NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • **Governor**
KODY H. KINSLEY • Secretary
MARK PAYNE • **Director, Division of Health Service Regulation**

VIA EMAIL ONLY

December 30, 2024

Fatimah Wilson
Fatimah.wilson@freseniusmedicalcare.com

No Review

Record #:	**4674**
Date of Request:	December 4, 2024
Facility Name:	FMC of Kinston Dialysis Unit
FID #:	955898
Business Name:	Bio-Medical Applications of North Carolina, Inc.
Business #:	160
Project Description:	Provide peritoneal dialysis services to residents of Signature Healthcare of Kinston
County:	Lenoir

Dear Ms. Wilson:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the representation in your request and the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. **As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.**

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Gregory F. Yakaboski
Project Analyst

Micheala Mitchell
Chief

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

FRESENIUS KIDNEY CARE

Certificate of Need
3943 New Bern Avenue
Raleigh, NC 27610
Phone: 984-268-8421

December 4, 2024

Mr. Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

No Review Request – Add a new SNF Program

Facility:	FMC of Kinston Dialysis Unit
Project Description:	Add a new SNF Program to the FMC of Kinston Dialysis Unit
County:	Lenoir
FID#:	955898

Dear Mr. Yakaboski:

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC of Kinston Dialysis Unit (FMC Kinston) is currently certified to provide in-center hemodialysis (ICHD) as well as training and support services for both home hemodialysis (HHD) and peritoneal dialysis (PD). FMC Kinston will be entering into a new agreement with Signature Healthcare of Kinston located at 907 Cunningham Road, Kinston, NC.

We are not requesting any new stations or the relocation of any existing stations from the dialysis unit to the nursing home. The agreement with Signature Healthcare of Kinston is to add PD services in a nursing home for patients that are already on PD. The nursing home staff will not be training any PD patients to do their therapy; instead, the nursing home staff will act as a caregiver to assist the patient with their treatment while they are in rehab at the nursing home. The nursing home staff will be functioning as the patient's caregiver just as a family member or friend would be if the patient were not in a nursing home.

BMA is committed to the growth of home dialysis as the modality of choice for dialysis treatment and more and more patients are being referred to home dialysis when appropriate because of its many benefits. Patient choice has always been at the heart of everything we do, and a greater emphasis for home dialysis is now being met with more physician engagement, intuitive education describing the benefits of each modality and advanced support programs to empower more patients, including patients who may reside in a nursing home to choose and continue their home dialysis treatments when appropriate.

By entering into an agreement with the Signature Healthcare of Kinston, residents who are already on PD will be able to have the assistance that they need to continue with

home dialysis while undergoing rehab in the nursing home, their place of residence. This agreement between FMC Kinston and Signature Healthcare of Kinston is aligned with the 2019 Executive Order on Advancing American Kidney Health and encourages greater rates of home dialysis that we know will improve the quality of life and care for dialysis patients, and thus this is strong evidence that home dialysis will continue to grow in the future.

Under G.S. §131E-176(16), FMC Kinston entering into an agreement with a nursing home that will allow an existing home dialysis patient to continue their home dialysis within a patient's home (in this case, a nursing home) does not constitute a "new institutional health service." As previously stated, BMA d/b/a FMC Kinston will enter into a written coordination agreement with Signature Healthcare of Kinston as required by CMS (see attached). FMC Kinston 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.

FMC Kinston respectfully requests confirmation that the services proposed do not constitute a new institutional health service and is not subject to a certificate of need review. The facility would like to be able to offer these services as soon as possible, so we appreciate your review of this request. If you have any questions, please contact me by phone at 984-268-8421, or email Fatimah.Wilson@freseniusmedicalcare.com.

Sincerely,

Fatimah Wilson

Fatimah Wilson
Director, Certificate of Need

Attachment: CMS Memorandum *Survey Process for Reviewing Home Dialysis in a Long-Term Care (LTC) Facility* (Ref: QSO-18-24-ESRD REVISED 3/22/2023)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

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

Ref: QSO-18-24-ESRD
REVISED 3/22/2023

DATE: **August 17, 2018**

TO: State Survey Agency Directors

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

SUBJECT: *Guidance and* Survey Process for Reviewing Home Dialysis Services in a *Nursing Home* ***REVISED***

Memorandum Summary

- **Dialysis Services in a Long-Term Care (LTC) Facility:** *In 2018, CMS issued guidance that addressed care at home provisions for nursing home residents that were receiving home dialysis. Since that time, CMS has received questions, comments, and feedback from the state survey agencies, the dialysis provider community, as well as other Federal and non-Federal stakeholders. This memorandum addresses those questions and incorporates the feedback that we received.*
- **Survey Process for Evaluation of Home Dialysis in an LTC Facility:** The End-Stage Renal Disease (ESRD) Core Survey Process has been updated to include additional survey activities which evaluate dialysis services provided by an ESRD facility to residents in an LTC facility.
- **Attachments:** Included as an attachment to this memorandum is an advance copy of the survey *procedures* for ESRD surveyors reviewing dialysis in nursing homes.

