

Questions and Answers-Licensing of Nursing Home Hemodialysis Services

I. Application Questions

Q1. Is this guidance now in effect, or still a draft?

A1. Yes, this guidance is now in effect. Limited Review Applications (LRA) for Nursing Home Hemodialysis can be submitted through NYSE-CON

Q2. Does the nursing home have to submit an LRA to add these services to their operating certificate?

A2. Yes. Note that in order to be approved for the Nursing Home Dialysis service to operate a treatment room, the LRA must also include information to demonstrate that the program meets the architectural, engineering and staffing requirements for bedside programs as described in the LRA Guidance document. Nursing homes will need the flexibility to dialyze patients at the bedside especially in cases where isolation is required, such as patients with C-difficile or influenza, since treatment room has no provision for isolation.

Q3. Does an ESRD provider need to file an LRA for each nursing home they enter into this arrangement with?

A3. Once the ESRD provider is approved to offer Nursing Home Hemodialysis service, they do not need to submit subsequent LRAs for each nursing home for which they provide services.

Q4. Can a nursing home have more than one den?

A4. Yes, nursing homes can submit an LRA for approval to operate multiple dens initially. Once approved, any subsequent dens will require the submission of a new LRA.

Q5. If an ESRD provider is approved for nursing home dialysis services, does the nursing home need to submit something?

A5. Each nursing home must submit an LRA to provide dialysis services.

Q6. Does this approval allow the nursing home to provide outpatient services or can they only provide services for in house residents?

A6. This approval only allows nursing homes to provide services for their residents. If the nursing home seeks to provide services for outpatients, it must be licensed under Article 28 to operate a diagnostic and treatment center in a separate and distinct space.

Q7. Should the nursing home wish to become an ESRD provider to facilitate treatment of their own ESRD patients, would they have to go through the full CON process as any freestanding ESRD provider might?

A7. Yes.

Q8. Is there a limit to how many nursing homes can be serviced by one ESRD provider? Will there be a geographical limit to how far the ESRD provider can be located from the nursing homes it is servicing?

A8. Currently there will be no limits on the number of nursing homes that an ESRD provider can service or the geographical distance from the nursing homes. The application must describe how the ESRD provider will provide adequate staffing.

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- Q9.** Do facilities that have already been approved for bedside dialysis now need to submit an LRA to continue offering this service?
- A9.** Nursing homes that have already been approved for bedside dialysis or a den will not need to submit an LRA. The operating certificates for these nursing homes will be reissued to include the service *Nursing Home Hemodialysis-Bedside Only* or *Nursing Home Hemodialysis*, as appropriate. If a treatment room or den will be constructed after initial bedside only approval, then an LRA will need to be submitted.
- Q10.** If an ESRD provider has already been approved to provide bedside ESRD services to nursing home patients and a contract already exists to cover these services, must they now apply along with the nursing home to continue these services?
- A10.** The ESRD Provider will not be required to submit an LRA if previously approved, but any nursing home that the ESRD provider seeks to provide services, that is not already approved, must submit an LRA.
- Q11.** What about requests for approval for bedside dialysis that have already been submitted to the Department?
- A11.** Requests submitted prior to the stakeholder webinar held on June 19, 2019 will be processed in the order they were received. Requests after this date must be submitted through the LRA process. If a nursing home submitted a request for bedside approval prior to June 19, 2019 and has not yet been approved, and subsequently submits an LRA to construct a den, the request for bedside approval must be resubmitted along with the LRA for the den and will be considered as part of that application.
- Q12.** When will the LRA application be available? Will regulations need to be revised to implement this program?
- A12.** The LRA application guidance is now available. Regulatory revisions are not required. The Department is applying existing State regulations which require the submission of an LRA when applying for an additional level of service or when doing construction or reconfiguration of space. These regulations can be found at 10 NYCRR Section 710.1.
- Q13.** How long will it take for an LRA to be approved?
- A13.** That will depend on the completeness of the application and whether it is an application for the bedside model or the den model, which requires an on-site survey.
- Q14.** How many nursing homes will get approved for dialysis services? Will there be a limit?
- A14.** Currently there are no plans to impose a limit on the number of nursing homes approved to offer dialysis services.
- Q15.** Can a nursing home be approved to perform bedside dialysis while constructing the den?
- A15.** The nursing home can submit an LRA to perform bedside dialysis and once approved, can submit an LRA for the den model.

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II. Contract and Provider Responsibility Questions

Q16. Is there list of provisions that must be included in the contract between the nursing home and the dialysis provider?

