

**Acute Care Services Committee
Agency Report
Petition to Create an ESRD Policy to Allow for the
Development or Expansion of a Kidney Disease Treatment Center
at a Skilled Nursing Facility**

Petitioner:

Liberty Healthcare & Rehabilitation Services

Contact:

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Request:

Liberty (Liberty) Healthcare & Rehabilitation Services requests the creation of Policy ESRD-4 to allow to for the development or expansion of a kidney disease treatment center (“outpatient dialysis facility”) at a skilled nursing facility.

Background Information:

Chapter Two of the *North Carolina 2022 State Medical Facilities Plan (SMFP)* 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 allow for submission of petitions for changes to policies and methodologies to the State Health Coordinating Council (SHCC) in the spring.

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.

Outpatient (in-center) dialysis services in nursing homes have never been provided in North Carolina. Thus, the Petitioner requests the creation of the following policy as an alternative to the county need methodology for entities seeking to develop a kidney disease treatment center in a nursing home:

Policy ESRD-4: Development or Expansion of a Kidney Disease Treatment Center in a Nursing Home

Licensed nursing homes (see stipulations in 131E-102 (el)) may apply for a certificate of need to develop or expand an existing Medicare-certified kidney disease treatment center (outpatient dialysis facility) without regard to a county or facility need determination if all the following are true:

1. The nursing home proposes to develop or expand the facility on any campus on its license where nursing home beds are located.
2. The nursing home must own the outpatient dialysis facility*, but the nursing home may contract with another legal entity to operate the facility.
3. The nursing home must document that the patients it purposes to serve in an outpatient dialysis facility developed or expanded pursuant to this policy are appropriate for treatment in an outpatient dialysis facility located in a nursing home.
4. The nursing home must establish a relationship with a hospital-based dialysis facility (where applicable) to assist in the transition of patients from the hospital dialysis facility to the nursing home facility wherever possible.

*An independently certified End-Stage Renal Disease (“ESRD”) facility may be located within or proximal to an independently certified nursing home. Each facility is responsible for meeting the Medicare conditions or requirements for Medicare participation for the specific provider/supplier type and would be separately surveyed. Therefore, the certified ESRD facility must be owned by the same individual, parent or affiliated company as the nursing home.

The nursing home shall propose to develop at least the minimum number of stations allowed for Medicare certification by the Centers for Medicare & Medicaid Services (CMS). Certificate of Need will impose a condition requiring the nursing home to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.

The performance standards in 10A NCAC 14C .2203 do not apply to a proposal submitted by a nursing home pursuant to this policy.

Dialysis stations developed pursuant to this policy are excluded from the inventory in the State Medical Facilities Plan and excluded from the facility and county need methodologies.

Outpatient dialysis facilities developed or expanded pursuant to this policy shall report utilization to the Agency in the same manner as other facilities with outpatient dialysis stations.

Analysis/Implications:

The Centers for Medicare and Medicaid Services (CMS) regulates dialysis services. In 2018, CMS released guidance on the provision of dialysis to nursing home residents:

Residents of a nursing home may receive chronic dialysis treatments through two options:

1. In-Center Dialysis:
 - a. Transporting the resident to and from a separately certified ESRD facility that is located off-site of the nursing home for dialysis treatments; or
 - b. 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. (CMS Manual System, Pub.100-07 State Operations, Provider Certification, September 21, 2018 ([R181SOMA.pdf](#) ([cms.gov](#))))

Additional provisions in this same guidance document include discussion of procedures related to dialysis supervision and administration, qualifications and training of staff, coordination of care, and emergency plans. The language in the guidance assumes that the nursing home will have an agreement with a dialysis provider. However, it appears that an entity owned by the nursing home is not prevented from becoming certified as a dialysis provider, if it can meet the same stringent qualifications as any other provider.

The Agency was able to find one source of information regarding the extent of dialysis in nursing homes. BKD CPAs & Advisors reports that as of 2020, at least 25 states offer either home hemodialysis or in-center dialysis in nursing homes (<https://www.bkd.com/alert-article/2020/03/nursing-home-based-hemodialysis-opportunity-broaden-snf-patient-populations>). BKD, however, did not cite the original source for this information.

Dialysis providers in North Carolina currently may partner with a nursing home to provide home and/or in-center dialysis services in the nursing home. However, in-center services would require them to relocate dialysis stations from one of their existing facilities to the nursing home. The Petitioner seeks a method to develop new dialysis stations at a nursing home.

Although the Petitioner requested a policy as the means to “open the door” to the provision of dialysis in nursing homes, an existing option currently available to providers is to submit a summer petition to the SHCC for an adjusted county need determination. 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” (to use the CMS language, above). In addition, an adjusted need determination would exempt a CON applicant from the requirement to show a need for at least 10 stations (10A NCAC 14C .2203(a)), as it is unlikely that a nursing home would require that many stations. The applicant would still be required to show compliance with GEN-3, which requires the CON applicant to demonstrate in detail how the proposed project will promote the basic principles of the SMFP.

In general, county need determinations are rare. A county need determination is the only mechanism by which a new dialysis provider may enter a service area. A county need determination for dialysis stations at a nursing home would allow for the possibility of a new provider, but that new provider could only operate stations at a nursing home. Because of their rarity, CON applications for county needs are usually competitive.

It is important to note that even though stations would be sited at a nursing home, CMS regulations do not allow providers to limit service to residents of a specific nursing home. That is, any ESRD patient eligible for in-center dialysis might be served by a facility at a nursing home if a station is available. Whether this occurs depends on a referral from the patient’s nephrologist.

Commenters have noted that because North Carolina has over 400 nursing homes considerable unnecessary duplication of services would exist. Specifically, a large number of nursing home residents who are currently being served in existing dialysis facilities could be served at their nursing home instead. However, the substantial regulatory, staffing, and financial challenges associated with this endeavor may preclude many nursing homes from filing a CON to provide any type of dialysis services.

Additional comments received by the Agency on this Petition expressed doubt that nursing homes would be able to provide the services in a safe and medically sound manner. The Agency does not minimize these concerns and caveats, but resolving them is outside the purview of the SHCC. Moreover, the SHCC cannot guarantee that any nursing home, related entity, or contractor will be certified to provide dialysis in nursing homes. Rather, these concerns could be addressed via public comments in response to a CON application and, if approved, through the CMS certification process.

Agency Recommendation:

The Agency supports the standard methodologies for ESRD facilities. Given available information and comments submitted by the March 16, 2022 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition.