

Frequently Asked Questions Licensure of Home Hemodialysis in Nursing Homes

Terms Used in This Document:

- a. Nursing Home = Skilled Nursing Home (SNF) or a Nursing Facility (NF) that is located in New Jersey.
- b. ESRD Facility = A Medicare-certified end-stage renal disease (ESRD) facility that is located in New Jersey and that retains overall responsibility for all the dialysis care and services of the patient/resident.
- c. Coordination Agreement = A signed contract between the Nursing Home and the ESRD Facility to delineate coordination, collaboration, and responsibilities before, during, and after dialysis treatment.

1. When did CMS initiate the new modality of Home Hemodialysis in Nursing Homes?

- ESRD Facilities are licensed by the Department and can be certified by CMS to provide Home Hemodialysis Training and Support to their patients and/or the patient's caregivers to perform hemodialysis in the patient's home.
- In 2017, CMS recognized the benefits of dialysis being performed in the resident's home, that being, the Nursing Home. Residents would no longer need to be transported off-site to an ESRD Facility three times a week for multiple hours for each dialysis treatment.
- In August 2018 (revised 3/22/2023), CMS released guidance for home hemodialysis in a Nursing Home.¹ This modality allows dialysis to be provided in Nursing Homes that may contract with an ESRD Facility to provide dialysis services to its residents.

2. What are the models of hemodialysis service delivery in a Nursing Home?

There are currently two models of service delivery that may be implemented in a Nursing Home:

- Bedside hemodialysis: Hemodialysis at the resident's bedside can only be provided in a private room.² The Department has determined a "private room" to mean that the resident's room is single occupancy.

¹ CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home REVISED, dated August 17, 2018, revised 3/22/23. Ref: QSO-18-24-ESRD.

² Bedside hemodialysis ". . . shall be provided only in private rooms." N.J.A.C. 8:39-2.9(a)(3)(ii).

- Den setting: A common area within the Nursing Home where hemodialysis is provided to multiple residents.³ The “space required by the [Nursing Home] programs shall not be used.”⁴

3. How will this service delivery model appear on the license of the Nursing Home and ESRD Facility?

- a. Nursing Home: The following will be listed under the Services category:⁵
 - If dialysis is provided only in resident rooms: “Home Hemodialysis – Bedside.”
 - If dialysis is provided only in a den setting: “Home Hemodialysis - Den - # of Stations.”
 - If dialysis is provided at the bedside and in a den setting: “Home Hemodialysis – Bedside” and “Home Hemodialysis – Den - # of Stations.”
- b. Contracted ESRD Facility:
 - The den setting will be licensed as a Satellite of the contracted ESRD Facility.⁶
 - The contracted ESRD Facility license will state: “Satellites = #”.
 - The Satellite license will be assigned a 5-digit Satellite number and state under the Services category: “Satellite - Home Hemodialysis in [Name of Nursing Home].”

4. What ownership structure of the den setting is permitted in NJ?

- Home dialysis services are provided to residents within the Nursing Home in which they live, that is, within their “home.”
- Therefore, a den setting, inclusive of all required architectural components and the hemodialysis treatment chairs, must be exclusively owned by the Nursing Home in which home dialysis services will be provided to the residents. No other ownership structure is permitted.

5. How far can the Satellite be from the contracted ESRD Facility?

- N.J.A.C. 8:43A-1.3 requires that a Satellite be “. . . within 30 miles of the separately licensed ambulatory care facility.” The Department will consider a waiver to this requirement based on the ESRD Facility’s submission of the following:

³ See Footnote 1. Section, Nursing Home Dialysis in a Common Area. Page 7.

⁴ See N.J.A.C. 8:39-2.9(d)(2).

⁵ “Hemodialysis shall be listed as a “service” on the facility’s license.” N.J.A.C. 8:39-2.9(c)(7).

⁶ “Each site of service provision shall be considered a satellite.” N.J.A.C. 8:39-2.9(c)6. Also, “A satellite . . . shares the same governing authority and provides the same principal service as the separately licensed ambulatory care facility.” N.J.A.C. 8:43A-1.3.

