2163 unless otherwise specified by the regulations.
- With respect to the provision of home dialysis training and support in LTC facilities, the Centers for Medicare & Medicaid Services (CMS) will approve only those ESRD applications that meet the specifications put forth in this memorandum and attachments. Applicants seeking approval must file the Form CMS-3427 or CMS-3427A as specified in this memorandum and may be subject to an on-site survey prior to approval.
- Attachments: Survey protocols for ESRD facilities and LTC facilities where residents qualify for and receive home dialysis. These protocols reflect currently existing requirements found in either the ESRD or LTC regulations.

This memorandum describes the steps CMS is taking to ensure that necessary safeguards are in place for residents of LTC facilities who receive dialysis. To that end, we are providing clarifications regarding the approval process for facilities that intend to provide dialysis to LTC residents.

We recognize that many residents of LTC facilities (skilled nursing facilities (SNFs), and nursing facilities (NFs)) who require dialysis would prefer the convenience of receiving dialysis in the LTC facility. And there has been a great deal of interest in the provision of home dialysis training and support in the LTC setting. While CMS regulations do not preclude this type of arrangement under certain circumstances, CMS has been holding all initial applications to provide home dialysis and training within LTC facilities pending assessment of their ability to provide home dialysis in a way that ensures the provision of adequate safeguards, clear lines of responsibility and accountability between the ESRD facility and the LTC facility, and quality care.

The purpose of this memorandum is to ensure that there are necessary safeguards and coordination of care for Medicare-approved facilities that provide home dialysis services for residents of LTC facilities. Specifically, this memorandum intends to: 1) clarify the applicable certification requirements and approval processes for Medicare-certified ESRD facilities; 2) specify the conditions under which home dialysis and training may be provided; and 3) augment CMS surveyor guidance to ensure that there is coordination of care, with defined lines of accountability and responsibility for quality safeguards for ESRD facilities providing home dialysis and training for LTC patients.

Certification Requirements

Part 42 of the Code of Federal Regulations (CFR), §405.2102, defines an ESRD facility as a Renal Transplantation Center, a Renal Dialysis Center, a Renal Dialysis Facility, a Self-Dialysis Unit, or a Special Purpose Facility. This section further defines an ESRD facility as “a facility which is approved to furnish at least one specific ESRD service.” These services are: transplantation service; dialysis service; and self-dialysis and home dialysis training. While an ESRD facility may opt to provide all, or only one of the above services, Medicare-certified ESRD facilities must meet all of the ESRD Conditions for Coverage (CfC) unless otherwise provided by the regulations. For example, all ESRD facilities must meet the CfCs at Sections 405.2130 through 405.2163. However, sections 405.2161, 405.2162, and 405.2163 apply only to Renal Dialysis Centers and Renal Dialysis Facilities. Similarly, section 404.2164 exempts special purpose facilities from certain CfCs, but also applies additional standards. Therefore, while an ESRD “facility” may opt to offer home dialysis training as its only service, it must comply with all applicable CfCs, which include all ESRD CfCs except those specifically applicable to renal transplant centers (405.2170 and 405.2171) and special purpose dialysis facilities (405.2164).

The State Operations Manual (SOM) at §2274 states that an ESRD facility must file an application with its State Survey Agency (SA) to establish eligibility for a change, expansion, or initial provision of an ESRD service. Therefore, prior to providing home dialysis training and support for LTC residents, a facility must seek Medicare approval. This memorandum is intended to provide guidance for facilities, states, and regions regarding determinations of approval for this service. Where this ESRD service already exists, states and regions will use this memorandum to determine compliance with the current regulations through the ongoing recertification process.

The SA will work with the relevant Regional Office (RO) to determine whether an on-site survey will be required before approval of an ESRD home dialysis training and support program. According to section 2278 of the State Operations Manual (SOM), a SA survey is required if the facility has not been surveyed in more than six months, or if substantial changes have been made. If a survey is not required, the RO includes the rationale for not surveying the ESRD facility.

If the SA determines a survey is needed to add the “training and support” services or if an initial certification survey is required, the SA visits the ESRD facility that is requesting approval for the service and the LTC facilities with which the ESRD facility has an agreement to provide “training and support” services.

Upon receipt of the survey report from the SA, the RO reviews all material and approves or disapproves the ESRD facility’s request for “Patient Dialysis Training.” The RO, in accordance with SOM 2278, forwards a copy of the notice to the SA and other required information to the fiscal intermediary.

ESRD facilities approved for training and support services for LTC residents are required to meet applicable regulations at 42 CFR 405.2130-405.2163. During a recertification visit, the SA surveys the facility using the guidance presented in this Memorandum. If the SA determines the ESRD facility’s “training and support program” for LTC residents does not meet applicable requirements, the SA issues a CMS-2567, Statement of Deficiencies. The ESRD facility may have an opportunity to submit an acceptable plan of correction and regain compliance with required regulations.

