

Petition to Adjust the draft 2022 State Medical Facilities Plan

July 28, 2021

North Carolina Division of Health Service Regulation
Healthcare Planning
809 Ruggles Drive
Raleigh, North Carolina 27603
Via email: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

1. Petitioner

Petitioner:	Contact:
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2. Statement of Requested Adjustment / Correction

Carolina Dialysis, LLC requests a correction to the Draft 2022 State Medical Facilities Plan (SMFP), Table 9B, Column N, “Projected Total Available Stations for Orange County”.¹ The Draft SMFP reports only 37 stations are available for Orange County. There are in fact 41 stations available for Orange County.

3. Reasons for the Proposed Adjustment / Correction

The Draft 2022 SMFP incorrectly reports 37 dialysis stations available for Orange County in Table 9B, Column N. The Carolina Dialysis Carrboro facility currently has 41 dialysis stations. On February 22, 2021, DHHS approved CON Project ID # J-11995-20 allowing Carolina Dialysis to relocate 4 stations from Carolina Dialysis Carrboro to new facility within Orange County. Once those stations are relocated, Orange County will continue to have 41 dialysis stations: 37 stations at the Carrboro facility, and 4 stations at the new facility. At no time will those stations be removed from the county or cease to be available in the county for dialysis patients.

It appears that the Healthcare Planning Section has removed 4 dialysis stations from the Orange County inventory as a result of CON Project ID # J-11995-20, submitted pursuant to Policy ESRD-2 in the 2020 SMFP. Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. [...]”

¹ This petition focuses on Column N in Table 9B with respect to Orange County; however, inclusive in this request is the corresponding change to Column O which would result from application of Step 5 in the County Need Determination Methodology.

Throughout its Findings in support of its Conditional Approval of CON Project ID # J-11995-20 (“Findings”) the Department emphasizes that the stations are to be relocated *within* Orange County pursuant to ESRD-2, and it explicitly states “The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 *because the proposal does not change the dialysis station inventory in Orange County.*”² (Emphasis added). As demonstrated above, there is no change in the total inventory of stations in Orange County.

Additionally, not counting the 4 dialysis stations planned for the Orange County Home Dialysis facility in Table 9B is inconsistent with SMFP Chapter 9, Assumptions of the Methodology, which clearly states that dialysis stations dedicated to training of home dialysis patients are included in the planning inventory:

2. *Facilities may have been approved to use at least one dialysis station dedicated to training of home dialysis patients. If so, **these stations are included in the planning inventory.*** [Emphasis added].

There is nothing in the Assumptions of the Methodology outlined above that would indicate that it would not apply to dialysis stations at a home training facility. The proposed Carolina Dialysis Orange County Home Dialysis facility will be, by definition, a “dialysis facility”.³ To be consistent with the SMFP, the four stations planned to be relocated to Carolina Dialysis Orange County Home Dialysis will still exist in Orange County and be available, and thus these four stations should remain included in the dialysis station inventory of Orange County.

a. Statement of the adverse effects if the adjustment is not made.

If the petition is not approved, the resulting Orange County deficit would be inaccurate according to the policies and methodologies outlined in the SMFP and the Department’s own findings with respect to CON Project ID # J-11995-20, and there would be an unsupported and unjustified reduction in the planning inventory. Further, including home hemodialysis stations in Table 9B and then removing them due to a relocation within the county despite there being no functional change in status is fundamentally arbitrary. Providers rely on the SMFP to inform their planning, and patients rely on the SMFP to the extent it supports equitable access to care and maximized healthcare

² State Agency Findings with respect to Project ID # J-11995-20, Feb. 22, 2021, *available at* <https://info.ncdhhs.gov/dhsr/coneed/decisions/2021/feb/findings/2020-Orange-J-11995-20-Carolina-Dialysis-Orange-County-Home-Dialysis-200890-Findings.pdf>

³ Dialysis facility” is defined in the Certificate of Need Regulations as “a kidney disease treatment center as defined in G.S. 131E-176(14e).” 10A NCAC 14C .2201(2). G.S. 131E-176(14e) defines “kidney disease treatment center” as “[a] facility that is certified as an end-stage renal disease facility by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, pursuant to 42 C.F.R. § 405.” N.C. Gen. Stat. § 131E-176.

