

**Acute Care Services Committee
Agency Report
Adjusted Need Petition for an End-Stage Renal Disease Facility
at a Skilled Nursing Facility as a
Pilot Demonstration Project
in the 2023 State Medical Facilities Plan**

Petitioner:

Liberty Healthcare & Rehabilitation Services

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Request:

Liberty (Liberty) Healthcare & Rehabilitation Services requests a nursing home pilot demonstration project of six outpatient dialysis stations in Mecklenburg County to be located at Royal Park (Royal Park) of Matthews Rehabilitation and Health Center.

Background Information:

Chapter Two of the State Medical Facilities Plan (SMFP or the “Plan”) provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The annual planning process and timeline allows for submission of petitions requesting adjustments to need projections to the State Health Coordinating Council (SHCC) in the summer. Any person may submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

There are two methodologies in the SMFP for End-Stage Renal Disease (ESRD) services: the county need methodology projects need for the county; the facility need methodology projects need for a specific facility. When a county need determination exists, an existing provider may apply to add stations in an existing facility. Anyone may apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations. The Petitioner is seeking a special need determination that falls outside both standard methodologies.

Outpatient (in-center) dialysis services in nursing homes have never been provided in North Carolina. In March 2022, the Petitioner requested Policy ESRD-4 be added to the 2023 SMFP. The Policy would have allowed for the development or expansion of a kidney disease treatment center at a skilled nursing facility. The Agency recommended denial of the petition because the summer petition process is available to propose an adjusted county need determination for this purpose. The Acute Care Services Committee and the SHCC voted to accept the Agency's recommendation and deny the Petition. The Agency also noted that the county need determination could stipulate that the new stations would have to be sited at a nursing home facility or "proximate to the nursing home building."

Analysis/Implications:

The Petition states that the development of an outpatient dialysis facility at a nursing home helps meet the Basic Principles outlined in the SMFP. Specifically, a facility would make dialysis services more accessible to patients and encourage home dialysis. It would also provide dialysis services at times that do not interfere with the patient's scheduled treatments, therapies/rehab, meals, medication, and family visits.

The use of demonstration projects in the SMFP are reserved to test the delivery and viability of unique approaches to health services having a statewide impact. The request to establish a new dialysis outpatient facility in a single county does not meet the requirements of a demonstration project.

Comments in response to the Petition discussed the proximity of dialysis facilities to Royal Park, suggesting that the patients have ample dialysis options nearby. The Petition makes the point that having a dialysis facility at a nursing home would alleviate the burden of transporting nursing home dialysis patients to existing dialysis facilities. Commenters also noted that because Mecklenburg County has 22 existing certified outpatient dialysis facilities and one proposed facility for a total of 579 stations (in the 2023 Proposed SMFP), the addition of six outpatient dialysis stations would create an unnecessary duplication of dialysis services in the county. It is doubtful that the addition of six stations at a nursing home facility would have an appreciable impact on dialysis providers in Mecklenburg County.

Additional comments expressed doubts that a nursing home facility could manage and provide quality dialysis in the same manner as an outpatient dialysis facility. It appears that the commenters assume that "regular" nursing home staff would be providing dialysis services. Conversely, as noted in the Agency Report presented at the April 12, 2022, Acute Care Services Committee meeting, the Centers for Medicare & Medicaid Services (CMS) established specific requirements for the provision of dialysis to nursing homes patients in the community and in nursing home facilities. The *CMS State Operations Manual*¹ (CMS SOM) (attached) specifically states that in-center dialysis may be provided by: transporting the resident to and from a separately certified ESRD facility located off-site of the nursing home; or transporting the resident to and from a separately certified ESRD facility providing in-center dialysis located within the nursing home or

¹ CMS State Operations Manual. (Rev. 205, 3-11-22). Chapter 2: The Certification Process, section 2271A – Dialysis in Nursing Homes, pp. 275-281. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>. Accessed August 22, 2022.

“proximate to the nursing home building.” These dialysis treatments must be administered and supervised by personnel who meet the criteria for training and competency verification set forth in 42 CFR 494.100(a) and (b). In addition, dialysis services must be provided through a written agreement between the nursing home and the ESRD facility. In addition, home dialysis may be provided in nursing homes. Further, the CMS SOM outlines the requirements and provides guidance for mitigating risk for residents receiving dialysis treatment in a nursing home facility. In short, a dialysis facility at a nursing home must meet all the same qualifications and certification requirements as a dialysis facility in the community.

Agency Recommendation:

The Agency recognizes that dialysis patients in nursing homes are typically fragile. As such, it is reasonable that dialysis should be provided in a manner that is most appropriate to their healthcare needs. Providing dialysis in the nursing home facility is a viable option to achieve this goal. The SHCC has echoed these notions in previous discussions.

The Petition requested a “pilot demonstration” project. Demonstration projects in the SMFP test the delivery and viability of unique approaches to health services. Dialysis is provided successfully in nursing homes in quite a few states. Therefore, neither a formal pilot study nor a demonstration project is needed.

The Agency supports the standard methodologies for ESRD facilities. Based on these standard methodologies, the Agency cannot recommend a pilot demonstration project.

As an alternative, the Agency recommends approving a county need determination for six outpatient dialysis stations at a nursing home facility in Mecklenburg County with the following stipulations:

- 1) a licensed nursing home facility shall propose to develop at least the minimum number of stations required for Medicare certification by CMS as a dialysis facility; and
- 2) the new stations must be sited within a nursing home facility or “proximate to the nursing home building,” i.e., on the same property as the nursing home facility; and
- 3) the dialysis facility must comply with the federal life safety and building code requirements applicable to a nursing home if located within it and the life safety and building code requirements applicable to dialysis facilities if located within the nursing home or “proximate to the nursing home building;” and
- 4) the Certificate of Need will include a condition requiring the dialysis facility to document that it has applied for Medicare certification no later than three years from the effective date of the CON; and
- 5) dialysis stations developed pursuant to this need determination are excluded from the planning inventory in the SMFP and excluded from the county and facility need methodologies; and
- 6) outpatient dialysis facilities developed pursuant to this need determination shall report utilization to the Agency in the same manner as other outpatient dialysis facilities.

As stated above, any person may submit a CON application for this need determination.

Excerpt from

State Operations Manual
Chapter 2 - The Certification Process

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(Rev. 205, 03-11-22)

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>

space/dimension and other requirements for each in-center dialysis stations and the home dialysis training and support room/area.

Home Training and Support Program:

Approval to provide home training and support services requires the dialysis facility to provide both home training to the patient and/or their care partner in the modality and ongoing support and monitoring of the patient/care partner, as outlined in 42 CFR §494.100. An approved home training and support program must include both training and support services. A dialysis facility that is approved to provide services to home patients must ensure through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable ESRD CfCs.

There are no requirements for a specification of the number of training stations. The expectation for these services is that there will be sufficient space to provide an appropriate learning environment for each patient and care partner, if applicable. The in-facility home dialysis training and support space must be large enough to accommodate the dialysis equipment, routine and emergency care, to afford patient privacy, and to prevent cross-contamination with pathogens.

In accordance with §494.100(c)(1)(vii), facilities which provide only home dialysis training and support must have a plan/arrangement in place to provide emergency back-up dialysis services when there is an interruption, or anticipated interruption, in a patient's routine home dialysis treatment. Situations that may require back-up dialysis services include, but are not limited to, non-functional equipment, power or water outages, availability of a designated care partner and/or a patient's anticipated travel away from their home.

The home dialysis support services may be provided directly by the ESRD facility or by arrangement with another ESRD facility. If the support services are provided by another ESRD facility, such arrangements should be made at a location as convenient to the patient's home as possible, regardless of facility ownership.

2271A - Dialysis in Nursing Homes

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

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.

Overview: Dialysis for Nursing Home Residents

Medicare reimbursement for dialysis services is available to certified ESRD facilities. All dialysis patients must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare.

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:

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

2. Home Dialysis in a Nursing Home:

Residents may receive dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for training, and competency verification in 42 CFR 494.100(a) and (b) as also stated in this guidance, and are provided through a written agreement between the nursing home and the ESRD facility.

Mitigating risks for residents receiving dialysis treatments in a nursing home include: 1) ensuring only qualified personnel administer, monitor, and supervise the dialysis treatments; 2) monitoring the dialysis patient's status before, during, and after the treatments; and 3) ensuring a safe and sanitary environment for the treatments.

