

Guidance and Instructions for Submitting a Limited Review Application for Nursing Home Hemodialysis Services

Part One-Guidance

End Stage Renal Dialysis (ESRD) providers may enter into agreements with nursing homes (NH) to provide hemodialysis services to residents on-site. The ESRD provider must be State licensed and federally certified to perform Home Hemodialysis and Training and submit a Limited Review Application (LRA) to apply to be State licensed in the service of Nursing Home Dialysis.

Services provided on-site at nursing homes may be provided to residents only. Hemodialysis can be performed on residents using machines such as NxStage that are approved for home use. This process is not appropriate for ESRD providers seeking to license a dialysis facility that will serve nursing home residents as well as the general community, or that will provide services using machines that are approved for multiple users and that operate using a dedicated, common water supply. Such facilities must be licensed as Diagnostic and Treatment Centers (D&TC) or hospital extension clinics, must be separate and distinct from the nursing home, and the appropriate CON application (Administrative or Full Review) must be submitted.

Except for residents who are currently trained and capable of self-performing home hemodialysis with a partner, only RN's who are employees of the ESRD provider and meet the requirements at 10 NYCRR 757.2(a)(4) may perform hemodialysis. Staff RNs from the ESRD provider may provide hemodialysis treatment to no more than two residents at one time, in one room, at the bedside; treatment rooms are limited to four residents at one time.

Each nursing home at which services will be provided must submit an LRA to add the appropriate Nursing Home Hemodialysis service to the operating certificate. The LRA requires completion of all the standard schedules, some of which require additional information specific to this project type. Services available are:

Nursing Home Hemodialysis-Bedside Only Hemodialysis performed in the resident's room. Additional information, including floorplans, must be submitted with the LRA.

Nursing Home Hemodialysis: Hemodialysis performed in a dedicated area known as a treatment room or "den". Additional information, including floorplans and architectural certification, must be submitted with the LRA. If there is any renovation or construction, all schedules required for a minor construction LRA must be included. NH licensed for this service may also perform hemodialysis at the bedside.

Note: Any NH may admit patients on peritoneal dialysis provided the resident is under the care of an ESRD that is State licensed and federally certified in Peritoneal Dialysis. The ESRD provider must submit a notice to the appropriate area office of the Division of Hospitals and Diagnostic and Treatment Centers for each NH, along with an updated CMS-3427 form which is available at the following link:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/cms3427esrdapplication.pdf>

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Initial Survey Requirements

Once the LRA has been approved, the NH project will be referred to the Area Office of the Division of Nursing Homes. If the ESRD provider is already State licensed to perform dialysis services in a NH, and the NH is only performing bedside hemodialysis, a survey may not be required, but may be performed at the discretion of the Department. Approval from the Area Office for the new NH location will be based on the review of policies and procedures and environmental checklists, that are uploaded through the NYSECON system. If the LRA is for the construction of a treatment room, then in addition to a review of these materials, an on-site survey will be conducted by staff from the Division of Hospitals and Diagnostic and Treatment Centers and may also include staff from the Division of Nursing Homes. Final approval will be contingent upon meeting all requirements, including the submission of an updated CMS 3427 form by the ESRD provider to reflect the addition of the new NH.

Recertification Survey Requirements

If a NH offers on-site dialysis services, surveyors from the Division of Nursing Homes will include residents receiving dialysis services during the recertification survey as part of the resident sample and will review the overall quality of care provided to residents receiving dialysis as described in the LTC State Operations Manual. Surveyors from the Division of Hospitals and Diagnostic and Treatment Centers will include visits to one or more of the NHs as part of the recertification surveys of the ESRD providers and will be responsible for reviewing the quality of the dialysis services provided.

Complaints

Complaints about dialysis services provided at NH will be reviewed and triaged according to established policies. A determination will be made as to the whether an on-site survey will be performed to investigate the complaint. Depending on the nature of the complaint this survey may be performed by staff from the Division of Nursing Homes or the Division of Hospitals and Diagnostic Treatment Centers, or a joint investigation may be performed.