Home Dialysis and Self/Home Dialysis Training in LTC Facilities

Part 42 CFR §405.2102 defines home dialysis as dialysis performed by an appropriately trained patient at home. CMS has considered LTC facilities as the patient's home for purposes of this benefit. This section further defines self-dialysis and home dialysis training as programs that train ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis. In order for Medicare payment of home dialysis to be made, the patient must have actively elected to become a home dialysis patient and have completed a training program provided by an approved ESRD facility. Home dialysis is intended to be self-dialysis performed by the patient and/or with the assistance of other individuals, (i.e., a designated family member or caregiver). However, there is the recognition that some Medicare beneficiaries may have physical, developmental, or cognitive limitations that would preclude the patient from completing the required home dialysis training without significant involvement and assistance from other individuals. As a result, for purposes of payment CMS permits the patient to play a secondary or limited role in the dialysis training and service provision in instances where a designated family member or caregiver is present to actively participate.

Coordination of Services and Clarification of Responsibility and Accountability

While this model of care provides greater flexibility for dialysis patients, it also creates additional programmatic vulnerabilities that we believe can be minimized by adherence to the CfCs and active and ongoing care coordination between LTC and ESRD facilities. CMS will only approve applications of ESRD facilities to provide home training and support for LTC residents if the ESRD facility can assure CMS that the applicable facilities have a documented coordination agreement that outlines clear lines of responsibility and accountability.

Both the ESRD facility and the LTC facility will be held accountable for the coordination and quality of dialysis services delivered to LTC facility residents. The ESRD facility is responsible for providing the dialysis treatments, including training the patient and caregiver, monitoring the patient and patient's home, dietary and nutritional consultations, assuring continuity of care, installing and maintaining equipment, testing and treating the water, and ordering supplies. The LTC facility remains responsible for the overall care delivered to the resident including monitoring after completion of the dialysis treatment.

Under the ESRD regulations at 42 CFR §405.2136(b), 405.2136(c), 405.2136(d), and 405.2136(e) written documentation is required which specifies the terms and responsibilities of various providers of services. Therefore, to ensure that there is adequate coordination of care to effectively provide home dialysis training and support services to residents of LTC facilities, the ESRD facility will enter into a written coordination agreement with each LTC facility in which home dialysis patients reside. The purpose of this agreement is to coordinate the provision of such specific services to maximize patient safety and program efficiency. However, in no case may the ESRD facility or the LTC facility transfer responsibility for matters that each are otherwise required by law or regulation to provide.

Identify the Provision of Home Dialysis in LTC Facilities

Consistent with section 2274 of the SOM, in order to establish eligibility to provide ESRD services under Medicare, an applicant must complete Part I of the ESRD Application and Survey and Certification Report, Form CMS-3427/CMS-3427A. The Form CMS 3427/CMS-3427A is required when requesting initial approval, expansion or addition of stations, and a change in location, ownership, and/or in services provided. Any ESRD facility that plans to perform home dialysis and/or training as part of its initial application or as a part of an expansion of its services must request CMS approval. Part I of Form CMS-3427 must be submitted for an Initial Application. Part I of Form CMS-3427A must be submitted to request the "Addition of Services." Item 27 of CMS-3427 must identify those ESRD facilities that plan to provide or are providing training and support services to residents in a SNF and/or NF in lieu of transporting those patients to an ESRD facility to be dialyzed. Item 27 should include a list of the LTC facilities that are participants in the ESRD facilities' home training and support program. Item 27 does not need to reference those situations in which the dialysis is being furnished by a Medicare-approved ESRD outpatient facility.

ESRD surveyors should ensure that Item 27 of CMS-3427/CMS-3427A is appropriately completed to identify the provision of home dialysis in LTC facilities. LTC surveyors should report to the SA which LTC facilities provide home dialysis to residents and any concerns that they have about the provision of dialysis services in a specific facility. The appropriate CMS RO will then ensure this information is entered into QIES/OSCAR in a timely manner so that these arrangements may be appropriately monitored.

Protocols

To assist with consistent application of the guidance in this memorandum, we are attaching two survey protocols that provide guidance in regard to the application of specific regulatory requirements. Attachment A provides guidance to qualified ESRD surveyors who survey ESRD facilities that provide home dialysis to residents of LTC facilities. Attachment B includes guidance to qualified LTC surveyors who survey facilities having residents who receive dialysis. These protocols reflect already existing requirements found in either the ESRD or the LTC regulations. These protocols are not all inclusive, but rather they are intended to assist facilities and surveyors in determining compliance with current requirements.

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Effective Date: This guidance is effective immediately for all recertifications, complaint surveys or initial application reviews. Nothing in this Memorandum should be construed to require the rescheduling of a recertification review.

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers and ESRD Networks.

/s/

Thomas E. Hamilton

Attachments:

A – Survey Protocol for the Medicare-approved ESRD Facilities

B – Survey Protocol for Long-Term Care Facilities