The goal of this guidance is to ensure that an ESRD facility, providing home dialysis services to a nursing home resident under a written agreement with the resident's nursing home, maintains direct responsibility for the dialysis related care and services provided to the nursing home resident(s) consistent with the ESRD Conditions for Coverage (CfC) requirements as well as the terms of an applicable agreement with the nursing home.

ESRD Notification to the State Survey Agency of a New or Additional Contract with a Nursing Home to Provide Dialysis Services On-Site

No additional approval is required from CMS for an ESRD facility to enter into an agreement with a nursing home to provide dialysis services to nursing home residents. However, the ESRD facility must notify its State Survey Agency (SA) 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. Only the following applicable fields of the Form CMS-3427 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?

Written Agreement between the ESRD Facility and the Long Term Care Facility

The ESRD facility is expected to enter into a written agreement with any individual nursing home for which they will provide dialysis services. The agreement delineates the responsibilities of the ESRD facility and the nursing home regarding the care of the resident before, during, and after dialysis treatments.

The ESRD facility is ultimately responsible for the safe delivery of dialysis to the nursing home resident which would include review of the qualifications, training, competency verification, and monitoring of all personnel who administer dialysis treatments in the nursing home and who provide on-site supervision of dialysis treatments. The ESRD facility is responsible for the quality and safety of the dialysis treatments and the management of the residents' ESRD-related conditions. The ESRD facility is also responsible for providing all equipment necessary for the resident's dialysis treatment and for the maintenance of such equipment.

The nursing home is responsible for providing a safe environment for the dialysis treatments, monitoring the resident before, during, and after dialysis treatments for complications possibly related to dialysis, and provides all non-dialysis related care. Nursing home staff must be prepared to appropriately address and respond to dialysis related complications and provide emergency interventions, as needed. See 42 CFR §483.25(l) and SOM App. PP at tag F698.

Both the ESRD facility and the nursing home are responsible for ensuring the collaboration necessary to provide dialysis care coordination to each nursing home resident receiving dialysis treatments.

The written agreement must be signed by authorized representatives of the Medicare-certified dialysis facility and the nursing home prior to the provision of dialysis care at the nursing home and must:

1. Delineate the lines of authority of each party;
2. Delineate the responsibilities of each party;
3. Describe how coordination between the parties will occur;
4. Describes the accountability for the dialysis services provided;
5. Be consistent with the written policies and procedures of the ESRD facility and the nursing home;
6. Specify the method by which the parties will ensure adherence to the terms of the agreement, communicate as issues arise, and take remedial action when appropriate; and
7. Be reviewed at least annually, and updated as needed.

ESRD Policies and Procedures for Services to Residents Located in a Nursing Home

At a minimum, the ESRD facility, in collaboration with the nursing home, must develop and implement protocols for the delivery of ESRD services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. The protocols must include requirements set forth at 42 CFR 494.30 and 494.80 through 494.100. These protocols include procedures for infection control, patient assessment, patient plans of care, and care of the dialysis patient at home.

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

Dialysis Supervision and Administration

The ESRD facility providing services to a resident in a nursing home must ensure:

1. Onsite supervision of dialysis by a trained registered nurse (RN) (who has completed a training course approved by the ESRD facility) whenever a resident is receiving hemodialysis (HD) in the nursing home, and by a trained RN or licensed practical/vocational nurse (LPN/LVN) (who has completed a training course approved by the ESRD facility) when a resident is receiving peritoneal dialysis (PD) treatment in the nursing home;
2. Qualified/trained dialysis administering personnel are present in the room and maintain direct visual contact with the resident receiving HD throughout the entire duration of the treatment (the supervising nurse may also be the dialysis administering personnel); and
3. If a situation occurs where the nursing home is unable to provide dialysis treatments due to reasons such as insufficient trained staff and/or supervision, the ESRD facility is notified and provides the dialysis treatments to avoid a delay or cancellation of treatment.

Documentation of training and competency verifications for nursing home staff should be maintained by both the ESRD and nursing home facility.

Hemodialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a trained supervising RN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's hemodialysis treatment. The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs who supervise hemodialysis treatments in the nursing home must have successfully completed a training program which:

- Covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii);
- Is approved by the dialysis facility medical director and governing body;
- Is administered under the direction of a home training nurse meeting the qualifications at §494.140(b)(2); and
- Is 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).