Terms Used in This Guidance

The term "nursing home" in this guidance refers to a Skilled Nursing Facility (SNF) or a Nursing Facility (NF).

The term "ESRD facility" refers to the certified end-stage renal disease (ESRD) facility that retains overall responsibility for all the dialysis care and services of the patient.

Depending on the health care services provided, individuals may be referred to as patients, residents, clients, and more. This memorandum focuses on nursing home dialysis and will use the term "patient" and "resident" interchangeably to refer to any individual that receives dialysis-related care from a certified ESRD facility.

Background

Medicare-certified ESRD facilities must comply with the Conditions for Coverage at 42 CFR Part 494. Under these provisions, ESRD facilities with an approved Home Training and Support modality may provide home dialysis services to residents in an LTC facility.

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. *For individuals residing in nursing homes with dialysis needs, dialysis treatments may be provided in an in-center setting or they may receive dialysis in the nursing home, i.e., home dialysis. It is important to note that in-center dialysis may be furnished by a certified dialysis facility that is located offsite, adjacent to the nursing home, or occupying leased space within the nursing home itself.* Nursing homes are not required to accommodate dialysis services on-site. Some State regulations may not allow dialysis services to be provided in a nursing home setting or may have additional requirements regarding the qualifications of personnel who provide dialysis treatments in a nursing home.

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 *or on-site* certified ESRD facility for dialysis treatments; or
   - Transporting the resident to a *certified ESRD facility that is located* within or *adjacent* to the nursing home building.
2. Home Dialysis: The resident receives dialysis treatments in the nursing home. Dialysis treatments may be administered by the patient, a family member or friend, dialysis facility staff, or nursing home personnel. *Any individual(s) that administers dialysis treatments must be trained, competent, and knowledgeable in all aspects of dialysis care before initiating treatments, per §494.100(a). Home dialysis services in the nursing home* are provided under the auspices of a written agreement between the nursing home and the ESRD facility.

For purposes of this memorandum, the guidance will be focused on home dialysis care provisions for the nursing home population.

Discussion

In 2018, CMS issued QSO-18-24-ESRD which addressed care at home provisions for nursing home residents that were receiving home dialysis. Since that time, CMS has received questions, comments, and feedback from the state survey agencies, the dialysis provider community, as well as other Federal and non-Federal partners on areas that were not adequately addressed through guidance. The current revised guidance incorporates these long-standing stakeholder feedback, questions submitted by the public as well as state survey agencies, and models of care that are currently being implemented for home dialysis care of a nursing home resident. The goal of this guidance is to promote an efficient and consistent way to apply care at home survey procedures that adequately evaluate patient safety and quality of care of the nursing home population requiring dialysis services. Information in this memorandum also reinforces guidance that was added as an Attachment to QSO-18-24-ESRD, but it is not in attachment form. The guidance in the attachment from the 2018 memo is now included in this revised memo with revisions that are noted in red font.

The number of patients receiving home dialysis services in the nursing home represents a small, but growing fraction of the total population of home dialysis patients. The characteristics of this group, such as age and multiple comorbidities, increase their risk of experiencing adverse health and safety events, such as hospitalization, infection, and death. Offering home dialysis as a treatment option for nursing home residents that addresses certain disadvantages of in-center dialysis, such as transportation times and disruption of the resident's daily activities. However, due to the dynamics of the respective care teams (i.e., nursing home and ESRD facility care teams) and the varying clinical complexities of this population, ensuring protections are in place will secure effective and safe treatments. These include:

1. *Ongoing collaboration of care between the dialysis facility and nursing home;*
2. *Adequate training for **anyone** that administers dialysis treatments;*
3. *Appropriate monitoring of the dialysis patient's status before, during, and after the treatments; and*
4. *Ensuring a safe and sanitary environment for the treatments.*

An ESRD facility providing home dialysis services to a nursing home resident maintains direct responsibility for the dialysis-related care and such services provided to the nursing home resident(s) must be consistent with the ESRD Conditions for Coverage (CfC) requirements. The goal of this 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.

