



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 13, 2021

Esther Fleming, Director Healthcare Planning
Esther.fleming@davita.com

No Review – Home Hemodialysis Training

Record #: 3646
Date of Request: September 9, 2021
Facility: Oak City Dialysis
Project Description: Offering of home dialysis training and support services to ESRD patients who reside in a nursing home
County: Wake
FID #: 160068

Dear Ms. Fleming:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your request regarding the offering of home dialysis training and support services to ESRD patients who reside in a nursing home. The proposal as described is not governed by, and therefore, does not currently require a certificate of need provided that the addition of home dialysis training and support services does not result in the development of dialysis stations that are in addition to the total number of authorized dialysis stations.

Sincerely,

[Handwritten signature of Michael J. McKillip]

Michael J. McKillip
Project Analyst

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

September 9, 2021

Mr. Michael McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

No Review Request – Home Dialysis in a Nursing Homes

Facility: Oak City Dialysis
County: Wake
FID#: 160068

Dear Mr. McKillip:

Oak City Dialysis (Oak City) is currently certified to provide in-center hemodialysis (ICHD) as well as training and support for home hemodialysis (HHD) and peritoneal dialysis (PD) modalities. Oak City would like to begin offering home dialysis services to patients who reside in nursing homes, specifically to residents of Cary Health and Rehabilitation Center in Wake County.

DaVita serves more home dialysis patients than any other provider in the U.S. and growth of our peritoneal dialysis (PD) and home hemodialysis (HHD) programs nationally is four times the growth rate of in-center treatment options. This growth is a result of a variety of factors. Patient choice has always been at the center of everything we do, and greater consideration for home dialysis is now being met with greater physician engagement, intuitive education detailing the benefits of each modality and innovative support programs to enable more patients, including patients who reside in nursing homes, to choose home treatments when appropriate.

Our physician partners are referring more patients to home dialysis when appropriate and both new and current dialysis patients are choosing home modalities because of the benefits. DaVita has developed technologies like home remote monitoring, which helps a patient's care team better manage their care, and a telehealth platform which allows patients to schedule and participate in virtual appointments with their care team, improve clinical outcomes and save on travel time and expense. All of these elements, which are aligned with the 2019 Executive Order on Advancing American Kidney Health encouraging greater rates of home dialysis to improve the quality of life and care for dialysis, are strong evidence that home dialysis will continue to grow in the future.

I have had a conversation with Lisa Pittman, Assistant Chief of the CON Section, and Micheala Mitchell, Chief of Healthcare Planning and CON, seeking clarification regarding the offering of home training and support services to an ESRD patient who resides in a nursing home. The

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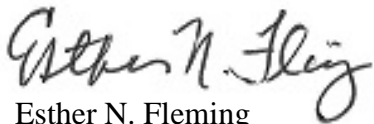
guidance we were provided was that under G.S. §131E-176(16), Oak City's proposal to offer home dialysis within a patient's home (in this case, a nursing home) does not constitute a "new institutional health service."

Oak City is proposing to offer home dialysis services to more of its patients within their residence, that being a nursing home. Oak City will provide training in all home modalities, including home peritoneal dialysis and home hemodialysis. Oak City will enter into a written coordination agreement with Cary Health and Rehabilitation Center as required by CMS (see attached). Oak City will comply with the survey standards imposed by the Acute and Home Care Licensure and Certification Section, and as needed, will coordinate with the nursing facility to ensure conformity with any requirements imposed by the Nursing Home Licensure and Certification Section.

Based on all of the foregoing, Oak City respectfully requests confirmation that the services proposed do not constitute a new institutional health service and are not subject to certificate of need review.

The facility would like to be able to offer these services as soon as possible, so we appreciate your prompt review of this request. You can contact me at 704-323-8384 if you have any questions or need more information.

Sincerely,



Esther N. Fleming
Director, Healthcare Planning

Attachment: CMS Memorandum *Survey Process for Reviewing Home Dialysis Services in a Long Term Care (LTC) Facility* (Ref: QSO-18-24-ESRD)



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-18-24-ESRD

DATE: August 17, 2018

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group (*formerly Survey & Certification Group*)

SUBJECT: Survey Process for Reviewing Home Dialysis Services in a Long Term Care (LTC) Facility

Memorandum Summary

- **Dialysis Services in a LTC Facility:** Medicare participating End Stage Renal Disease (ESRD) facilities must comply with the Conditions for Coverage at 42 CFR Part 494. Under this provision, Medicare-approved ESRD facilities may provide dialysis services to LTC residents in a LTC facility with an approved Home Training and Support modality. ESRD facilities that provide home hemodialysis or peritoneal dialysis services to LTC residents must maintain compliance with these requirements, including the requirements set forth at §494.100: Care at home.
- **Survey Process for Evaluation of Home Dialysis in a LTC Facility:** The ESRD Core Survey Process has been updated to include additional survey activities which address dialysis services provided by an ESRD facility to residents in a LTC facility.
- **Attachments:** Included as an attachment to this memorandum is *Exhibit IV: Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes* for evaluation of home dialysis services provided in a LTC facility.