A16. The list of provisions that must be included in the agreement between the nursing home and the dialysis provider is included in a Quality Safety and Oversight Group (QSOG) memorandum published by CMS on August 17, 2018. It is available at this link:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-24-ESRD.pdf>

The contract provisions are also included in the Guidance and Instructions for Submitting a Limited Review Application for Nursing Home Hemodialysis Services, available on the Department's CON website at the following link:

https://www.health.ny.gov/facilities/cons/more_information/docs/guidance_and_instructions_for_licensing_nursing_%20home_hemodialysis_services.pdf

Q17. How should the nursing home address residents receiving dialysis in their Emergency Preparedness (EP) plan?

A17. Federal ESRD regulations require that the dialysis center provide backup dialysis for all home dialysis patients, should the patient not be able to get dialysis at home. This requirement would also apply to residents receiving dialysis in a nursing home.

Q18. Who is responsible for administering any medications required during dialysis, the nurse employed by the nursing home or the ESRD nurse?

A18. The ESRD nurse is responsible for any medications administered during dialysis. Some medications may be included in the dialysis reimbursement.

Q19. If there is an emergency while a resident is receiving dialysis, who is responsible for responding, (providing medications and CPR if required). Would this be the responsibility of the nurse employed by the ESRD provider or the nurse employed by the nursing home? What emergency medications must be available?

A19. The nursing home is still responsible for the care of the resident, and procedures for handling emergencies should be spelled out in policies and procedures. The ESRD nurse will be responsible for terminating treatment, calling a code, and initiating CPR if applicable until the nursing home staff arrives to initiate their medical emergency protocols. The regulations do not list the required emergency medications.

Q20. Who is responsible for maintenance of the dialysis equipment?

A20. The ESRD provider is responsible for the maintenance of the dialysis machine. Preventative maintenance records must be available at the nursing home and will be reviewed by nursing home surveyors to ensure the equipment is in safe operating order and preventative maintenance has been completed by the ESRD staff per the manufacturer's recommendations.

Q21. Is the nursing home responsible for paying the ESRD nurses?

A21. The nurses performing dialysis must be employees of the ESRD provider.

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Q22. Is there a list of ESRD providers?

A22. A list of Diagnostic and Treatment Centers licensed to offer renal dialysis services can be downloaded from the HealthDataNY website at this link:

<https://health.data.ny.gov/Health/HFIS-Diagnostic-and-Treatment-Centers-ESRDs-and-AS/dwvu-bqzs>

Q23. How do the nursing homes get reimbursed?

A23. The Department does not establish reimbursement criteria. The dialysis machines and associated costs are billed to Medicare.

Q24. Will there be shared governance and liability for these arrangements? Will there have to be additional insurance?

A24. The nursing home and dialysis provider will be expected to address these issues in the terms of their agreement.

Q25. What is the process to follow if the nursing home will no longer provide in-center services?

A25. If a nursing home will no longer offer in-center services, the nursing home must submit an LRA to decertify the NH Hemodialysis service from their operating certificate. The ESRD provider and nursing home must work together to develop a plan to transition residents to outpatient dialysis before ceasing in-center services and the NH must submit the plan to the Department for review and approval as part of the LRA to decertify the service.

Q26. Can a NH enter into an exclusive arrangement with an ESRD provider? What about resident choice?

A26. The Department does not dictate business arrangements between providers. However, before entering into an exclusive contract with an ESRD provider, a nursing home should consider that a resident may have a pre-existing relationship with another ESRD provider and wish to continue that relationship and receive services from that provider, either off-site or at their bedside. Nursing homes may want to consider language in their agreements with ESRD providers that allow them the option to honor resident choice.

III. Clinical, Staffing and Treatment Questions

Q27. Although four residents are allowed in a den, is the RN to resident ratio 1:2 as in the bedside model or will a ratio of 1:4 be allowed?

A27. The allowable ratio in a den is one nurse who meets the requirements of 10 NYCRR 757.2(a)(4) plus an additional direct care staff, for four residents. The nurse and the direct care staff member must both be employed by the ESRD provider.

Q28. If a nursing home wants to provide bedside hemodialysis but only has single rooms, would it be acceptable for one nurse to supervise two patients in two single rooms if the rooms were side by side or directly across from each other?

A28. No. The nurse must be able to maintain direct contact with the resident and there must always be a nurse in the room while the resident is connected to the dialysis machine.

Q29. Does the RN have to be present at the bedside or in the den for the entire treatment?

A29. Yes.