On April 15, 2008, CMS moved the ESRD Conditions for Coverage from 42 CFR Part 405 to 42 CFR Part 494. CMS currently defines “Dialysis facility” as “an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.” 42 CFR 494.10.

value for resources expended. Inconsistencies in the application of its own policies and methodologies undermine these goals of the SMFP.

b. Alternatives to the Proposed Adjustment / Correction.

This petition seeks to correct the Proposed 2022 SMFP due to an inaccuracy in the application of existing policies and methodologies. The alternative would be to leave in the SMFP a misleading and arbitrary statement of existing conditions, which is neither reasonable nor consistent with the SMFP. Failure to correct the Proposed 2022 SMFP results in published factual error and internal inconsistencies. The SHCC and Healthcare Planning are responsible to prepare the SMFP each year for approval by the Governor. It is imperative that the SMFP have correct and consistent information.

4. Evidence that the Proposed Change would not result in unnecessary duplication of health resources in the area.

The requested change seeks to prevent unnecessary duplication of health resources in the area. The Proposed 2022 SMFP understates the existing available resources. The stations are resident within Orange County and should be included in the Orange County inventory of dialysis stations at Table 9B.

5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the SMFP: safety and quality, access and value.

Safety and Quality

The dialysis stations in question are existing and approved healthcare resources serving the ESRD patient population of Orange County. These stations were developed pursuant to a Certificate of Need application which required Carolina Dialysis to demonstrate the facility would be operated safely and that quality care was provided to the patients projected to utilize the dialysis stations.

The SMFP also includes the following statement under the Safety and Quality Basic Principle:

To warrant public trust in the regulation of health services, monitoring of safety and quality using established and independently verifiable metrics will be an integral part of the formulation and application of the North Carolina State Medical Facilities Plan. (Emphasis added)

The Governor has delegated the responsibility to develop the SFMP to the SHCC and the Healthcare Planning Section at DHSR. The people of North Carolina deserve clear and accurate regulatory rules where their needs are accurately projected. The SHCC should ensure that the plan is consistent with the established processes as written by the SHCC and approved by the Governor.

The established process plainly says that a facility may have stations dedicated to home hemodialysis and that these stations “*are included in the planning inventory*”.

Access

Correcting Table 9B will not impair or impede access to dialysis care. The SMFP defines barriers to access as including but “*not limited to: geography, low income, limited or no insurance coverage, disability, age, race, ethnicity, culture, language, education and health literacy. Individuals whose access to needed health services is impeded by any of these barriers are medically underserved*”. The medically underserved will continue to have access to dialysis care in Orange County.

Value

Correcting Table 9B will not diminish the value of dialysis services in Orange County, or any other location in the State. The proposed correction to Table 9B identifies an inconsistency within the Proposed 2022 SMFP. Adoption of this correction will allow the SHCC to ensure continued confidence in the SMFP for all citizens of North Carolina and its accuracy promotes value in the health planning process.

Conclusion

Carolina Dialysis, LLC is asking the SHCC to correct an error in the Proposed 2022 SMFP. Approval of this request will assure the citizens of North Carolina of our state health planning process’ integrity and consistency.

Background on Carolina Dialysis, LLC

Carolina Dialysis, LLC is a Limited Liability Company, with two members: The University of North Carolina Hospitals (UNCH), a 67% owner, and Renal Research Institute, LLC⁴, a 33% owner.

Renal Research Institute (RRI) was formed as a joint venture formed in early 1997 between Beth Israel Medical Center in New York City and Fresenius Medical Care – North America (FMCNA). Today, RRI is a wholly owned subsidiary of FMCNA. RRI initiates a wide range of research activities including the development and evaluation of the latest technology with the goal of creating innovative clinical protocols for improved renal care. RRI is comprised of a collaboration of select dialysis facilities with strong ties to academic research institutions. This exchange among academic research, industry and dialysis clinics is the first of its kind in the renal care field.

⁴ Renal Research Institute, LLC is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc.