



## Department of Health

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September 25, 2019

DHDTC DAL 19-08  
NH DAL 19-09

Dear Hospital CEO, Dialysis and Nursing Home Administrators:

On August 15, 2018, DHDTC Dear Administrator Letter (DAL) 18-11 was distributed to inform nursing homes and end stage renal dialysis (ESRD) providers that the Department of Health (Department) would be conducting a review to develop the State licensure requirements for dialysis services that are provided to residents in nursing homes. The Centers for Medicare and Medicaid Services (CMS) allows ESRD providers to offer these services if they are already federally certified in Home Hemodialysis Training and Support. Further, it was determined that this service meets the provisions of State regulations at 10 NYCRR 710.1, which require that a provider submit a Limited Review Application (LRA) when applying for an additional level of service or when doing construction or reconfiguration of space. As indicated in DAL 18-11, nursing homes could continue to request approval to offer dialysis services at the resident's bedside while the Department conducted its review, however, requests for approval to construct dedicated treatment rooms in nursing homes, known as dens, were not accepted during this period.

The review was conducted by a multi-disciplinary workgroup which developed a LRA process for State licensure of both the bedside and den models of nursing home hemodialysis. The workgroup reviewed State regulations as well as the recently released CMS State Operations Manuals (SOM) for surveys of nursing home hemodialysis. A stakeholder webinar to announce the proposed model for State licensure of both ESRD providers and nursing homes was held on June 19, 2019. The webinar slides describing the licensure requirements, as well as a list of answers to questions submitted from the provider community, are included with this letter. The licensure process will include the following steps:

- Nursing homes seeking to offer dialysis services on-site must submit a LRA through the New York State Electronic Certificate of Need (NYSECON) system to add the service of Nursing Home Hemodialysis or Nursing Home Hemodialysis-Bedside Only to the operating certificate.
- The nursing home must establish an agreement with an ESRD provider that has a fixed location, has been federally certified in Home Hemodialysis Training and Support, and has been State licensed or has submitted a LRA to be State licensed in Nursing Home Hemodialysis.
- If the nursing home is only performing bedside hemodialysis, an initial survey will be at the discretion of the Department. Approval will be based on the review of the agreement

between the nursing home and the ESRD provider, as well as policies and procedures and environmental checklists uploaded through the NYSECON system.

- If the LRA is for the construction of a treatment room, in addition to a review of the materials uploaded through NYSECON, approval will require an on-site pre-opening survey. A separate LRA must be submitted for any subsequent dens in the same facility.

Hemodialysis can be provided to residents of the nursing home only, using machines that are approved for individual use. Except for residents who are trained and capable of self-performing home hemodialysis, RNs who are employees of the ESRD provider and meet the requirements at 10 NYCRR §757.2(a)(4), must perform the dialysis procedure and may perform dialysis on no more than two residents at one time, in one room, at the bedside; or four residents at one time in a den. Note that these licensure requirements will not apply to peritoneal dialysis. Any nursing home may admit patients on peritoneal dialysis provided the resident is under the care of an ESRD provider that is State licensed and federally certified in peritoneal dialysis.

Please refer to the attached webinar slides titled “Dialysis in Nursing Homes – Proposed Licensing Model”. The LRA “Nursing Home Hemodialysis Guidance and Instructions” and the “FAQs for Nursing Home Hemodialysis” are posted on the Department’s Certificate of Need (CON) website at: [https://www.health.ny.gov/facilities/cons/more\\_information/#applications](https://www.health.ny.gov/facilities/cons/more_information/#applications). Requests to offer bedside hemodialysis received prior to June 19, 2019 will be processed in the order in which they were submitted; any subsequent applications for either bedside or den services must be submitted using the LRA process, which is now available through the Department’s NYESCON system.

Questions can be directed to [hospinfo@health.ny.gov](mailto:hospinfo@health.ny.gov) or by phone at (518) 402-1004.

Sincerely,

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Division of Nursing Home and ICF/IID Surveillance

Sincerely,

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Director  
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Diagnostic & Treatment Centers



# Dialysis in Nursing Homes Proposed Licensing Model

June 2019

# Agenda

- Background
- Proposed Licensure Model and Process
- State Requirements
- Ongoing Surveillance
- Questions

## Background

- In August of 2018, the Centers for Medicare and Medicaid Services (CMS) released guidance for a new modality, *Home Hemodialysis in Long Term Care*, to allow dialysis to be provided in Nursing Homes.
- This service was previously allowed by CMS under Home Dialysis and was licensed by the Department of Health (DOH) on a limited basis under the State operating certificate service category of *Home Hemodialysis Training and Support*.

## Background

- A new CMS State Operations Manual (SOM) released in November 2017 includes more detailed requirements for federal LTC surveys in nursing homes performing dialysis on-site. The SOM for surveys of ESRDs was also updated to include a review of any care provided in nursing homes.
- There are currently two new models of service delivery being considered by providers: 1) delivery of dialysis at the resident's bedside, and 2) delivery of dialysis in a dedicated space in the nursing home, also known as a treatment room or den.

## Background

- To date one dialysis provider has been approved to provide hemodialysis in dedicated spaces or “dens” in four nursing homes. These approvals followed the existing process for licensing the service of *Home Hemodialysis Training and Support*.
- The Department determined that a review of the process for licensing the “den” model was needed. In the interim, no additional applications for this model have been approved. A workgroup was formed to develop a licensure model.