A dialysis facility that provides services to patients residing in a nursing home must meet all applicable Conditions for Coverage, including the requirements for Care at Home at §494.100. The ESRD core survey process has been updated to include an evaluation of home dialysis services provided in a nursing home. The survey process for evaluating home dialysis in the nursing home consists of *some* additional survey tasks and will be incorporated into the ESRD core survey process. 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 involve the following activities:

(1) survey tasks at the ESRD facility (before the on-site visit at the nursing home)
(2) survey tasks conducted *onsite* at the nursing home
(3) survey tasks conducted at the ESRD facility (after the on-site visit)

On-site visits to the nursing homes where ESRD patients are receiving home dialysis services will require surveyors to adequately evaluate the dialysis services and associated dialysis care being provided in the nursing home. The number of onsite visits that a surveyor must conduct will vary depending on how many nursing homes the dialysis facility has agreements with. The primary goal of the on-site visit is to evaluate the care and management of patients requiring dialysis, including adherence to infection control procedures, knowledge of the nature and management of ESRD, as well as the ability to detect, report, and manage potential dialysis complications.

The on-site visits *at the nursing home* will include observations of machine setup, vascular access care, and initiation and discontinuation of home hemodialysis (HD) treatments. *Peritoneal dialysis (PD) may be administered in two ways: (1) Continuous Ambulatory Peritoneal Dialysis (CAPD) – manual exchange and (2) Automated Peritoneal Dialysis (APD) - cycler.* 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 procedures and evaluate the peritoneal dialysis exit site for signs of infection or improper care.

Notification to the State Survey Agency: *Dialysis facilities that wish to offer home dialysis services to patients residing in a nursing home must have an approved home dialysis training and support program. An ESRD facility that enters* into an agreement with a nursing home to provide dialysis services to nursing home residents must notify its State Survey Agency (SA) *or Accrediting Organization (AO)* of any such agreement(s). This notification is accomplished through submitting a completed Form CMS-3427 End-Stage Renal Disease Application and Survey and Certification Report. The following fields of the CMS-3427 form must be completed for this notification:

- Field: (1) #6 Other
- Field: (2) Name of Dialysis Facility
- Field: (3) CCN
- Field: (4) Street Address of Dialysis Facility
- Field: (6) City
- Field: (7) County
- Field: (9) State
- Field: (10) Zip Code
- Field: (12) Telephone Number
- Field: (22) Dialysis in LTC Facility Field:
- Field: (26) How is isolation provided in the nursing home?

Guidance

The following guidance as well as the survey procedures for ESRD surveyors reviewing dialysis services in the nursing home will be incorporated into upcoming revisions to the State Operations Manual - Ch. 2 and Appendix H, respectively. Guidance regarding home dialysis in the nursing home setting contains information regarding (1) written agreement and the responsibilities of the ESRD facility and the nursing home, (2) qualifications and training of *any* dialysis administering personnel, and (3) coordination of care.

WRITTEN AGREEMENT

Arrangement Between an ESRD Facility and a Nursing Home*: Nursing home regulations at 42 CFR 483.70(g)(1) specify that "if the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement…" An agreement constructs a connection between both entities and fosters accountability that is vital to the health of each patient and the success of their plan of care. Each ESRD facility is responsible for ensuring the dialysis patient's/resident's needs and goals are addressed. The successful implementation of a care plan may be shared responsibilities that are divided between the nursing home and the ESRD facility, e.g., adhering to certain renal dietary restrictions based on the resident's fluid status.*

If a dialysis facility provides home dialysis services to a nursing home, the dialysis facility is expected to have an agreement with the nursing home. When an updated CMS-3427 form is submitted to notate a new or additional agreement with a nursing home, a copy of the agreement should be provided as an attachment. During the evaluation of compliance with dialysis facility

requirements, the agreement between a nursing home and dialysis facility may be requested by the survey team (CMS, state survey agency, or accrediting organization). Collaborative care planning and delineated division of responsibilities is critical to the successful implementation of a patient's plan of care. The section below outlines clinical areas that should be addressed in an agreement. This is not an exhaustive list, nor does it represent mandatory elements of a written agreement. The guidance below is provided as a resource for dialysis facilities to refer to prior to furnishing home dialysis care to nursing home residents.