- a. A detailed narrative that explains how communication, collaboration and coordination between the Nursing Home, the ESRD Facility, and the Satellite will be implemented and maintained; and
 - b. A fully executed Coordination Agreement between the Nursing Home and the ESRD Facility which solidifies the processes identified in Paragraph “a” above.
6. How many den settings are permitted in a nursing home?
- There is no limit to the number of den settings in a Nursing Home. However, in addition to architectural plans, the Nursing Home is required to submit, for each proposed den setting, a detailed narrative that confirms:
 - a. The space required by the Nursing Home programs is not used to establish the den setting(s); and
 - b. The Nursing Home will have, for each den setting, its own dialysis trained and dialysis competent RN who can recognize post-dialysis complications and assist with care in the event of an emergent situation.
7. What is the maximum number of stations that can be in a den setting?
- Currently, there is no limit to the number of stations that can be in a den setting.
8. Is there a limit to the number of resident rooms that may be utilized for bedside dialysis?
- Currently, there is no limit to the number of resident rooms that may be utilized for bedside dialysis.
 - However, a dialysis-qualified RN must “. . . remain in the [resident’s] room with direct visual contact of the resident and their vascular access throughout the hemodialysis treatment . . .⁷ Video surveillance is not permitted.
9. Is there a limit to the number of Nursing Homes that an ESRD Facility may contract with to provide hemodialysis services?
- Currently, there is no limit to the number of Nursing Homes in which the ESRD Facility may provide dialysis services.
10. Are all ESRD Facility personnel who provide dialysis to residents in a Nursing Home required to be employees of the ESRD Facility?
- The term “employee” is defined in N.J.A.C. 8:43A-1.3. Based on this definition:
 - a. All health care personnel, including but not limited to, Physicians and other clinical practitioners, RNs, LPNs, Patient Care Technicians, Social Workers and Dietitians, must be “employees” of the ESRD Facility.

⁷ CMS State Operations Manual, Chapter 2 – The Certification Process. Section, End Stage Renal Disease (ESRD) Facilities. Paragraph 2271A, Dialysis in Nursing Homes (effective 9/21/18). Subparagraph, Hemodialysis and Peritoneal Dialysis Administration – In-Room Presence.

- b. Physicians and other clinical practitioners must be either salaried by or be granted clinical privileges by the ESRD Facility to provide medical care to the patients of the ESRD Facility.

Note: Staffing by the contracted ESRD Facility for the provision of dialysis in a Nursing Home, whether at the bedside or in a den setting, must be in compliance with all State regulatory requirements, including N.J.A.C. 8:43A-24.7.

11. What are the State and Federal requirements for an ESRD Facility to provide hemodialysis in a Nursing Home?

The ESRD Facility must:

- State: “Demonstrate the ability to serve nine (9) patients Statewide within six (6) months of licensing approval.”⁸
 - If the ESRD Facility has not satisfied this requirement, the ESRD Facility may submit, for the Department’s consideration, a waiver application that includes a detailed explanation of the facility’s current ability to provide dialysis care and services in accordance with all Federal and State regulatory requirements.
- State: “Have a NJ office or execute a jurisdictional agreement with the Department.”⁹
 - This regulation is superseded by the CMS requirement that, in order for the contracted ESRD Facility to provide dialysis care and services to residents of a Nursing Home, both the contracted ESRD Facility and the Nursing Home must be located within New Jersey.
- State: Be licensed by the Department for Home Hemodialysis Training; and
- Federal: Be CMS certified for Home Hemodialysis Training and Support.¹⁰
- An ESRD Facility applicant must satisfy all eligibility requirements as listed above *before* submitting an application to the Department for consideration to provide home hemodialysis services to residents in a Nursing Home.

12. To initiate the licensure process for the addition of home hemodialysis in a Nursing Home, what must the Nursing Home and ESRD Facility submit to the Department?

a. The Nursing Home must submit:

Architectural Plans:

Bedside dialysis:

- A floor plan of each resident room in which dialysis will be provided. The floor plan must provide enough detail to clearly demonstrate that the architectural

⁸See N.J.A.C. 8:39-2.9(c)2.

⁹ See N.J.A.C. 8:39-2.9(c)3.