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Part Two-Instructions for Completing and Submitting the LRA

Each nursing home and ESRD provider applying for the Nursing Home Hemodialysis service must submit a Limited Review Application (LRA). The ESRD provider only has to submit an LRA once. The nursing home must have an agreement with an ESRD provider that is already licensed in the Nursing Home Dialysis service, or the ESRD provider must submit a concurrent LRA to be licensed. This application is necessary for those proposed projects which are subject to a limited review pursuant to 10 NYCRR 710.1(c)(5)-(7). The LRA consists of a cover sheet and the schedules listed below as applicable:

Executive Summary	Data entry done online
Total Project Cost	Schedule LRA 2
Proposed Plan for Project Finance	Schedule LRA 3
Outline of Architectural/Engineering Action	Schedule LRA 4
Space & Construction Cost Distribution	Schedule LRA 5
Architectural or Engineering Certificate Form	Schedule LRA 6
Proposed Operating Budget	Schedule LRA 7
Staffing	Schedule LRA 8
Impact of Limited Review Application on Operating Certificate	Schedule LRA10
Part-Time Clinic	Schedule LRA11
Assurances	Schedule LRA12

PLEASE NOTE: Not all the schedules listed above will need to be completed. The responses given on the cover sheet will determine which schedules to complete. Below are instructions for completing schedules that require modified or specific information when applying for bedside or treatment room dialysis. Please complete ALL schedules that are required, even specific instructions are not provided below.

General Tab

The general tab provides the overview of the application. This is where the viewer can find information on the main site, project site, the contact information, and the alternate contact information. If there is an impact on the operating certificate, the information will be found in the General Tab.

Executive Summary

This is a narrative summary giving an overview of the project. This should include the purpose of the project; the service the facility is adding, whether it will be provided at the bedside or in a dedicated treatment room; the facility identification number, name and address of the ESRD provider the nursing home is choosing to contract with.

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Sites

Please describe in the sites summary the services requested:

- Nursing Home Hemodialysis-Bedside Only
- Nursing Home Hemodialysis

Schedule LRA 2-Total Project Cost

Complete as instructed, however, the nursing home should only provide the cost of the equipment and construction they are providing, not the cost of the equipment the dialysis company is providing.

Schedule LRA 6-Architecture/Engineering Submission

The Architectural Narrative shall include but not be limited to the following, for each type of service. A floor plan must be included for both bedside and treatment room applications.

Architectural Requirements	Treatment Room	Bedside
Programmatic changes as defined by the currently accepted version of the FGI Guidelines for Design and Construction of Residential Health Care, and Support Facilities are being followed.	✓	
ADA compliant	✓	
80 square feet where dialysis chairs are used	✓	
90 square feet where dialysis beds are used	✓	
A minimum clearance of four (4) feet shall be provided between beds and/or dialysis chairs	✓	✓
Two (2) refrigerators (one for medications and one for labs)	✓	
A clean sink for handwashing and a dirty sink	✓	
A separate clean area and dirty area	✓	
A medication preparation area not in the patient area	✓	
A staff work area in close proximity to, with direct visualization of, the patients	✓	✓
A crash cart/emergency equipment	✓	
Ability for dialysis staff to summon help (PA system, telephone paging system, etc.)	✓	✓
Access to a bathroom in close proximity to the dialysis treatment room	✓	
Generator and a sufficient number of plugs/outlets to provide dialysis services	✓	✓
Type 2 or Type 3 EES	✓	✓
Provision for drainage for the instrument effluent.	✓	✓
Liquid waste and drainage system shall be designed to minimize odor and prevent backflow	✓	✓
Secure storage to protect the personal dialysis equipment and supplies from unauthorized access	✓	✓

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Architectural Requirements	Treatment Room	Bedside
Environmental Services Room	✓	
Storage area for chronic dialysis supplies and equipment, must provide room for a 5-day reserve of emergency supplies/equipment for each patient	✓	✓
Two bedded resident rooms must have water and drainage access for dialysis, that does not prevent access or usage of the bathroom by residents of that room.		✓
Location of dialysis treatment room/support services shall be arranged to avoid unrelated travel through the resident units.	✓	

Other

The following information must be uploaded in the Applications tab under “Other”:

1. A copy of a contract with a back-up ESRD facility to provide dialysis services if the primary dialysis company is unable to provide dialysis service. It is unacceptable for an Emergency Department to be the primary back-up provider.
2. A copy of the contract with a hospital for residents who require transfer to a higher level of care.
3. The required education and experience requirements for RNs providing dialysis services at the nursing home. Except for residents who are currently trained and capable of self-performing home hemodialysis with a partner, only RN’s who are employees of the ESRD provider and meet the requirements at 10 NYCRR 757.2(a)(4) may perform hemodialysis. Staff RNs from the ESRD provider may provide hemodialysis treatment to no more than two residents at one time, in one room, at the bedside; treatment rooms will be limited to four residents at one time.
4. A signed contract between the ESRD facility and the nursing home staff to delineate responsibilities before, during, and after treatment. The chart below indicates the required elements of the contract and the respective responsibilities of the ESRD provider and the nursing home.