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- Q30.** Is the RN expected to set up machines, perform water testing, initiate treatment, record vitals, administer medication, assess patients, verify vaccines, deal with emergent issues and plans of care all alone? Are patient care technicians allowed to assist with dialysis services? If so what services can they provide? Can they be employed by the nursing home or do they have to be employed by the ESRD provider?
- A30.** Patient care technicians may assist the nurse with some tasks and would satisfy the requirement for the additional direct care staff member described in Q27, above. All staff who provide hemodialysis care must be employed by the certified ESRD center and there must always be a nurse in the room while a patient is on the machine. The nurse must also initiate and terminate the hemodialysis treatment.
- Q31.** If the hospital's ESRD has an agreement to provide dialysis in a nursing home, do the nurses employed by the hospital dialysis have to perform the dialysis?
- A31.** The hemodialysis treatment must be provided by a licensed and certified outpatient ESRD center that is also approved for home hemodialysis. Only qualified staff employed by the outpatient ESRD center may perform home hemodialysis in this program.
- Q32.** Must the dialysis machine be one that is manufactured for home use only or can a machine normally being used in a dialysis center be used for nursing home patients if it is dedicated to one patient only?
- A32.** This model is based on the premise that residents are receiving services comparable to home dialysis, thus only machines approved by the FDA for home dialysis can be used. Each resident must have their own machine. If the machines are not approved by the FDA for home use, the nursing home must license the center under Article 28 as a diagnostic and treatment center, the center must be federally certified, and the facility must be separate and distinct from the nursing home.
- Q33.** In the den setting, must there be a dedicated reverse osmosis (RO) unit for each patient or can there be a dedicated RO per station?
- A33.** Each resident must have their own dialysis machine, but a dedicated RO per station will be allowed.
- Q34.** Can the NH use their own water supply, or must they use pre-packaged dialysate?
- A34.** Instruments used must have the capacity to use sterile prepared dialysate, a pre-configured system or a portable reverse osmosis (RO) unit that purifies the water. The use of a central water treatment system that would supply all the machines in the den will not be allowed.
- Q35.** Home dialysis patients are required to be seen by the nephrologist monthly. Will the nephrologist be required to visit nursing homes monthly to see residents receiving dialysis services?
- A35.** The ESRD provider must ensure that all dialysis patients are seen by a physician, nurse practitioner or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record. This requirement applies equally to residents receiving dialysis treatment in a nursing home, as they are expected to receive equivalent care to individuals receiving care at a dialysis center. A monthly visit is required for each resident by either a physician, an advanced practice registered nurse, or a physician assistant employed by the ESRD provider. This visit may be conducted in the dialysis facility, at the physician's office, or in the nursing home.

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- Q36.** How will the social worker from the nursing home be involved in the care for these residents? Can you give guidance as to the role of the dietician and social worker employed by the dialysis provider? What about the laboratory services that must be available?
- A36.** The roles of the social worker and dietician for both the nursing home and ESRD center are described in the respective federal regulations. It is expected that both providers will be in full compliance with all applicable regulations. Responsibilities for laboratory services should be described in the policies and procedures submitted by the nursing home.
- Q37.** How would a patient who is being discharged from a hospital to a nursing home be assessed for dialysis?
- A37.** All dialysis patients must be accepted into a certified ESRD center before their first outpatient treatment. There is no exception for home patients or individuals who will receive dialysis in a nursing home. The accepting/ attending nephrologist would have to assess the patient and write orders for treatment before the patient's first treatment in the nursing home. The outpatient nephrologist can accept the discharge summary from the hospital as an assessment, but the orders for dialysis must come from a physician that works at the certified ESRD center. At the first treatment in the nursing home, the RN does an assessment before treatment is initiated. The ESRD interdisciplinary team (IDT) must complete their assessment in 30 days or 13 treatments. From that IDT assessment, a treatment plan is developed.
- Q38.** If a resident must be transferred to either an ESRD center or hospital for dialysis, how will it be certain that there would be capacity?
- A38.** Back up treatment is the responsibility of the ESRD provider. This is required by the federal ESRD regulations. The hospital that admits the patient will be responsible for the inpatient dialysis.
- Q39.** Will the backup ESRD provider also have to be certified for Nursing Home Hemodialysis?
- A39.** No. The ESRD provider is responsible for identifying a plan and arranging for timely emergency back-up dialysis whenever needed by the nursing home dialysis patient. The Back-up dialysis plan should provide dialysis services that are equivalent to a certified facility.
- Q40.** Can a Transitional Care Unit (TCU) take dialysis patients?
- A40.** A TCU is a hospital demonstration project and is not a nursing home under New York State licensing and federal certification requirements, thus this model would not be applicable. If the hospital has been approved to provide acute dialysis, there is no restriction as to where the hospital can provide dialysis services (ER, ICU, bedside etc.)