¹⁰ See Footnote 1. Section, Background. “. . . ESRD facilities with an approved Home Training and Support modality may provide home dialysis services to residents in a LTC facility.” Page 2.

requirements for bedside dialysis are met. Each room in which dialysis will be provided must be identified with a specific room number.

Dialysis Den:

- Architectural plans, which are fully scaled, detailed, and labeled, must be submitted in succession, for review and approval by the Department of Health, Department of Community Affairs, and the local building authorities.
- Architectural plans must comply with the requirements set forth in N.J.A.C. 8:43A-24.¹¹

Licensure Documentation:

- A licensure application to add one of the hemodialysis services identified in Item 3 (Page 2) of this document.
- A Coordination Agreement that is signed and dated by an authorized representative(s) of the Nursing Home and the approved ESRD Facility.¹² The provisions that must be included in the Coordination Agreement are listed on Page 8 of this document.
- A licensure application must be submitted by the Nursing Home, for review and approval, prior to a change (addition and/or deletion) of the location (bedside and/or den setting) where dialysis services will be provided.
- The Nursing Home must notify the Department, in writing, 30 days prior to a change of the contracted ESRD Facility and “. . . shall include a plan for the continuing care of any dialysis patients.”¹³

b. The ESRD Facility must submit:

Architectural Plans: None.

Licensure Documentation:

- An application for licensure of its Satellite to provide home hemodialysis in a Nursing Home.¹⁴ The application must be linked to a specific Nursing Home.
- A licensure application must be submitted for each Satellite in which the ESRD Facility wishes to provide home hemodialysis services in a Nursing Home(s).

¹¹ See N.J.A.C. 8:39-2.9(d)(2).

¹² “A copy of the contract between the dialysis provider and the long-term care facility shall be included with the licensing application. The contract shall clearly state the roles and responsibilities of both the dialysis provider and the long-term care facility.” N.J.A.C. 8:39-2.9(c)5.

¹³ See N.J.A.C. 8:39-2.9(c)(8).

¹⁴ “The dialysis provider shall file a licensing application in order to be authorized to provide the service.” N.J.A.C. 8:39-2.9(c)(1). Also, “Any change in dialysis provider shall require prior authorization and submission of a separate licensure application by the new dialysis provider.” N.J.A.C. 8:39-2.9(c)(5) and (d)(1).

13. May individuals from the community receive hemodialysis in the dialysis den?

- Inasmuch as the Nursing Home is the resident's "home," the dialysis patient population in the den setting, is restricted to only those residents of the Nursing Home in which home dialysis services are provided by the contracted ESRD Facility.
- This licensure model is *not* inclusive of ESRD providers seeking to license an ESRD Facility that will serve Nursing Home residents as well as individuals from the community. These ESRD providers must be licensed as freestanding ESRD Facilities and be separate and distinct from the Nursing Home.

14. What type of dialysis machine can be used in the Nursing Home?

- Both conventional and non-conventional hemodialysis machines may be used in the Nursing Home.
- A non-conventional hemodialysis machine is a preconfigured machine that offers water purification and dialysate production in one integrated unit, i.e., NxStage PureFlow SL machine.

15. Is each nursing home resident required to have his/her own dialysis machine?

- "The ESRD Conditions for Coverage do not explicitly require that each home dialysis patient have their own designated home dialysis machine."¹⁵

16. Is a central water treatment and delivery system permissible for nursing home dialysis in a den setting?

- Per CMS, "A central water treatment and delivery system remains the traditional method for water purification for multiple hemodialysis machines in a *dialysis facility*."¹⁶
- The terms "dialysis facility" or "ESRD facility" refer to a ". . . *certified* end-stage renal disease (ESRD) facility that retains overall responsibility for all the dialysis care and services of the patient."¹⁷
- Inasmuch as a den setting is not a certified ESRD facility and inasmuch as a central water treatment and delivery system is not consistent with a home dialysis program, the use of the aforementioned system in a den setting is not permitted.
- Alternative methods of delivering AAMI quality water to the point of use (hemodialysis machine) in a den setting can include portable reverse osmosis

¹⁵ COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, updated 10/13/22. Section, Home Dialysis Machine Designation – Clarification. Page 28.