Background

All chronic dialysis patients receiving dialysis services must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare.

Residents of a nursing home may receive chronic dialysis treatments through two options:

1. **In-Center Dialysis:** This may involve either:

- Transporting the resident to and from an off-site certified ESRD facility for dialysis treatments; or
- Transporting the resident to a location within or proximate to the nursing home building which is separately certified as an ESRD facility providing in-center dialysis.

- 2. Home Dialysis in a Nursing Home:** The resident receives dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for qualifications, training, and competency verification as stated in this guidance and are provided under the auspices of a written agreement between the nursing home and the ESRD facility.

If an ESRD facility provides dialysis services to LTC residents within the LTC facility, the ESRD facility must submit a Form CMS-3427 to the State Agency, completing Section 22, and all other applicable fields. No separate approval is required to provide these services.

Discussion

The ESRD core survey process has been updated to include evaluation of home dialysis services provided in a nursing home. The survey process for evaluating home dialysis in the nursing home consists of additional survey tasks and has been incorporated into the ESRD core survey process as *Exhibit IV: Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes*. The review of dialysis services in a nursing home should be considered an extension of the ESRD core survey and as such will require additional survey time. The ESRD survey tasks for review of dialysis in a nursing home involves the following activities: (1) survey tasks at the ESRD facility prior to the on-site visit at the nursing home, (2) survey tasks conducted at the nursing home and (3) survey tasks conducted at the ESRD facility after the on-site visit.

On-site visits to a minimum of two nursing homes where ESRD patients are receiving home dialysis services will be required to adequately evaluate the dialysis services and associated dialysis care being provided in the nursing home. The on-site visits will include observations of machine setup, vascular access care, initiation and discontinuation of home hemodialysis treatments. Observations of actual peritoneal dialysis care are not required unless the survey team identifies concerns such as high rates of infection or complaints. If observations of peritoneal dialysis care are indicated, the surveyor should observe connection and disconnection from the cyclor or manual CAPD exchange and evaluate the peritoneal dialysis exit site for signs of infection or improper care.

Exhibit IV: Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes will be incorporated into upcoming revisions to Appendix H.

Guidance: Additional guidance regarding home dialysis in the nursing home has been incorporated into the revised ESRD section of the State Operations Manual, Chapter 2. The guidance contains information regarding (1) qualifications and training of dialysis administering personnel, (2) coordination of care and (3) responsibilities of ESRD facility and the nursing facility. Please refer to SOM, chapter 2, section 2271A *Dialysis in Nursing Homes* for more information.

Contact: ESRDQuestions@cms.hhs.gov.

Effective Date: This policy becomes effective in 30 days. This memo should be communicated with all survey and certification staff, their managers, and the State/Regional Office training coordinators within 30 days of the memorandum.

/s/
David R. Wright

Attachments- (1) Exhibit IV: Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes

cc: Survey and Certification Regional Office Management

Exhibit IV: “Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes”

NOTE: This survey process is to be used in conjunction with survey procedures and guidance found in the ESRD Core Survey process and the ESRD Initial Survey process. This process includes additional survey activities and guidance which address dialysis services provided by the ESRD facility to residents in a nursing home setting. If ESRD facility surveyors identify possible concerns about the quality of the non-dialysis care provided to a nursing home resident(s), those concerns should be communicated to the SA for a possible complaint investigation.

Survey Procedures

When an ESRD facility has patients on their current census who are receiving dialysis treatments in a nursing home (Hemodialysis (HD) or Peritoneal Dialysis (PD) provided by the ESRD facility under written agreement with the nursing home, the ESRD survey team will include on-site visits to one or more of the nursing home(s) as part of the ESRD survey.

Initial/Recertification ESRD Surveys: ESRD surveyors select a minimum of two nursing homes where ESRD patients are receiving dialysis services by the ESRD facility, for on-site review. The selection of the nursing homes may be done randomly unless there are concerns identified during the pre-survey preparation (e.g. poor patient clinical outcomes, complaints, etc.).

The purpose for conducting the on-site nursing home portion of the ESRD survey is to verify that:

- Dialysis is being administered in a safe environment by qualified, competent dialysis administering personnel;*
- Dialysis treatments are supervised by a trained RN for HD, and by a trained RN or LPN/LVN for PD; and*
- Coordination between the ESRD facility and the nursing home ensures that the nursing home residents on dialysis receive quality care and timely and appropriate interventions to optimize their dialysis outcomes.*

The survey team should schedule the on-site visits to the nursing homes to include, at a minimum, direct observations of machine preparation, initiation of dialysis, vascular access care and discontinuation of dialysis. In the event there is only one patient receiving services in a nursing home, the ESRD surveyor may need to do observations in the nursing home on more than one day in order to observe both initiation and disconnection.

