CLIENT ALERTS & INSIGHTS

CMS Updates Guidance on Home Dialysis Services Provided in Nursing Homes

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On March 22, 2023, the Centers for Medicare and Medicaid Services ("CMS") issued revised Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home (Rev QSO-18-24-ESRD) to State Survey Agency Directors, which is effective immediately ("Revised Guidance"). The Revised Guidance supplements CMS's established requirements for home dialysis services rendered by a certified End Stage Renal Disease facility ("ESRD Facility") in long-term care facilities that became effective September 16, 2018 ("2018 Guidance"). The revisions address feedback that CMS received from state survey agencies, dialysis facilities and other federal and state stakeholders since releasing its 2018 Guidance.

Background

Skilled nursing and long-term care facility (collectively "Nursing Homes") residents requiring dialysis care have options for receiving dialysis treatment. Residents may receive dialysis care (i) in an outpatient Medicare-certified ESRD Facility, (ii) at a satellite ESRD Facility located in, or adjacent to, a Nursing Home, or (iii) in their room or in a dedicated dialysis "den" space within the Nursing Home. Over the past decade, the number of patients receiving dialysis services in Nursing Homes has increased significantly as home hemodialysis and peritoneal dialysis modalities of treatment have grown in popularity. This trend is consistent with clinical peer-reviewed studies finding that home dialysis results in better patient outcomes, removes transportation-related risks and costs, mitigates secondary infections, decreases disruption to patients' daily activities, among other benefits.

The Revised Guidance addresses a number of issues that have arisen since the 2018 Guidance was originally released. CMS's main focus is on instances where a Nursing Home's care team may not have the knowledge and skill set required for administering dialysis. The revisions aim to ensure additional protections are in place to secure effective and safe treatment, including:

1. Ongoing collaboration of care between an ESRD Facility and Nursing Home;
2. Adequate training for anyone that administers dialysis treatments;
3. Appropriate monitoring of a resident's status before, during, and after dialysis treatment; and
4. Ensuring a safe and sanitary environment for dialysis care.

The Revised Guidance

An ESRD Facility providing home dialysis services to a Nursing Home resident must maintain direct responsibility for dialysis-related care, and such services provided to Nursing Home residents must comply with the ESRD Conditions for Coverage (CFC), including the requirements for care at home. [1] The stated goal of the Revised Guidance is to "enable an effective and consistent approach to evaluate the quality of care and promote improvements in performance and outcomes for the Nursing Home dialysis population." To that end, CMS is instructing its surveyors to evaluate the care and management of residents requiring dialysis, including adherence to infection control procedures, knowledge of the nature and management of ESRD, and the ability to detect and manage potential dialysis complications during Nursing Homes on-site visits where ESRD patients are receiving home dialysis services.

Approved Home Dialysis Training and Support Program Required

ESRD Facilities that wish to offer home dialysis services to Nursing Home residents must have an approved home dialysis training and support program and notify their State Survey Agency or Accrediting Organization of any agreement with a Nursing Home to provide dialysis services to residents. ESRD Facilities must submit a completed Form CMS-3427 End-Stage Renal Disease Application and Survey and Certification Report to comply with this notification requirement.

Clarified Requirements for Written Arrangements between an ESRD Facility and Nursing Home

CMS noted new requirements for written agreements between an ESRD Facility and Nursing Home. The agency clarified that apart from the requirement to submit a copy of the written agreements as part of an updated CMS-3247 form, as discussed above, during the evaluation of compliance with ESRD Facility requirements, the written agreement between a Nursing Home and ESRD Facility may be requested by the survey team. The written agreement must make clear that an ESRD Facility is responsible for ensuring dialysis patients' needs and goals are addressed, and must outline how the Nursing Home and ESRD Facility will jointly implement a care plan for each resident. This ultimate responsibility of the ESRD Facility cannot be contracted away to the Nursing Home.

While CMS has not laid out an exhaustive list of what should be included in a written agreement between the parties, certain responsibilities must be integrated into the agreement, including the following:

- Methods for enabling timely communication and collaboration between an ESRD Facility and Nursing Home care team;
- Ensuring a safe and sanitary environment where dialysis treatments occur;
- Ensuring active participation of a Nursing Home care team in developing and implementing an individualized care plan;
- Delineation of resident monitoring responsibilities before, during, and after each treatment,
- Ensuring that any state scope of practice laws and limitations are adhered to;

- Ensuring a review of the qualifications, training, competency and monitoring of all personnel, patients, and caregivers (family members or friends) who administer dialysis treatments;
- Procedures for preparing Nursing Home staff to appropriately address and respond to dialysis-related complications and provide emergency interventions, as needed; and
- Procedures for ensuring that all equipment necessary for the resident's dialysis treatment is available and maintained in working condition.

While an ESRD Facility survey team does not have authority under Federal ESRD Facility regulations to evaluate compliance, they are encouraged to refer concerns to an applicable State Agency survey unit. As such, ESRD Facilities and Nursing Home operators should both be ready for their written agreements be reviewed by state survey agencies.

Who Can Administer Dialysis Treatments

Many types of caregivers may administer home dialysis treatments in a Nursing Home, subject to any more restrictive state-specific limitations, including RNs, Patient Care Technicians (PCTs), Residents and their caregivers, and other trained professionals.

Any caregiver that performs dialysis treatments, in any capacity, must have documented competency verification before providing such services, in accordance with the care at home Conditions for Coverage for End-Stage Renal Disease Facilities.[2] Records of verification must be maintained by both the ESRD Facility and Nursing Home.

Those individuals must comply with the training requirements outlined in the 2018 Guidance. Accordingly, the training must be (i) approved by the ESRD Facility medical director and governing body, (ii) administered at the direction of a home dialysis training nurse, (iii) specific to the dialysis modality and individualized needs of each resident, and (iv) equivalent to the ESRD Facility training for home dialysis patients. The training must address, among other things: (a) the nature and management of ESRD, (b) the full range of techniques associated with the treatment modality selected, (c) how to detect and report potential complications, (d) infection control precautions, (e) proper waste storage and procedures, and (f) how to address emergencies.

The determination of the scope of duties for the professionals administering dialysis treatments is also subject to state laws and regulations, and that both ESRD Facilities and caregivers responsible for initiating, monitoring or discontinuing dialysis must follow their state’s requirements.

Bedside vs. Den Dialysis Care

The Revised Guidance provides additional guidance for home dialysis based on whether treatments are provided in a resident’s room or in a common “den” area:

- Bedside Dialysis. When a Nursing Home resident, or resident's caregiver, receives dialysis training they must be educated on how to detect, manage, and report dialysis-related complications. Some residents who are attempting to administer their own dialysis treatment may have physical or cognitive limitations that may make it difficult to detect and address complications. Therefore, an ESRD Facility and Nursing Home should either: (1) ensure a resident is trained on potential complications and is able to act on them, or (2) provide qualified personnel to administer dialysis and remain in the room with direct visual contact over a resident and his/her vascular access during the treatment. Because cognitive and physical limitations could change over time, Nursing Homes are required to monitor and report on changes periodically and determine whether in-room supervision is required.
- Den Dialysis. Dialysis administration in a common area, commonly referred to as a "den" dialysis, is permissible under federal law, but requires compliance with additional requirements. First, the den must meet Medicare's standards for infection control, patients' rights, and patient's safety with which all certified ESRD Facilities must comply. Depending upon the size of the den, states' licensure and certificate of need laws, applicable infection control laws, and federal and state patient privacy laws, it may be difficult to provide den dialysis in certain states in compliance with applicable laws. Second, staff administering home dialysis must maintain adequate skill, training and availability. Accommodations also must be made for patients requesting privacy or requiring isolation during treatment. The ESRD Facility is responsible for ensuring compliance with these additional requirements.

Coordination Between an ESRD Facility and Nursing Home

CMS noted the importance of the following areas of care coordination:

- Communication. CMS describes a requirement for continued communication between the facilities and obligates an ESRD Facility to establish a mechanism for bi-directional communication between an ESRD Facility and Nursing Home. As articulated in the 2018 Guidance, an ESRD Facility must provide the Nursing Home an on-call schedule and contact information for physicians and/or ESRD Facility nurses who can be called in the event of questions and emergencies.
- Patient Management. An ESRD Facility and Nursing Home must designate points of contact within a Nursing Home to ensure successful coordination between the facilities. Designated Nursing Home staff must be actively involved in all aspects of a Resident's dialysis related care, including resident assessments, management, and plans of care and ongoing adjustments in treatment plans.
- Quality Assessment and Performance Improvement (QAPI). ESRD Facilities have an ongoing obligation to develop and implement an effective, data-driven QAPI program addressing the organizational structure of the facility and the specific services that the facility provides. ESRD Facilities must integrate both members of an ESRD Facility and Nursing Home in the QAPI program and facilitate the sharing of information about matters pertinent to a resident's plan of care.

- Emergency Plans. CMS clarified the requirement for ESRD Facilities to have emergency plans in place. While most ESRD Facilities are already required to have emergency plans by their ESRD Network, CMS is now also requiring these plans to be in a written agreement between the parties These emergency plans are not meant to address natural disasters,[3] but instead delays or interruptions in treatment. The emergency plans must be compliant with all applicable state laws and regulations. Anyone providing dialysis treatment, as well as anyone working within a facility where dialysis is provided, should be educated and prepared to address potential emergencies relating to dialysis treatment. In particular, Nursing Home staff should be prepared to execute emergency plans relating to:
    - Plans for Back-Up Dialysis. ESRD Facilities are required to have established back-up plans addressing any interruption of routinely-scheduled treatments, including delay or cancelation of treatments due to staffing shortage, dialysis equipment failure, or change in resident condition.
    - Managing Complications. Home dialysis training must ensure caregivers and staff are aware of potential complications and can detect, communicate, and act upon any complications based on procedures described above. As previously mentioned, any individual providing the dialysis treatment must be trained in managing resident complications in the case of an emergency care that may be required before, during, or after dialysis treatments. CMS expects the physician treatment orders for ESRD patients to include instructions on emergency medications which are to be kept onsite at the Nursing Home to address emergency situations. CMS also stressed that emergency plans and procedures must abide by state regulations that govern Nursing Home practice and operations.[4]

- Equipment Failure: An ESRD Facility has the obligation to maintain, install and repair all home dialysis supplies and equipment, and all supportive actions taken by an ESRD Facility must be documented in such ESRD Facility's records.

Conclusion

It is important to remember that these above outlined requirements are in addition to the requirements laid out in the 2018 Guidance. Nursing Homes that arrange for ESRD Facilities to furnish these services in their facilities, and ESRD Facilities that furnish services in Nursing Homes, should familiarize themselves with these updates and the emphasis on care coordination between the parties.

The Benesch Healthcare+ team monitors developments in this area of the law and may provide additional updates as they become available. For additional questions, please contact the authors of this article.

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[1] 42 C.F.R § 494.100.

[2] 42 CFR § 494.100

[3] Emergency planning and intervention in the event of a natural or man-made disaster such as flooding, power outages, or fires are addressed separately in the Emergency Preparedness standards at 42 C.F.R. § 494. 62.

[4] 42 C.F.R § 494.100(a)(3)(vi).