## Background

- Applications for performing dialysis at the resident's bedside have continued to be accepted and approved while the new licensure model is under development.
- These approvals have been based on a similar process for approvals for Home Hemodialysis, which requires a notice to the regional office and review of supporting documents by the Division of Hospitals & Diagnostic and Treatment Centers.

## Background

The Department recognizes the benefits of dialysis performed on-site in nursing homes, including:

- Less disruptive-residents do not have to be transported off site.
- Cost-effective for the facility.
- Vent-dependent and fragile residents requiring dialysis, who would normally not have the opportunity to reside in a nursing home, can be treated safely.
- Treatment using dialysis machines approved for home use is less taxing (although generally treatments must be given five days a week instead of the three days as is done for in-center dialysis).

## Background

The proposed model will require nursing homes seeking to offer services on site to submit a Limited Review Application (LRA) through NYSECON. Why is an LRA needed?

- Unless specifically required in NYCRR Title 10, Section 710.1 to submit a *higher* level application for a service (e.g. ADHCP), the regulation requires an LRA for the addition of services. Programmatic review will include State requirements.
- Additionally, per 710.1 an LRA or higher level of application is required for construction and/or reconfiguration impacting resident space. Through the LRA there is an evaluation of the impact on construction to nursing home residents.

## Proposed Licensure Model

Two new licensure categories will be established for nursing homes:

- **Nursing Home Hemodialysis-Bedside Only:** Hemodialysis performed in the resident's room.
- **Nursing Home Hemodialysis:** Hemodialysis performed in a dedicated area known as a treatment room or "den". Nursing homes licensed for this service may also perform hemodialysis at the bedside.

## Proposed Licensure Model

One new licensure category will be established for ESRD providers:

**Nursing Home Hemodialysis:** ESRDs licensed in this service can provide hemodialysis services at the residents bedside or in a dedicated area known as a treatment room or “den”. The ESRD provider must first be State licensed and federally certified to provide Home Hemodialysis Training and Support.

## Proposed Licensure Model

- Note that these new services would not impact peritoneal dialysis. Any nursing home will be permitted to admit patients on peritoneal dialysis provided the resident is under the care of an ESRD provider that is State licensed and federally certified in Peritoneal Dialysis.
- Services provided on-site at nursing homes may be provided to residents only. Hemodialysis can only be performed on residents using machines that are approved for individual use.

## Proposed Licensure Model

- 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 are considered Diagnostic and Treatment Centers (D&TC). The D&TC must be separate and distinct from the nursing home and the appropriate CON application must be submitted.

## Proposed Licensure Process

- Each nursing home at which services will be provided must submit an LRA to add the appropriate Nursing Home Hemodialysis service to its operating certificate.
- The LRA requires completion of all the standard schedules, as well as specific information for this project type, including:
  - Floorplans, and for a treatment room, architectural certification;
  - A contract with the ESRD provider;
  - A description of ESRD staff qualifications and training.

## Proposed Licensure Process

- The ESRD provider must already be licensed and federally certified to perform Home Hemodialysis and Training and Support before submitting an LRA to apply to be State licensed in the service of Nursing Home Hemodialysis.
- The LRA requires completion of all the standard schedules, as well as specific information for this project type, including a contract with a nursing home.
- The ESRD provider only has to submit an initial LRA, which must be linked to a nursing home LRA. Any additional nursing homes the ESRD serves must apply individually.

## Proposed Licensure Process

- Once the LRAs have been approved by the respective programs, the project will be referred to the appropriate Area Office of the Division of Nursing Homes.
- If the nursing home is only performing bedside hemodialysis, an initial survey will be at the discretion of the Department.
- Approval from the Area Office will be based on the review of policies and procedures and environmental checklists uploaded through the NYSECON system.

## Proposed Licensure Process

- If the LRA is for the construction of a treatment room, in addition to a review of the materials uploaded through NYSECON, approval will require an on-site pre-opening survey. A separate LRA must be submitted for any subsequent dens in the same facility.
- The initial pre-opening survey will be performed by staff from the Division of Hospitals and Diagnostic and Treatment Centers and may include staff from the Division of Nursing Homes.

## State Requirements

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 at the bedside; treatment rooms will be limited to four residents at one time.

## State Requirements

- Nursing home personnel (RNs and LPNs) may assist with peritoneal dialysis treatments only.
- They must first complete a training course and may provide assistance only under the supervision and direction of the certified ESRD provider.

## Ongoing Surveillance

- Surveyors from the Division of Nursing Homes will include residents receiving dialysis services in their sample during the nursing home recertification survey.
- These surveys will include a review of the overall quality of care of dialysis services provided, as described in the CMS LTC State Operations Manual.

## Ongoing Surveillance

- Surveyors from the Division of Hospitals and Diagnostic and Treatment Centers will include visits to one or more nursing homes as part of the recertification surveys of the ESRD providers.
- These surveys will review the compliance of dialysis services provided with federal and State requirements.

## Ongoing Surveillance

- Complaints about dialysis services provided at nursing homes will be reviewed by the appropriate program (DNH or DHDTTC) depending on the nature of the complaint, and triaged according to established policies. A determination will be made as to whether an on-site survey will be performed to investigate the complaint.
- Depending on the nature of the complaint the survey may be performed by staff from DNH or DHDTTC, or a joint investigation may be performed.

# Questions?

## Resources

- 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/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) (See Section 483.25(l) *Dialysis*)