The ESRD survey tasks for review of dialysis in a nursing home are:

- I. ESRD Core Survey Tasks at the ESRD Facility Prior to the On-site Visit at the Nursing Home***
- II. ESRD Core Survey Tasks Conducted at the Nursing Home***
- III. ESRD Core Survey Tasks Conducted at the ESRD Facility after the Nursing Home On-site Visit***

I. ESRD Core Survey Tasks at the ESRD Facility Prior to the On-site Visit at the Nursing Home

a) ► TASK: Pre-survey Preparation

Prior to an ESRD initial or recertification survey, review applicable Forms CMS-3427 on file to determine if the ESRD facility has patients who receive their dialysis treatments at a nursing home and

plan the survey team composition and time schedule to accommodate onsite visit(s) to the nursing home(s). The review of dialysis services in a nursing home should be considered an extension of the ESRD Core Survey and as such will require additional survey time.

b) ► TASK: Entrance Conference at the ESRD Facility

To facilitate planning for on-site visits to nursing homes, the following information should be requested at the time of the ESRD survey entrance conference:

- *List of all nursing homes with which the ESRD facility has a current written agreement to provide dialysis services and the address for each nursing home;*
- *The names of all patients currently receiving dialysis services from the ESRD facility at each nursing home;*
- *The modality and treatment schedule (including the scheduled times for the hemodialysis treatments) for each nursing home resident named above;*
- *Names and credentials (e.g., RN, PCT) of any nursing home personnel who deliver the residents' dialysis treatments;*
- *Names and credentials of all RNs who provide on-site supervision of HD or PD and of LVNs/LPNs who provide on-site supervision of PD treatments at the nursing home(s); and*
- *A copy of the written agreement between the ESRD facility and each nursing home.*

c) ► TASK: Patient Sample Selection

The ESRD Core survey must include an on-site visit to a minimum of two nursing homes with which the ESRD facility has written agreements (if the ESRD has only one agreement in place visit that nursing home). Select one nursing home resident from each modality (PD and HD) from each nursing home and add the residents to the ESRD patient sample for the survey. Surveyors may use their discretion to expand the patient sample to include additional patients receiving care in nursing homes and also may conduct on-site visits at additional nursing homes as indicated by any concerns or findings identified.

If an ESRD facility provides dialysis services to residents in more than one nursing home, surveyors should review any clinical information available at the time of the entrance conference to identify any indicators of poor outcomes to assist in the selection of nursing homes and nursing home residents for the sample. If no concerns are identified, the nursing homes and residents may be selected at random.

d) ► TASK: ESRD Personnel Interviews Prior to Nursing Home Visit

Prior to going onsite to the nursing home, ESRD surveyors should interview the following members of the ESRD facility Interdisciplinary Team (IDT) to gather information regarding the services provided by the ESRD facility to the nursing home and/or the resident(s) of the nursing home.

- **ESRD Home Training Nurse:**

Interview Questions:

- 1) *What qualifications are required of the dialysis administering personnel who deliver dialysis treatments in the nursing home? (V681, V688, V692-V695)*
- 2) *What training do the administering personnel receive? (V582-V586, V693-V694)*
- 3) *Who conducts the training? (V685)*
- 4) *How does the ESRD facility verify competency of nursing home personnel providing dialysis treatments? (V585-V586)*

- 5) *What training do the on-site facility nurses who supervise the dialysis treatments in the nursing homes receive? (V582-V586)*
- 6) *Do you or another qualified ESRD IDT member conduct periodic site visits for each nursing home resident receiving dialysis and where are these visits documented? (V589, V590)*
- 7) *What system does the ESRD have in place for nursing home dialysis equipment maintenance and repair? (V403)*
- 8) *What provisions are in place at each nursing home to accommodate isolation during dialysis if needed? (V128, V130, V131)*
- 9) *What is the expected interaction among the ESRD IDT, the nursing home IDT and residents on dialysis in the nursing home? Where is this interaction documented? (V540-V562)*
- 10) *How are interim changes in the nursing home patient's plan of care communicated between the ESRD facility and the nursing home? (V541, V557-V559)*
- 11) *How are the comprehensive patient assessments conducted by the ESRD IDT for the nursing home residents; how are the ESRD facility plans of care then developed for those residents; and how are the ESRD facility plans coordinated with the nursing home plans of care? (V501-V520, V541-V562)*
- 12) *How is home dialysis performed in the nursing home incorporated into the ESRD facility QAPI program? (V626)*

- ***ESRD Social Worker and Dietitian:***

Interview Questions:

- 1) *Who do you communicate with at the nursing home, and how often?(V590-V592)*
- 2) *How often do you see nursing home residents on dialysis and where is this documented? (V501,V542,V588, V592)*
- 3) *When and how do you conduct an assessment of the nursing home dialysis residents and how is that assessment coordinated with the nursing home psychosocial assessment? (V500-V520)*

e) ► TASK: Review of Written Coordination Agreement:

Briefly review each written agreement between the ESRD facility and the nursing home(s) selected to ensure that each agreement(s) contains clear delineation of responsibilities for each entity. If concerns about coordination of care between the entities are identified during the survey, the ESRD surveyor should review the written agreement more closely to determine whether a lack of specificity in role responsibilities may have contributed to the issues and may extend to additional agreements if indicated.

The written agreement should specify the following, at a minimum:

The ESRD Facility is Responsible for--

- *Compliance with the ESRD Conditions for Coverage at 42 CFR §494.1-494.180 related to the care of residents receiving dialysis treatments at the nursing home.*
- *Coordination between the ESRD IDT and the nursing home IDT in the provision of dialysis treatments and ongoing communication regarding the resident's condition and their treatments;*
- *Coordination with the nursing home to ensure on-site supervision of dialysis treatments consisting of a trained RN for hemodialysis, and a trained RN or LPN/LVN for peritoneal dialysis;*

- *Coordination with the nursing home to ensure qualified dialysis administering personnel remain in visual contact with the resident throughout the dialysis treatment;*
- *Initial and ongoing verification of the competency of dialysis administering personnel;*
- *Initial and ongoing training of the dialysis administering personnel;*
- *Ordering and providing dialysis supplies and medications;*
- *Communicating/resolving any concerns with the nursing home regarding safety and cleanliness of the nursing home dialysis environment for each resident on dialysis;*
- *The provision of emergency care, if necessary, during dialysis, in accordance with the resident's preferred intensity of care and/or advance directives, as applicable (e.g., full code, DNR);*
- *Immediately reporting any unexpected/adverse event during dialysis to the resident's nephrologist and the resident and/or the resident's responsible party;*
- *Following the nephrologist-ordered dialysis prescription as well as dialysis-related medications, and communication of all changes in the orders to the dialysis administering personnel and nursing home IDT;*
- *Review of treatment records to ensure accurate documentation of the dialysis treatments delivered and the intra-dialytic (during treatment) effects on the resident at each treatment including adverse events;*
- *Receiving, monitoring and acting upon, if indicated, resident laboratory results as related to dialysis (e.g., anemia, dialysis adequacy, mineral metabolism, other chemistries, etc.);*
- *Ensuring that all dialysis equipment is maintained in good working order;*
- *Testing and monitoring the water and dialysate quality for HD equipment;*
- *Providing consultation to the nursing home IDT by the ESRD Masters Social Worker (MSW), ESRD Registered Dietitian (RD), and qualified ESRD RN regarding the condition of the resident as needed, including face-to-face meetings with the resident;*
- *Monthly visits with the resident by the nephrologist or other medical practitioner treating the resident's ESRD;*
- *Providing periodic training to nursing home staff regarding the basic care of dialysis patients. The training should include, but not be limited to, fluid and dietary restrictions; care and monitoring of dialysis access between treatments; and monitoring residents pre- and post-dialysis for complications related to the dialysis treatment such as symptoms of fluid overload or depletion, infection, and electrolyte imbalance; and*
- *Incorporation of the services provided to nursing home residents into the ESRD facility Quality Assessment and Performance Improvement (QAPI) program. The QAPI program must include at least: 1) monitoring resident outcomes in clinical areas; 2) technical operations; 3) water and dialysate quality; and 4) adverse events. When issues or negative trends are identified by the QAPI program, the ESRD facility collaborates with the nursing home to develop, implement and follow-up on corrective actions to resolve the issues and improve performance.*

The Nursing Home is Responsible for:

- *Compliance with all Long Term Care Requirements for Participation under 42 CFR Part 483 applicable to the care of residents receiving dialysis treatments at the nursing home;*
- *Providing a safe and sanitary environment for dialysis treatments such as, but not limited to,:*
 - 1) *Ensuring ongoing infection control practices;*
 - 2) *Appropriate room type for residents requiring isolation and roommate selection;*
 - 3) *Monitoring and mitigating hazards;*
 - 4) *Prohibiting unauthorized intrusions into the dialysis environment during treatments;*
and
 - 5) *Adequately cleaning and disinfecting all dialysis equipment and usable supplies. If the dialysis occurs in a common area used by other residents, the chair and any other furniture in the immediate treatment area must be cleaned and sanitized.*
- *Protecting the personal dialysis equipment and supplies of each resident from unauthorized access;*
- *Assisting with the provision of emergency care, if necessary, during dialysis, in accordance with the resident's preferred intensity of care and/or advance directives (e.g., full code, DNR);*
- *Immediately reporting any change in the resident's condition, which may possibly be related to their dialysis regimen, to the ESRD facility and the resident's attending physician at the nursing home;*
- *Prompt notification to the ESRD facility by the nursing home of its inability to provide dialysis treatments, for example insufficient staffing; and*
- *All supportive care of the resident including, at a minimum, monitoring the resident's:*
 - *Weight as required by the ESRD and Long Term Care plans of care;*
 - *Dietary and fluid intake and adherence to fluid and dietary restrictions as required by the plan of care;*
 - *Dialysis access including assessment of the resident's hemodialysis vascular access to ensure no signs of bleeding after treatment and ongoing for signs of infection;*
 - *PD catheter for signs of infection and leakage; and*
 - *Condition as related to symptoms of fluid overload or depletion, infections, and electrolyte imbalance.*

Shared Responsibilities of the ESRD Facility and Nursing Home:

- *Written communication between the nursing home and ESRD facility including, but not limited to, dialysis treatment orders, medication orders, patient assessment and any changes in patient condition;*
- *Review of each resident's ESRD and LTC plans of care, and collaborative revisions to each plan of care in order to ensure that the needs of the resident are met and their goals are attained;*
- *Complete, timely and accurate documentation of all assessments, care provided and interventions by both facilities;*

- *Written procedures addressing when a personal home dialysis caregiver/care partner, who previously assisted the resident in their home with dialysis, may assist the resident with dialysis in the nursing home.*

II. ESRD Core Survey Tasks Conducted On-site at the Nursing Home

a) ►TASK: Introductions, Entrance Conference with Nursing Home Administration

Introduce the members of the ESRD survey team to the nursing home administrator/designee in charge.