Peritoneal Dialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a qualified supervising RN/LPN/LVN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's PD treatment (i.e. automated PD, continuous ambulatory PD). The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and be readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs/LPNs/LVNs who supervise PD treatments in the nursing home must successfully complete a training program that is:

- Specific to PD care and covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii)
- Approved by the dialysis facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
- 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).

Hemodialysis and Peritoneal Dialysis Administration

Qualifications: The personnel who initiate and discontinue dialysis treatments for HD and PD to nursing home residents must be a RN, LPN or LVN who meets the practice requirements in the State in which he or she is employed. A trained nursing home staff member such as a nurse aide or trained caregiver may monitor the patient for the duration of the patient's treatment, but initiation and discontinuation of HD and PD must only be performed by the supervising nurse.

Training: The dialysis administering personnel, for example RN, LPN/LVN, nurse aide or trained caregiver, must receive adequate training and possess sufficient competency to ensure that the resident on dialysis receives a safe and effective treatment. The training must be:

- 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).
- 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) and;
- Specific to the dialysis modality. The training program for HD and PD must include at least the subject matter listed at §494.100 (a)(3)(i-viii) .

Ongoing competency for dialysis administering personnel must be verified through visual audits by an ESRD RN who meets the qualifications of home training nurse at §494.140(b)(2) . Frequency for competency verification is 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 may be an indicator to review dialysis procedures performed by the nursing home staff and possible re-training.

In-Room Presence

To assure resident safety, the ESRD facility and nursing home must ensure that qualified dialysis administering personnel remain in the room with direct visual contact of the resident and their vascular access throughout the hemodialysis treatment, in accordance with §494.60(c)(4).

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 dialysis treatments in the nursing home. The collaborative decision-making process for such situations must be addressed in the written 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.

Coordination of Care Communication

The ESRD facility and nursing home must establish procedures for 24/7 communication between the two entities. 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 RN's to be called for emergencies. There should be written agreement on a communication process to include how communication and responses will be coordinated and documented between the ESRD facility and nursing home staff.

Interdisciplinary Team (IDT) Coordination between ESRD Facility and Nursing Home Staff

The dialysis facility 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 both teams.

Emergency Plans

The dialysis facility maintains overall responsibility to prepare the nursing home to address all emergencies related to the dialysis needs of the resident receiving treatments in the nursing home. The following emergency plans must be clear and communicated to nursing home staff in a manner that allows for the continuity of care and be incorporated into the written agreement between the two entities:

1. Emergency Staffing

When the nursing home staff are functioning as the caregiver for the nursing home resident and providing the dialysis treatment for the resident, it is the responsibility of the nursing home staff to notify the ESRD facility of any delays or interruptions in the provision of the prescribed dialysis treatment. The ESRD facility is responsible for ensuring that a backup plan is in place to ensure the resident receives the treatment.

2. Emergency Care

Nursing Home residents receiving dialysis may have complications which require treatment with emergency medications or equipment. The physician treatment orders for the ESRD patient should include what emergency medications are to be kept on hand.

3. Equipment Failure

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.

Any equipment that is non-functional must be replaced or restored by the ESRD facility to avoid interruption of a patient's dialysis treatment.

4. Emergency Supplies

Nursing homes should maintain all necessary medication and 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 in excess of 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 must be in place for the safe delivery of additional supplies in the event of an emergency.

2271B - Dialysis in Hospitals

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

A department/unit of a hospital (other than a psychiatric hospital) may, as permitted under State law, provide either inpatient or outpatient dialysis services.

In certain situations dialysis services may be provided in a hospital department/unit for non-ESRD patients requiring temporary dialysis or for ESRD patients who are admitted to the hospital for other diagnoses or injuries. These dialysis services are referred to as "acute dialysis." A department /unit of a hospital that provides acute dialysis services must provide those services in compliance with the hospital Conditions of Participation (CoP) and are not subject to the ESRD CfCs.

Hospitals that provide outpatient dialysis services must be certified as a hospital-based ESRD facility.

2272 - ESRD Facility Classification

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Hospital-Based ESRD Facility

A hospital-based ESRD facility is a separately certified ESRD facility that is an outpatient department of a hospital and that meets the ESRD CfCs at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital (CAH) and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CMS certification number (CCN).

A hospital-based ESRD facility is discussed at 42 CFR §413.174(c) and meets the following criteria:

- The ESRD facility and hospital have a common governing body and are subject to