Note: The dialysis facility survey team does not have the authority under Federal dialysis facility regulations to evaluate compliance with nursing home Requirements for Participation. Failure to produce an agreement would not be considered non-compliance with the dialysis facility CfCs; however, the survey team should refer concerns to the State Agency survey unit responsible for oversight of Medicare- Medicaid-certified nursing homes.

Guidance on clinical areas that should be addressed in an agreement:

- *Methods for enabling timely communication and collaboration between the ESRD facility and nursing home care team;*
- *Ensuring a safe and sanitary environment where the dialysis treatments occur;*
- *Ensuring active participation of the nursing home care team in the development and implementation of an individualized care plan;*
- *Delineation of patient monitoring responsibilities before, during, and after each treatment, ensuring any state scope-of-practice laws and limitations are adhered to when delineating responsibilities;*
- *Process that ensures a review of the qualifications, training, competency verification, and monitoring of all personnel, patients, and caregivers (family members or friends) who administer dialysis treatments in the nursing home;*
- *Procedures for preparing nursing home staff to appropriately address and respond to dialysis-related complications and provide emergency interventions, as needed; and*
- *Procedures to make sure that all equipment necessary for the resident's dialysis treatment is available and maintained in working condition.*

See 42 CFR §483.25(l) and SOM Appendix PP at tag F698 *for the CMS nursing home requirements and guidance applicable to residents with dialysis needs.*

ESRD Policies and Procedures for Nursing Home *Dialysis*: *Due to the nature of home dialysis, patients can receive their treatments in their homes without having to physically enter a dialysis facility. In the long-term care setting, treatments may be administered by the residents themselves, but most often it is administered by either the dialysis facility staff or trained nursing facility staff. The dialysis facility should make sure its policies and procedures address this setting. Certain elements of nursing home dialysis will require coordination and cooperation between the nursing home and dialysis facility and the training/preparation thereof of the individuals that care for them. For example, for the dialysis facility to appropriately address dialysis complications that might occur, the nursing facility staff should be involved in the training on how to detect, report, and manage potential complications that may occur before, during, or after a dialysis treatment.* The ESRD facility, in collaboration with the nursing home, should develop and implement protocols for the delivery of ESRD services, *and to the extent possible,* ensure that they are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. The protocols should include requirements set forth at

42 CFR 494.30 and 494.80 through 494.100, addressing:

- *Procedures for infection control*
- *Patient assessment*
- *Patient plans of care*
- *Care of the dialysis patient at home*
- *Emergency planning and preparedness*

Policies and procedures should be reviewed and updated as necessary to be consistent with the most current standards of practice. Timeframes for the re-evaluation of policies and procedures should be determined by each ESRD facility.

QUALIFICATIONS AND TRAINING

Home **Dialysis Administration:** *Individuals who administer home dialysis treatments in the LTC facility may include the RN, LPN/LVN, certified nursing assistant (CNA), patient care technician (PCT), resident, or the resident's existing designated caregiver. Any individual that performs dialysis treatments, or any part of the treatment, must have documented competency verification before providing the service (see §494.100(b)(1)).* Documentation of training and competency verifications for all nursing home staff or other individuals who initiate, monitor, and discontinue home dialysis treatments should be maintained by both the ESRD and nursing home facility.

Note: Some states have statutes, regulations, Nurse Practice Acts, etc., that determine the scope of duties for patient care technicians, nurse aides, and LPNs/LVNs, and list expressly permitted or prohibited duties. If the dialysis facility will be training staff member(s) (that are employed by either the dialysis facility or nursing home) to perform the home dialysis, they must make sure any state limitations are considered when assigning individuals to administer dialysis treatments. The individuals who initiate, monitor, and discontinue home HD and PD treatments for nursing home residents must meet the practice requirements in the State in which they are employed.

Training: In the nursing home setting, any individual administering dialysis must receive adequate training and possess sufficient competency to ensure that the resident on dialysis receives safe and effective treatments. The training must be:

- Approved by the ESRD facility medical director and governing body.
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2).
- Specific to the dialysis modality *and the individualized needs of each resident*. The training program for HD and PD must address, *at a minimum,* the areas listed at §494.100(a)(3)(i-viii).
- Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100(a)(3)(i-viii) and §494.100(b)(1). Ongoing competency should be verified through visual audits by an ESRD RN who meets the qualifications of a home training nurse at §494.140(b)(2). The frequency at which competencies are verified should be determined by the ESRD facility. More frequent competency checks may be warranted if problems in care are identified. For example, a concern of poor clinical outcomes, such as frequent infections, may indicate infection control issues and would prompt the dialysis facility to review dialysis procedures performed by the nursing home staff and possible re-training. Training must address the following areas:

- The nature and management of ESRD.
- The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.
- How to detect, report, and manage potential dialysis complications, including water treatment problems.
- Availability of support resources and how to access and use resources.
- How to self-monitor health status and record and report health status information.
- How to handle medical and non-medical emergencies.
- Infection control precautions.
- Proper waste storage and disposal procedures.

In-Room Presence *for Hemodialysis:* *When home dialysis patients or their caregiver(s) are trained, they are educated on how to detect, report, and manage complications. Timely recognition of complications and interventions may be required at any time throughout the patient's hemodialysis treatments. Some complications may require immediate action, e.g.,. drop in blood pressure or accidently dislodging cannula. Nursing home residents may or may not be able to identify and handle medical and non-medical emergencies based on cognitive or physical limitations.* To ensure patient safety *and prompt recognition of complications requiring medical attention,* the ESRD facility and nursing home should either (1) ensure that *the resident is trained and understands and is aware of situations that require attention and is capable of requesting help independently or (2)* provide qualified dialysis administering personnel to remain in the room with direct visual contact of the resident and their vascular access throughout the *entire duration of the* hemodialysis treatment. *Also, a resident's cognitive or physical status may change over time. Both the nursing home and dialysis facility staff should monitor and communicate such changes and adjust their patient monitoring approach based on the situation. For example, if there is an indication that the resident is no longer capable of independently requesting help, they should have qualified dialysis administering personnel remain in the room throughout the entire duration of the hemodialysis treatment.*

Nursing Home Dialysis in a Common Area: *Medicare standards for infection control, patient rights, and patient safety apply to all certified ESRD facilities that provide in-center and/or home dialysis. CMS is aware of scenarios where some nursing homes provide home dialysis treatments to multiple residents in a common area within the nursing home, more commonly referred to as a den setting. The ESRD facility is responsible for determining that the staff's level of skill and availability in a nursing home is adequate and the ESRD facility is responsible to ensure that home dialysis is not provided unless the safety of the patient can be guaranteed.*

ESRD facilities are required to periodically monitor the patient's home to evaluate their adaptation to home dialysis (42 CFR 494.100(c)(1)(i)). Home visits generally occur at the time of home dialysis initiation and periodically thereafter based on facility policy, patient concerns, and complaints. The dialysis facility that is responsible for its patient's care should ensure that they are aware of the environment and setting where the dialysis treatments will be performed, i.e., in the resident's room or a common area. Residents requesting privacy or requiring isolation should not be dialyzed in the same room or area as others.

COORDINATION OF CARE

***Communication**: The dialysis facility should establish a mechanism for bi-directional communication between the dialysis facility and the nursing home. Communication efforts may be supported through the development, implementation, and adherence to policies that address when certain communication should occur and how that communication is documented.* The ESRD facility must provide to the nursing home an on-call schedule with the names and contact information of physicians and/or ESRD facility RNs to be called for *questions and* emergencies. The *ESRD facility* should *have a policy that addresses* how communication and responses will be coordinated and documented between the ESRD facility and nursing home staff.

***Patient management:** The ESRD facility is responsible and accountable for the safe care and management of its patients. When the patient resides in a long-term care setting, e.g., a nursing home, there should be identifiable, designated points of contact within the nursing home where the patient resides to ensure successful coordination between the dialysis facility and nursing home. It is critical that these designated nursing home staff, who are acting on behalf of the resident's designated caregiver, be actively involved in all aspects of the patient's dialysis-related care, such as patient assessments, patient management, and plans of care, including any adjustments needed in the patient's treatment plan. The dialysis facility interdisciplinary team (IDT) team must* coordinate with the nursing home staff for the development and implementation of an individualized care plan based on the patient's assessment. Both the nursing home staff and ESRD facility staff are responsible for monitoring and addressing any medical or non-medical needs that are identified. Any identified barriers or issues that are preventing residents from meeting the established ESRD facility goals identified through a patient assessment and/or defined in the plan of care should be promptly communicated between the ESRD facility IDT and the nursing home IDT. Any barriers experienced by a dialysis patient will require re-assessment and an updated plan of care by *the ESRD facility*. *The most recent assessment and plan of care should be shared with the nursing home IDT to promote coordination of care efforts between the facilities*.

***Quality Assessment and Performance Improvement (QAPI)**: The Medicare regulations for dialysis facilities require that they develop and implement an effective, data-driven QAPI program that reflects the complexities of its organization and services, including those services provided under arrangement. This includes continuously monitoring its performance for home dialysis services provided in the nursing home. To ensure the dialysis facility can effectively assess, monitor, and implement sustainable performance improvement, it must include participation from members of the dialysis facility and should include participation from the nursing home where the patient resides. The dialysis facility should share information with the nursing home and receive information from the nursing home about matters pertinent to each patient's plan of care.*

Emergency Plans: *The following guidance for emergency plans is to address medical and non-medical emergencies that may occur at the nursing home and could interrupt or delay a resident's treatment, e.g., unavailability of dialysis-trained caregivers/staff. It does not apply to emergency planning and intervention in the event of a natural or man-made disaster such as flooding, power outages, or fires. These are separate and addressed in the Emergency Preparedness standards at §494.62. When dialysis treatments are provided by trained nursing home staff, the dialysis facility must educate and prepare the nursing home to address all potential emergencies related to the dialysis needs of the resident receiving treatments in the*

nursing home (§494.100(a)(3)(vi)). Expectations and responsibilities for both the dialysis facility and the nursing home should be incorporated into the written agreement between the two entities. The following emergency plans must be clear and should be communicated to nursing home staff:

1. ***Plans for Back-Up Dialysis***
   Dialysis facilities are required to have back-up plans in place for situations where a patient's routinely scheduled treatment is impacted due to reasons beyond their control. These plans should be communicated to the nursing home so that they can be implemented when needed. For example, dialysis postponed or canceled due to lack of sufficiently trained and qualified staff or caregivers, dialysis equipment failure, or change in resident condition (health decline, acute illness, or resident complications)..
   The ESRD facility is responsible for ensuring that a backup plan is in place to ensure the patient/resident receives *timely* treatment, which would include confirming *that the nursing facility has received this information and they understand the procedures that are in place for such events. (42 CFR 494.100(c)(1)(vii))*

2. ***Managing Complications***
   Nursing home residents receiving dialysis may have complications that require *emergency interventions or* treatment with emergency medications or equipment. *Home dialysis training must ensure that caregivers and staff are aware of complications that should be recognized, communicated to the dialysis facility, and acted upon based on established procedures. Dialysis facilities must develop plans to address any emergency care that may be required before, during, or after dialysis treatments. Individuals that provide home dialysis treatments must be trained and competent in the protocols to be implemented in the event of an emergency. If there are* physician treatment orders for the ESRD patient, these should include what emergency medications are to be kept *onsite at the nursing home. Emergency care within the nursing home must be consistent with state regulations and limitations. Emergency plans and procedures must not conflict with any state regulations that govern nursing home practice and operations. (42 CFR 494.100(a)(3)(vi))*

3. **Equipment Failure**
   The dialysis facility must install, repair, and maintain all home dialysis supplies and equipment. Record-keeping systems must be in place to document all supportive actions taken by the dialysis facility. Any non-functional equipment must be replaced or restored by the ESRD facility to avoid interruption of a patient's dialysis treatment. The ESRD facility must provide nursing home staff with:
   - Adequate and appropriate education for possible equipment failures and risk(s) associated with equipment failures;
   - Troubleshooting techniques; and
   - Contact information for assistance in resolving issues with equipment failure.

4. **Emergency Supplies**
   Nursing homes should maintain necessary supply inventories to prevent any delays or interruptions to a resident's prescribed dialysis treatment. The ESRD facility and the nursing home should ensure a reserve of supplies to be available in emergency circumstances. The emergency supply reserve is more than the routine supply inventory and generally includes at least five (5) days of emergency supplies for each resident. To

assist with the inventory, the ESRD facility should provide nursing homes with medications, equipment, and dialysis-related supplies through routine deliveries. Plans should be in place for the safe delivery of additional supplies in the event of an emergency.

Existing Personal Caregiver: If an existing ESRD facility home dialysis (PD or home HD) patient is admitted to a nursing home and that patient has a trained personal caregiver who administered the dialysis treatments at home, that caregiver may be approved by the ESRD facility and the nursing home to continue to administer the patient's home dialysis treatments in the nursing home. The collaborative decision-making process for such situations should be addressed in the agreement between the ESRD facility and nursing home. If the nursing home and ESRD facility determine that an existing home dialysis caregiver may continue to administer the dialysis in the nursing home, the ESRD facility must assure that the caregiver meets the training requirements at §494.100(a)(3)(i)-(viii), and the verification of demonstrated competency at §494.100(b)(1). The ESRD facility is responsible for the ongoing monitoring of the competency of the personal caregiver.