Explain that the visit is a component of an associated ESRD facility survey and the purpose of the visit is to determine compliance with the ESRD Conditions for Coverage and not the nursing home regulations. Further explain that if any concerns unrelated to the dialysis services provided in the nursing home under written agreement by the ESRD facility are observed during the visit, those concerns will be shared with the applicable State Survey Agency to process with the team responsible for oversight of the nursing home and not discussed by the ESRD surveyors with the nursing home Administrator. Provide the Administrator with a general overview of the anticipated survey activity to be performed in the nursing home, including the names of the residents who will be observed during their dialysis treatments and nursing home staff who may be interviewed. Explain that a review of associated medical records while on site will be done to confirm that ESRD responsibilities are accomplished as required and to evaluate the level of coordination between the ESRD and the nursing home. Provide the Administrator with an estimated amount of time that will be spent on site.

b) ►TASK: Tour of the Nursing Home Dialysis Environment

Observe the location where the resident(s) receive their dialysis treatments. This may be in the resident's room or in another location in the nursing home. Observe the location where dialysis equipment and supplies, including dialysate concentrates, are stored.

Observations indicating non-compliance may include, but are not limited to:

- *Unsanitary conditions that may be associated with a dialysis treatment, including but not limited to blood spots/spills, dirty dialysis equipment, uncontained infectious wastes, dirty dialysate containers, etc.; (V111, V121-V122)*
- *Dialysis supplies stored near contamination sources; (V116, V119)*
- *Insufficient space between and surrounding resident treatment areas (dialysis machine, chair/bed/water treatment equipment) to prevent cross-contamination, provide personal privacy or provide emergency care; (V404, V406)*
- *Dialysis equipment in poor repair (e.g., missing components, alarms non-functional, components rusted); (V403)*
- *Portable water treatment unit(s) lacking two carbon tanks and sample port between (does not apply to pre-configured systems) (V192)*
- *No documentation of chlorine testing after preparation of each new SAK for pre-configured systems; (V192, V276-V277)*

- *Dummy drip chamber(s) present where hemodialysis machine is prepared and treatment is delivered; this would be considered Immediate Jeopardy (IJ) if used to prepare machine for patient use. Does not apply to preconfigured systems. (V400, V403)*
- *Absence of an operating resident call system to enable the resident to summon immediate assistance in the case of patients receiving PD treatments ; (V413)*
- *Dialysis equipment and supplies not protected from unauthorized access; (V402)*
- *Resident(s) receiving hemodialysis without qualified dialysis administering personnel being present with the resident; (V407, V757)*
- *No trained RN present on-site and immediately available in the location of resident(s) receiving hemodialysis (V681, V688, V757). No qualified RN/LPN/LVN on-site and immediately available in the location of resident(s) receiving PD; (V681, V688, V757)*
- *Resident(s) receiving hemodialysis with the vascular access covered or not promptly uncovered if inadvertently covered; (V407)*
- *Resident(s) receiving hemodialysis but total chlorine test(s) were not performed and/or recorded (as applicable to HD equipment in use) prior to the start of the current HD treatment(s)(V196);*
- *Reagents are expired or they are incorrect reagents for testing the equipment; (V196)*
- *Dialysis resident requiring isolation, such as HBV+ residents, but are not isolated in a private room with dedicated supplies and separate administering personnel. (V128, V130, V131)*

c) ► TASK: Observations of Nursing Home Dialysis Care

Observe the direct dialysis care of the sampled resident(s). For hemodialysis, use the observation checklists in the ESRD Core Survey “Observations of Hemodialysis Care and Infection Control Practices” worksheet applicable to the care activities (e.g., Checklist #1 and Checklist #4 to observe hemodialysis initiation with a central venous catheter, arteriovenous fistula or graft; Checklist #7 to observe preparation of a conventional hemodialysis machine). Observations of residents receiving hemodialysis include:

- *Set-up;*
- *Initiation of treatment;*
- *Vascular access check; and*
- *Discontinuation of treatment.*

Typical hemodialysis treatments can last 2-4 hours, therefore all required observations do not have to be conducted on the same resident. If the survey team determines observation of peritoneal dialysis care is indicated (e.g. high rates of infection), observe staff connecting/disconnecting the resident to/from the cyclor (for automated PD), or performing a manual exchange (for continuous ambulatory PD), and the patient’s PD catheter site for signs of infection or improper care.