IV. Architectural and Survey Requirements

- Q41.** What are the architectural specifications for dens?
- A41.** The architectural specifications are included in the *Guidance and Instructions for Submitting a Limited Review Application for Nursing Home Hemodialysis Services*, available on the Department's CON website at the following link:
https://www.health.ny.gov/facilities/cons/more_information/docs/guidance_and_instructions_for_licensing_nursing_%20home_hemodialysis_services.pdf

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- Q42.** Are floor plans required for an LRA for certification of the service of Nursing Home Hemodialysis – Bedside only and, if they are required, what is the necessary level of detail for those plans?
- A42.** Yes, floor plans are required. The plans should provide enough detail to clearly demonstrate that the architectural requirements for bedside approvals will be met (see table above).
- Q43.** Included in the checklist of Architectural Requirements is “a staff work area in close proximity to, with direct visualization of the patients”. This is not normally feasible due to considerations for patient privacy. Given that a nurse will be present in the room with the resident during treatment, is this necessary?
- A43.** Patients must be in view of the nurse during hemodialysis treatment to ensure patient safety. Video surveillance will not meet this requirement. Each patient, including his/her face, vascular access site, and bloodline connections must be able to be seen by the ESRD nurse throughout the dialysis treatment. If the ESRD nurse needs to be at a work area, for example to complete paperwork, the patients must remain in direct view of the ESRD nurse.
- Q44.** If a nursing home provides a treatment room for dialysis, an environmental services room is required. Can the nursing home environmental services room be used or does the treatment room have to have a separate environmental services room?
- A44.** The dialysis treatment room can have its own independent environmental services room or access to a general environmental services room on the same floor that is not department specific (e.g. a rehabilitation therapy or food service area environmental services room).
- Q45.** If the ratio for the den model is one nurse for every four residents, can a den be constructed to accommodate eight residents, if it is staffed by two nurses?
- A45.** Dens will be limited to four residents receiving dialysis services at one time. If there is a need to accommodate more residents, additional dens must be constructed.
- Q46.** What are the on-site survey guidelines?
- A46.** Survey guidelines are described in the CMS State operations manuals for nursing homes and for ESRD providers, available at the following links:
- CMS guidance for performing ESRD surveys in Long Term Care facilities:
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-24-ESRD.pdf>
- CMS State Operations Manual –Guidance for Surveyors for Long Term Care Facilities:
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf> (See Section 483.25(l) Dialysis)
- Q47.** Our facility is looking at a possible site for a dialysis den that would be in a building adjacent to our nursing home. Is it acceptable to locate the den in another building?
- A47.** No. The den must be located on the premises of the nursing home to ensure that it has the same level of support for fire protection and immediate availability of nursing home staff in the event of a medical emergency.

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- Q48.** The architectural requirements described in the LRA guidance state that the currently accepted version of the FGI Guidelines for Design and Construction of Residential Health Care and Support Facilities must be followed for treatment rooms. The current FGI guidelines typically used for a full dialysis center require a separate HVAC unit for six air changes. Does this requirement apply to the treatment room or can the treatment room rely on the existing HVAC system in the nursing home?
- A48.** FGI guidelines refer to Part 3 of the ANSI/ASHRAE/ASHE Standard 170: Ventilation of Health Care Facilities. Section 2.1-8.2.1.2 of FGI states the following: "Individual spaces used for imaging, infusion, and dialysis services that are listed in Table 8.1 in Standard 170 are treated the same as a space in a licensed facility and have the same HVAC requirements". Thus, the existing HVAC system in the nursing home would be acceptable if it meets the requirements of this section.
- Q49.** Can a nursing home construct a den on a residential unit, and move all residents needing dialysis to that floor?
- A49.** The Department has determined that this is not allowed. Per CFR 483.10(e)(7)(iii) and 10 NYCRR 415.3(d)(2)(ii)(a), a resident cannot be relocated simply for the convenience of staff, or cohorted by diagnosis. There are also FGI guidelines that state residential units should "be arranged to avoid unrelated travel through the units". We also have determined this would be inconsistent with regulations requiring nursing homes to provide residents with privacy and a home-like setting. Having a den on a residential unit will result in increased traffic through the unit, noise from alarms, and chemical smells from disinfection of the dialysis equipment, all of which will be disruptive for the residents. Locating a den on a residential floor may be considered on a case-by-case basis only if the proposed location does not require traversing the residential unit to access the service. Residents could not be cohorted, and approval would be contingent on the applicant demonstrating how the disruptive nature of the den would be mitigated. If the proposed den is not feasible, applicants will continue to have the option to apply for bedside hemodialysis treatment for residents of the facility.