Contact: ESRDQuestions@cms.hhs.gov.

Effective Date: Immediately. This memo should be communicated with all survey and certification staff, their managers, and the State/Regional Office training coordinators.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Attachments - Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes

ATTACHMENT

"Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes"

This survey process is to be used in conjunction with survey procedures and guidance found in the ESRD Core Survey process. It includes additional survey activities and guidance which address dialysis services provided by the ESRD facility to residents in a nursing home setting.

If, during the onsite visit at a nursing facility, ESRD facility surveyors identify concerns about the quality of the care provided to a nursing home resident(s) that is unrelated to dialysis facility requirements or dialysis-related concerns that overlap with existing nursing home requirements, those concerns should be communicated to the appropriate SA authorities for a possible nursing home complaint investigation.

Survey Procedures

When an ESRD facility has patients on their current census receiving *home hemodialysis (HD) or peritoneal dialysis (PD) treatments* in a nursing home under a written agreement, the ESRD survey team will include on-site visits to *the* nursing home(s) as part of the ESRD survey. *The total number of nursing home onsite visits will be guided by the number of agreements that are established with the dialysis facility (see table below).* The selection of the nursing homes *will be based on* concerns *that are* identified during the pre-survey preparation (e.g., poor patient clinical outcomes, complaints, etc.) *and/*or *quality of care issues identified during the ESRD facility survey*.

Number of Agreements with Nursing Home(s)	***Number of Nursing Homes (for onsite visits)***
1-10	*2*
11-20	*3*
20+	*4*

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 *and sanitary* environment
- *Treatments are administered* by qualified, *trained, and* competent dialysis administering personnel;
- Coordination between the ESRD facility and the nursing home is occurring to ensure 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 on-site visits to the nursing homes to include, at 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 *perform their* observations in the nursing home over multiple days 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 (Before 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 (Before the On-site Visit at the Nursing Home)

►TASK: Pre-survey Preparation

Before 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 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.

►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, *including how treatments are provided in each distinct nursing home, i.e., in the patient's private room, in a common area, or both;*
- 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;
- A copy of the written agreement between the ESRD facility and each nursing home.

►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). *The total number of on-site visits will depend on the number of agreements in place. See the table above under the Survey Procedures section for guidelines on the total number of on-site visits.* Select one nursing home resident from each modality, i.e. PD and HD, from each nursing home and add the resident(s) to the ESRD patient sample for the survey. Surveyors may use their discretion to expand the patient sample and include additional patients receiving care in nursing homes and also may conduct on-site visits at additional nursing homes if any concerns or findings of non-compliance are 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.

►TASK: ESRD Personnel Interviews Before Nursing Home Visit

Before going onsite to the nursing home, ESRD surveyors should interview the home training nurse, social worker, and dietician 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 individual(s) who deliver dialysis treatments in the nursing home? (V681, V688, V692-V695)
2. What training do the individual(s) receive? (V582-V586, V693-V694)
3. Who conducts the training? (V685)
4. How does the ESRD facility verify the competency of an individual(s), e.g. nursing home staff that provides 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 are the expected interactions 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 assess the nursing home dialysis residents and how is that assessment coordinated with the nursing home psychosocial assessment? (V500-V520).

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

►TASK: Introductions, Entrance Conference with Nursing Home Administration

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

charge.

The focus of this review is to ensure administration of dialysis treatments and management of the resident receiving home dialysis is consistent with the training and education that was provided by the dialysis facility. 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 any non-dialysis-related quality of care concerns or dialysis-related concerns that overlap with existing nursing home requirements observed during the visit can be shared with the applicable State Survey Agency with oversight of nursing home compliance with Medicare health and safety standards. Such concerns and findings will not be shared or 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 facility and the nursing home. Provide the Administrator with an estimated amount of time that will be spent on site.

►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 another location in the nursing home. Observe the location where dialysis equipment and supplies, including dialysate concentrates, are stored.