- ***Observed lapses in infection control technique may include, but are not limited to:***
 - *Improper hand hygiene or glove use; (V113)*

- *Supplies taken to the individual dialysis location but not disposed of, disinfected or dedicated to that resident after use; (V116)*
- *Clean dialysis supplies not protected from potential contamination; (V119)*
- *Lapses in aseptic practices for CVC (V147); AV fistula/graft care (V550); PD catheter care; (V142)*
- *Inadequate disinfection of dialysis equipment after treatment; (V122)*
- *Improper disposal of infectious waste and effluent; (V121)*
- *Staff not wearing appropriate personal protective equipment for the procedure; (V115)*
- *Lack of aseptic technique during medication administration such as drawing saline flush syringes from single use containers or single use bags. (V117, V118)*
- ***Concerns with Hemodialysis equipment operation may include, but are not limited to:***
 - *Testing water for total chlorine with expired reagents; (V196, V403)*
 - *Failure to test hemodialysis machine alarms; does not apply to preconfigured machines. (V403)*
 - *Failure to use an independent method to test conventional HD dialysate pH/conductivity or lack of staff knowledge of acceptable parameters for pH/conductivity; (There are a variety of devices used to test pH and conductivity. Each ESRD facility may use a different device for this purpose as long as DFUs are followed and appropriate testing strips are used. The ESRD facility must set limits for allowed variability of the independent method and machine reading. (V250)*
 - *Failure to prime hemodialyzers according to manufacturer's DFU; (V403)*

Note that expectations/requirements for equipment operation vary with the type of hemodialysis equipment in use. If not familiar with the HD machine and water treatment equipment being used, the surveyor may wish to review the manufacturer's Directions for Use (DFU) prior to the observation.

- ***Concerns with patient monitoring during dialysis may include, but are not limited to:***
 - *Failure to assess residents before and after dialysis or monitoring during hemodialysis treatment according to ESRD facility policy; (V504, V543, V550, V551, V715)*
 - *Failure to monitor vital signs throughout the treatment; (V407, V504, V541)*
 - *Failure to maintain visualization of the vascular access throughout the treatment; (V407)*
 - *Failure to promptly notify appropriate nursing home and ESRD facility personnel for dialysis related complications. (V503, V504)*

d) ► TASK: Interviews with Residents who Receive Dialysis in the Nursing Home

Interview the sampled residents who receive their dialysis treatments in the nursing home. If a resident is unable to be interviewed due to physical or mental status, interview a family member/guardian/friend who has contact with the resident and may be familiar with the resident's care experiences in receiving

dialysis at the nursing home. If a family member/guardian/friend is not available in person, surveyors should attempt to reach them by phone for the interview.

Interview Questions:

- 1) *How did you decide to get your dialysis treatments here in the nursing home? (V458)*
- 2) *Do you ever have any concerns when receiving your dialysis treatments here at the nursing home?(V465-V467)*
- 3) *Have you ever had problems during your dialysis? Was someone there to assist you? Who assisted you? (V588, V592,V681,V688, V757)*
- 4) *Does your dialysis equipment function well during the treatments? (V403)*
- 5) *Do the staff members providing your dialysis treatments wash their hands and change their gloves when caring for you? (V113)*
- 6) *Is the place where you receive your dialysis treatment clean? (V122)*
- 7) *Do the staff members who provide your dialysis treatments treat you with respect? (V452)*
- 8) *For HD: Do the staff members who provide your dialysis treatments stay with you throughout the entire treatment? (V407)*

e) ►TASK: Medical Record Review at the Nursing Home

Review the nursing home medical records for the sampled residents receiving dialysis:

- **Most recent dialysis treatment orders:** *Confirm that the dialysis treatment the resident is currently receiving is consistent with the most current physician order for treatment and cross check later at the ESRD facility to verify that the nursing home orders and the treatment are consistent with the most current orders on file at the ESRD.*
- **Dialysis treatment records:** *Confirm that the nursing home dialysis treatment record is completed after each treatment with any potential issues or concerns that may need to be reported to the ESRD facility team and there is evidence the information is promptly communicated with the ESRD facility.*
- **Interdisciplinary progress notes:** *Review the last three months of progress notes to confirm communication and collaboration between the nursing home IDT and the ESRD IDT to address each resident's issues with dialysis treatments, events, and clinical and psychosocial outcomes. Communication and collaboration should occur timely between the ESRD facility and nursing home regarding treatment orders, changes in plan of care, notification of dialysis related complications, adverse events and prompt identification and notification of the need to transfer a resident to a higher level of care.*

The remainder of the resident/patient medical record review is completed at the ESRD facility, as outlined in a later section of this survey process at Section III Task (c).

f) ►TASK: Interviews with Personnel at the Nursing Home

The on-site visit at the nursing home provides the ESRD surveyor an opportunity to interview any nursing home personnel administering and supervising dialysis treatments in the nursing home. Depending on any concerns identified (such as infections, treatment, and communication), surveyors may also wish to consider interviewing members of the nursing home IDT who coordinate with the ESRD IDT in the care of the residents. At a minimum, surveyors should conduct interviews with nursing home staff who administer dialysis treatments and the supervising nurse(s).