Contract Requirements	ESRD Provider	Nursing Home
Compliance with ESRD CfC 42 CFR 494.1-494.180 (related to care of residents receiving treatments in a nursing home).	✓	
Coordination between the ESRD Interdisciplinary Care Team (IDT) (MSW, RD, RN) and the Nursing Home IDT regarding the provision of dialysis treatments and ongoing communication regarding the resident’s condition and treatments. Provide consult with nursing home IDT regarding resident condition and provide face to face meeting if necessary.	✓	
Coordination with the nursing home to ensure that a RN trained in hemodialysis provides on-site supervision of the dialysis treatment.	✓	
Coordination with the nursing home to ensure qualified administering dialysis personnel remain in visual contact with the resident throughout the dialysis treatment.	✓	

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Contract Requirements	ESRD Provider	Nursing Home
Initial/on-going verification of competencies of the dialysis administering personnel including documented evidence of ESRD staff training in fire safety and medical emergencies prior to the start of initiation of patient care.	✓	
Ordering/providing dialysis supplies/medications.	✓	
Communication regarding the safety/cleanliness of the nursing home dialysis environment and resolution.	✓	
Provision of emergency care during dialysis in accordance with resident wishes and advanced directives.	✓	✓
Immediate reporting of any unexpected/adverse events during dialysis to the resident, their nephrologist, nursing home medical and nursing staff, and their responsible party.	✓	✓
Following the dialysis prescription, the dialysis related medications, communicating all changes in the orders to the dialysis administering personnel and nursing home IDT.	✓	
Review of treatment records to ensure accurate documentation of delivered dialysis treatments and effects on the resident during dialysis, including adverse events.	✓	
Monitoring lab values related to dialysis and acting upon them, if indicated.	✓	
Ensuring all dialysis equipment is maintained in good working order.	✓	
Test and monitor the water and dialysate quality for HD equipment.	✓	
Monthly visits with nephrologist or the practitioner treating the residents.	✓	
Providing periodic training to the nursing home staff regarding basic care of the dialysis patient.	✓	
Incorporation of services provided to residents into ESRD facility QAPI program.	✓	
Providing a safe and sanitary environment for dialysis including: infection control practices, room type specifics (isolation/roommate selection), monitoring/mitigating hazards, prohibiting intrusions into dialysis environment during treatment, and cleaning/disinfecting all dialysis equipment and usable supplies.	✓	✓
Protecting the personal dialysis equipment/supplies of the resident from unauthorized access.		✓
All supportive care of the resident (monitoring weight, dietary/fluid intake, conditions related to fluid overload/depletion/infection/electrolyte imbalance post dialysis)		✓
Written communication between the NH and ESRD on dialysis treatment orders, medication orders, patient assessment, and any changes in the patient condition.	✓	✓
Reviewing NH and ESRD plans of care and making collaborative revisions to ensure that the resident's needs are met, and their goals are attained.	✓	✓
Documentation that assessments, care provided, interventions by both facilities is complete, timely, and accurate.	✓	✓
Training and competency credential files for dialysis administering personnel are maintained by ESRD facility and NH.	✓	✓

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Contract Requirements	ESRD Provider	Nursing Home
Attestation that only an RN employed by the ESRD provider can initiate and discontinue dialysis and must be present throughout the entire dialysis treatment	✓	✓

The following Policies and Procedures will be required to be uploaded for review once the LRA is approved and referred to the Area Office:

Policies and Procedures	ESRD Provider	Nursing Home
Staffing (RN in room at all times, RN initiating and terminating treatments, qualifications of staff)	✓	
Emergency Preparedness (including a plan for backup dialysis that does not rely on an ER)	✓	✓
Medical Emergencies	✓	✓
Oversight of Water Treatment Systems	✓	
Reconciliation of Supplies Ordered	✓	✓
Monthly Physician Consult of the Nursing Home Dialysis Patient	✓	
Nursing Home Evaluation Prior to Accepting Patient into Program (include testing feed water)	✓	
Infection Control (include isolation, PPE use, storage of infectious waste, disinfection of machines and equipment)	✓	✓
Communication (ESRD staff must provide names and phone #s of on call staff available to NH 24/7)	✓	
Competency verification by visual audits of ESRD staff in NH while performing treatments (state frequency of audits)	✓	
Patient Assessment (Include timing of assessment by RN if patient has catheter vs fistula, and afterwards if patient shows signs of decompensating, include frequency of vital signs, call to the MD, communication between ESRD and NH staff)	✓	✓
Patient Plan of Care (include frequency of treatments, time of day for treatments, if resident refuses treatment, collaboration of IDT)	✓	✓
Care of the Dialysis Patient at Home	✓	✓
Providing Care for the Dialysis Patient during an Outbreak/Quarantine	✓	✓
Water Emergencies (Emergencies that interrupt water service prior to or during treatment)	✓	
Allowing a personal home dialysis caregiver/ care partner, who previously assisted the resident in their home with dialysis, to assist the resident with dialysis in the nursing home.	✓	✓