Dialysis administration and patient monitoring during treatments should be consistent with home dialysis education and training provided by the dialysis facility. Further, dialysis facilities are expected to periodically monitor the patient's adaptation to home dialysis by visiting the patient or resident's home (V589). Unsafe, unsanitary, or disordered/dirty conditions may indicate a lack of dialysis facility monitoring of the resident's adaptation to home dialysis or insufficient competency of home dialysis skills and methods that would otherwise trigger re-education/re-training or removal of the resident as an appropriate candidate for home dialysis when re-education or re-training does not resolve the concerns. Observations indicating non-compliance may include, but are not limited to:

Infection Control Precautions (V585)

- *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.*
- *Dialysis supplies stored near contamination sources.*
- *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.*

Effective Use of Dialysis Supplies and Equipment (V585, V593)

- *Dialysis equipment in poor repair (e.g., missing components, alarms non-functional, components rusted).*

- *Portable water treatment unit(s) lacking two carbon tanks and sample port between (does not apply to pre-configured systems).*
- *No documentation of chlorine testing after preparation of each new dialysate batch, i.e., SAK, for pre-configured systems.*
- *Resident(s) receiving hemodialysis, but total chlorine test(s) were not performed and/or recorded (as applicable to HD equipment in use) before the start of the current HD treatment(s).*

Ability to handle medical and non-medical emergencies (V585)

►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 the 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/*peritonitis*), observe staff connecting/disconnecting the resident to/from the cycler (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;
- Supplies taken to the individual dialysis location but not disposed of, disinfected, or dedicated to that resident after use;
- Clean dialysis supplies not protected from potential contamination
- Lapses in aseptic practices for CVC; AV fistula/graft care; PD catheter care;
- Inadequate disinfection of dialysis equipment after treatment;
- Improper disposal of infectious waste and effluent;
- Staff not wearing appropriate personal protective equipment for the procedure;
- Lack of aseptic technique during medication administration such as drawing saline flush syringes from single-use containers or single-use bags.

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) before 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)

►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? *If so, how do staff respond to your concerns?* (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)

►TASK: Medical Record Review at the Nursing Home

Review the following sections of 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 the 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 in Section III .

►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 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)

► 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 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 dialysis treatments have received the appropriate training before performing dialysis care. Surveyors should also verify the ESRD facility's method of

evaluating and documenting *the* competency of administering personnel continuingly. 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.

►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:** Before 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 *dialysate batch, i.e.,* "SAK"/batch, and before 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 the past two months; (V199)
- **Product water chemical analysis:** From each portable RO unit for the 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)

►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)

►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., an 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 a 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).

- ***Self-Monitoring Data:*** *Verify evidence of review of self-monitoring data and other information (e.g., treatment records, flowsheets, and medications administered), and confirm that an appropriate dialysis facility staff member has reviewed at least every 2 months. (V587)*
- **Patient Education:** Look for evidence of resident/designee education regarding all options for dialysis modalities and settings, and information on advanced directives. (V457, V458)

►TASK: Training and Competency Review at the ESRD Facility

Review the training and competency records of any nursing home staff that administer dialysis treatments to its resident(s). Ensure that each RN, LPN/LVN , nurse aide, or another dialysis administering personnel has completed a qualified home training program (V582-V586) and has initial and ongoing competency testing verified and documented (V586).

Note: This review is to confirm adequate training of any nursing home staff that administers dialysis treatments to its resident(s) acting in the role of their designated caregiver. If the dialysis treatments are administered to the resident(s) by the dialysis facility staff, their qualifications will be reviewed in the Personnel Record Review task outlined in the ESRD Facility Core Survey Process.

►TASK: Quality Assessment and Performance Improvement Review

During the QAPI Review at the ESRD facility, expect to see the 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. Evidence of collaboration and coordination may include, but are not limited to:
    - Recurring meetings and *bi-directional communication for information exchanges* between the ESRD facility and the nursing home leadership/*staff*;
    - Communication plans for reporting adverse events and appropriate interventions; and
    - 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:	Fatimah Wilson
To:	Yakaboski, Greg; Waller, Martha K; Stancil, Tiffany C
Subject:	[External] No Review FMC of Kinston Dialysis Unit No Review FID# 955898
Date:	Wednesday, December 4, 2024 9:51:08 AM
Attachments:	image001.png image002.png Lenoir FMC of Kinston Dialysis Unit Add a New SNF Program No Review.pdf

Good morning,

Hope you all are doing well. Please see attached a No Review request for the above referenced facility.

Let me know if you have any questions.

Thanks

FRESENIUS MEDICAL CARE

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Thrive On