- **Dialysis Administering Personnel Interview Questions:**
 - 1) What training did you receive to enable you to administer dialysis treatments? (V582-V586)
 - 2) Who provided the training? (V584, V685)
 - 3) Who is available to help if the resident has a problem during their treatment? (V592,V681, V688, V757)
 - 4) Who do you call if you have problems with dialysis equipment? (V403,V588, V598, V757)
 - 5) What do you do if a resident's machine breaks down during a treatment? (V588, V592,V596, V598, V757)
 - 6) Do you mix or add electrolytes to dialysate for the treatments? (V235, V233)
 - 7) How do you disinfect the dialysis machine/equipment, and dialysate jugs (if applicable)? (V122, V243, V244)

- **Supervising RN(s) (for HD) or Supervising RN/LPN/LVN (for PD) Interview Questions:**
 - 1) How long have you been taking care of dialysis patients? (V681, V688)
 - 2) What training in dialysis have you received? (V681, V582-V586)
 - 3) How do you supervise the dialysis administering personnel during residents' dialysis treatments in the nursing home? (V681, V688)

► **TASK: Training and Competency Review at the Nursing Home**

The ESRD facility is responsible for training and competency verification for all nursing home personnel who administer and supervise dialysis treatments. Training should be individualized to reflect the resident's needs. Surveyors should review applicable nursing home personnel records to ensure that personnel who administer and/or supervise dialysis treatments have received the appropriate training prior to performing dialysis care. Surveyors should also verify the ESRD facility's method of evaluating and documenting competency of administering and supervisory personnel on a continuing basis. This documentation in the nursing home personnel files will be later compared to competency records maintained by the ESRD facility.

III. ESRD Core Survey Tasks Conducted at the ESRD Facility after the Nursing Home Visit

The following additional survey tasks regarding ESRD care of the nursing home dialysis patients are completed at the ESRD facility after the nursing home site visits.

a) ► **TASK: Water Treatment and Dialysate Review**

The ESRD facility is responsible for assuring that the water and dialysate for nursing home hemodialysis equipment meet the quality standards of the ESRD Conditions for Coverage. The documentation of water and dialysate quality used in hemodialysis machines in the nursing home must be maintained at the ESRD facility. Although there may be duplicate records kept at the nursing home, the ESRD surveyor must conduct this review at the ESRD facility to ensure the ESRD technical personnel are available to facilitate the review.

Review the water and dialysate quality results during the "Review of water/dialysate logs" in the Core Survey task. Verify that the following tests were performed by the ESRD facility and that corrective actions were taken as appropriate by the ESRD facility pursuant to the results of the tests.

- **Total chlorine:** Prior to each treatment for each portable RO unit, and per manufacturer directions for use for any non-conventional HD system for the past two months; (V196, V270-V273). For the PureFlow SL, tests must be recorded after preparation of each “SAK”/batch and prior to the use of that batch of dialysate; (V276-V277, V403)
- **Product water conductivity/TDS:** Recorded for each treatment day from each portable RO unit for past two months; (V199)
- **Product water chemical analysis:** From each portable RO unit for past 12 months. For PureFlow SL, water chemical analysis is required at the end of the first “PAK” and annually thereafter; (V177, V201, V206, V276-V277, V403)
- **Microbial surveillance of water:** For the last six months including cultures and endotoxin results from each portable RO unit-(six separate reports required). (V178, V254, V594); Note that only dialysate testing is required for PureFlow SL.(V278)
- **Microbial surveillance of dialysate:** For the last six months, including cultures and endotoxin results from each conventional and non-conventional HD machine- at least quarterly for non-conventional machines, monthly for conventional machines, and at the end of the SAK life for the PureFlow SL. (V180, V276-278, V594)

b) ► TASK: Dialysis Equipment Maintenance Review

This review is conducted at the ESRD facility. The ESRD facility is responsible for the maintenance and repair of the dialysis equipment used at the nursing home. While equipment, maintenance and repair documentation may be kept on-site at the nursing home as well, it must be maintained at the ESRD facility to ensure appropriate monitoring and review. Note that some of the dialysis equipment that may be used for dialysis in the nursing home setting is not maintained by the ESRD facility (e.g. NxStage System One, PD cyclers), and malfunctioning equipment is exchanged by the equipment supplier. It is the responsibility of the ESRD facility to ensure that the equipment exchange occurs timely.

Review the preventive maintenance logs for the hemodialysis equipment for the sampled nursing home residents. If issues are identified, surveyors should use their discretion to expand the sample.