¹⁶ See Footnote 7. Paragraph 2273, Dialysis Modalities and Dialysis Related Services (effective 9/21/18). Subparagraph, Portable Reverse Osmosis (RO) Systems.

¹⁷ See Footnote 7. Paragraph 2271A, Dialysis in Nursing Homes (effective 9/21/18). Subparagraph, Terms Used in This Guidance.

(RO) units and/or preconfigured, non-conventional hemodialysis systems.¹⁸

17. Is an isolation room required in a nursing home den setting?

- The den setting “. . . must have the capacity to treat one or more Hepatitis B Virus Positive (HBV+) residents in an isolation room or isolation area . . .”¹⁹
- CMS has defined an isolation area as “. . . an area or space separated from other dialysis stations by a space equivalent to the width of a hemodialysis station.”²⁰
- An alternative to an isolation room in the den setting will be considered by the Department. Consideration will be based on a review of the applicant’s submitted detailed narrative which must include, at a minimum, the measures that will be implemented to (a) separate residents requiring isolation from the mainstream of activity and (b) ensure strict adherence to the Centers for Disease Control and Prevention recommendations and the regulatory requirements regarding infection prevention and control.

18. How is the Department informed if the Nursing Home and ESRD Facility determine to discontinue hemodialysis within the Nursing Home?

- The Nursing Home and the ESRD Facility, in addition to the Satellite, must each submit a licensure application to de-license the hemodialysis service at least 30 days prior to discontinuing dialysis services.
- The Nursing Home must submit, for the Department’s review and approval, a transition plan for the continuing dialysis care of its residents before ceasing hemodialysis services in its facility.²¹
- The Nursing Home/ESRD Facility must notify, in writing, the resident and/or the resident’s family member and the guarantors of payment at least 30 days prior to the termination of hemodialysis services.

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¹⁸See Footnote 1. Attachment titled, Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes. Section III, ESRD Core Survey Tasks Conducted at the ESRD Facility after the Nursing Home Visit. Paragraph, TASK: Water Treatment and Dialysate Review. CMS addressed surveyor review of water treatment and dialysate testing for *only* portable reverse osmosis (RO) units and non-conventional hemodialysis systems, i.e., NxStage PureFlow SL. CMS did not include surveyor review of testing of a central water treatment system.

¹⁹ See Footnote 7. Paragraph 2281A – Isolation Room Waiver.

²⁰ See Footnote 7. Paragraph 2281A – Isolation Room Waiver.

²¹ “Both the provider and the long-term care facility shall inform the Department in writing 30 days prior to any planned service interruption and shall include a plan for the continuing care of any dialysis patients.” N.J.A.C. 8:39-2.9(c)8.

The Coordination Agreement between the Nursing Home and the ESRD Facility must include, but not be limited to, the following <i>clinical</i> provisions: ²²
1. Methods for enabling timely communication and collaboration between the Nursing Home and the ESRD Facility care teams.
2. Ensuring a safe and sanitary environment where the dialysis treatments occur.
3. Ensuring active participation of the Nursing Home and the ESRD Facility care teams in the development and implementation of individualized care plans.
4. Delineation of patient monitoring responsibilities before, during, and after each treatment, ensuring that NJ State scope-of-practice laws and limitations are adhered to when delineating responsibilities.
5. Process that ensures a review of the qualifications, training, competency verification, and monitoring of all personnel, patients/residents and caregivers (family members or friends) who administer dialysis treatments in the Nursing Home.
6. Procedures for preparing the Nursing Home staff to appropriately address and respond to dialysis-related complications and provide emergency interventions, as needed.
7. Procedures to make sure that all equipment necessary for the resident's dialysis treatment is available and maintained in working condition.

The Coordination Agreement between the Nursing Home and the ESRD Facility must . ²³
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. Describe 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.
7. Be reviewed at least annually and updated as needed.

²² See Footnote 1. Section, Written Agreement. Page 5.

²³ See Footnote 7. Paragraph 2271A, Dialysis in Nursing Homes. Subparagraph, Written Agreement between the ESRD Facility and the Long-Term Care Facility.