- **Conventional HD machines and portable RO units:** Review the last 12 months of preventative maintenance logs and verify the maintenance was conducted per manufacturer’s Directions for Use (DFU) (V403)
- **Non-conventional HD and PD cyclers:** The ESRD facility must maintain documentation of dialysis equipment identification (e.g., serial numbers) and information regarding the equipment exchanges and recommended routine maintenance per manufacturer’s DFU. (V403)

c) ► TASK: Medical Record Review at the ESRD Facility

In addition to the dialysis order/prescription and dialysis treatment records reviewed at the nursing home, review the following information in the ESRD facility medical record of the sampled nursing home patients:

- **Labs/Indicators:** Review the most recent three months of hemoglobin, Kt/V, and albumin, as well as any lab values pertinent to the individual nursing home resident (i.e., outlier in a data-driven focus area for the survey). Look for frequency of monitoring, recognition when a goal is not met,

and actions taken to improve poor outcomes. Review Health Related Quality of Life (HRQOL) survey results to determine what actions were taken for any identified concerns.

- **Interdisciplinary Clinical Care:** *Review the last three months of medical record documentation for evidence of:*
 - *Communication and collaboration between the ESRD IDT members and the nursing home IDT members;(V501, V542, V590, V592)*
 - *Timeliness in assessment and care planning for the resident; (V501, V516, V519, V520, V542)*
 - *Review of all current medications administered at the nursing home (both by the ESRD facility and the nursing home) to avoid duplicates and contraindications; (V506)*
 - *Ongoing monitoring of resident current health status; (V502)*
 - *Nutritional status evaluation and monitoring by qualified ESRD Dietitian; (V509,V503)*
 - *Psychosocial and rehabilitation needs evaluation and monitoring and HRQOL survey administered initially and annually by an ESRD MSW; (V510, V514, V552)*
 - *Monthly visits of the resident with a medical practitioner (MD, APRN, PA) treating the resident's ESRD; (V560)*
 - *Ongoing consultation with resident/designee by the ESRD IDT (MSW, RD, home training nurse, care coordinator); (V590, V592)*
 - *Evidence in the medical record of identification and prompt action(s) relating to dialysis concerns identified during dialysis treatment (V587, V599).*
- **Patient Education:** *Look for evidence of resident/designee education regarding all options for dialysis modalities and settings, and information on advanced directives. (V457, V458)*

d) ►TASK: Training and Competency Review at the ESRD Facility

Review the training and competency records of the nursing home dialysis administering personnel. Ensure that each RN, LPN/LVN (V681,V688), dialysis administering personnel or certified dialysis patient care technician (V692-V695) has successfully completed a qualified training program (V582-V586, V693-V694) and has initial and ongoing competency testing verified and documented. (V681, V586).

Review the training and competency records of the RNs and LVN/LPNs supervising nursing home dialysis treatments to assure these personnel meet the qualifications of “staff nurse” (V688); and have successfully completed a qualified training program (V681, V582-V586).

e) ►TASK: Quality Assessment and Performance Improvement Review

During the QAPI Review at the ESRD facility, expect to see inclusion of nursing home dialysis in the QAPI process (V626). Look for:

- **Evaluation of outcomes for nursing home residents on dialysis at the nursing home:** *The ESRD facility must track, trend, and analyze data for residents on dialysis from each nursing home with which it has a current agreement.*

- **Performance Improvement:** *The ESRD facility must identify and investigate any problems/poor outcomes experienced by nursing home residents, develop and implement performance improvement plans, and evaluate the results and plans of action.*
- **Collaboration/coordination:** *There must be evidence of an effective working relationship between the nursing home and the ESRD facility. Examples of collaboration and coordination may include, but are not limited to:*
 - 1) *Recurring meetings between the ESRD facility and the nursing home leadership;*
 - 2) *Communication plans for reporting adverse events and appropriate interventions; and*
 - 3) *Timely and prompt response to dialysis related issues.*

Deficiencies related to the roles and responsibilities of the ESRD facility regarding its delivery of ESRD services to nursing home residents should be cited at the corresponding ESRD regulatory citation.

► **TASK: Decision Making**

Findings of deficient practices under the ESRD Conditions for Coverage related to the provision of dialysis to residents in a nursing home setting should be included in the ESRD survey Exit Conference and documented on the survey Form CMS 2567, “Statement of Deficiencies and Plan of Correction.”

From: [Mckillip, Mike](#)
To: [Waller, Martha K](#)
Cc: [Pittman, Lisa](#)
Subject: FW: [External] No Review Determination Request for Oak City Dialysis
Date: Thursday, September 9, 2021 10:24:22 AM
Attachments: [image003.png](#)
[image004.png](#)
[Oak City - No Review Request Add PD.HHD in LTC - 2021.09.09.pdf](#)

FYI

Michael McKillip

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From: Esther Fleming <Esther.Fleming@davita.com>

Sent: Thursday, September 9, 2021 10:02 AM

To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>

Cc: Pittman, Lisa <lisa.pittman@dhhs.nc.gov>

Subject: [External] No Review Determination Request for Oak City Dialysis

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Good morning Mike,

Attached is a request for a No Review determination for Oak City Dialysis (FID 160068) where we would like to begin offering home training and support services to patients who live in nursing

homes. Lisa and I have had a few conversations regarding this request over the past few weeks, so I've cc'd her as well.

Best,
Esther

Esther N. Fleming
Director, Healthcare Planning
TOPCATS & Carolina Waves Divisions

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-DaVita Inc-