

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 20, 2021

Findings Date: August 20, 2021

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: J-12080-21

Facility: Carolina Dialysis-Carrboro

FID #: 956088

County: Orange

Applicant: Carolina Dialysis, LLC

Project: Relocate no more than two dialysis stations from Carolina Dialysis Mebane pursuant to Policy ESRD-2 for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4 stations)

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Carolina Dialysis, LLC, hereinafter CDL or the applicant, operates a dialysis facility, Carolina Dialysis-Carrboro (CD-Carrboro), in Carrboro, Orange County. In this application, the applicant proposes to relocate no more than 2 dialysis stations from Carolina Dialysis-Mebane (CD-Mebane) to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

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, LLC, a 33% owner. Renal Research Institute, LLC is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc.

CD-Carrboro currently provides in-center (IC) dialysis, a home hemodialysis (HH) program, and a peritoneal dialysis (PD) program. However, as part of Project ID#J-11995-20, the entire home training program of Carolina Dialysis Carrboro will be relocated to a new facility, Carolina Dialysis Orange County Home Dialysis (CD-Orange County HD), which is scheduled to begin offering services as of December 31, 2021.

Need Determination

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 137, the county need methodology shows there is no county need determination for additional dialysis stations in Orange County. The applicant is proposing to relocate existing dialysis stations; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2021 SMFP apply to this proposal.

Policies

There is one policy in the 2021 SMFP that is applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*.

Policy ESRD-2: Relocation of Dialysis Stations, on page 21 of the 2021 SMFP, states:

“Relocations of existing dialysis stations to contiguous counties are allowed. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan, and*
- 3. demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan.”*

The applicant proposes to relocate existing dialysis stations from Alamance County to Orange County, which are contiguous counties. In Section B.5, pages 20-21, the applicant states, *“the ESRD Data Collection Forms submitted for the year ending December 31, 2020 demonstrate that Carolina Dialysis of Mebane was serving 27 in-center patients residing in Orange County.”* The proposed project is to relocate 2 dialysis stations from CD-Mebane (Alamance County) to CD-Carrboro (Orange County). According to Table 9B: ESRD Dialysis Station Need Determination by Planning Area in the 2021 SMFP, Alamance County has a surplus of 29 dialysis stations and Orange County has a deficit of 8 dialysis stations. See

pages 133 and 135 of the 2020 SMFP. Upon project completion Alamance County will have a surplus of 27 dialysis stations ($29 - 2 = 27$) and Orange County will have a deficit of 6 dialysis stations ($-8 + 2 = -6$). Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes the application is conforming to this criterion based on the following:

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because:
 - the facility losing stations to a contiguous county is currently serving patients from that county;
 - Alamance County, the county losing stations, currently has a surplus of stations and will still have a surplus of stations upon project completion;
 - Orange County, the county gaining stations, does not currently have a surplus of stations and will not have a surplus of stations upon project completion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

The following table, summarized from data on page 16 of the application, shows the projected number of stations at CD-Carrboro upon project completion.

CD-Carrboro		
Stations	Description	Project ID #
41	Total existing certified stations in the SMFP in effect on the day the review will begin.	
+2	Stations to be added as part of this project	J-12080-21
-4	Stations to be relocated to Carolina Dialysis Orange County Home Dialysis.	J-11995-20
39	Total stations upon completion of proposed project and previously approved project.	

The following table shows the current and projected number of dialysis stations at CD-Mebane upon completion of this project.

CD-Mebane		
Stations	Description	Project ID #
20	Total existing certified stations as of December 31, 2019 in the 2021 SMFP in effect on the day the review will begin	
+7	Stations to be added. Project complete, awaiting Certification Letter.	G-11403-17
-2	Stations to be deleted as part of this project	J-12080-21
25	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” CD-Carrboro is in Orange County. Thus, the service area for this application is Orange County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 24, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Carolina Dialysis Carrboro for CY2020, as summarized in the following table:

CD-Carrboro: Historical- Last Full FY (CY2020)

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Orange	82	74.55%	2	33.33%	13	54.17%
Durham	11	10.00%	1	16.67%	3	12.50%
Chatham	8	7.27%	0	0.00%	3	12.50%
Wake	3	2.73%	1	16.67%	4	16.67%
Alamance	1	0.91%	0	00.00%	0	0.00%
Bladen	1	0.91%	0	0.00%	0	0.00%
Cumberland	0	0.00%	1	16.67%	0	0.00%
Duplin	0	0.00%	0	0.00%	1	4.17%
Lincoln	1	0.91%	0	0.00%	0	0.00%
Northampton	0	0.00%	1	16.67%	0	0.00%
Sampson	1	0.91%	0	0.00%	0	0.00%
Vance	1	0.91%	0	0.00%	0	0.00%
South Carolina	1	0.91%	0	0.00%	0	0.00%
Total	110	100.00%	6	100.00%	24	0.00%

In Section C.2, page 25, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Carolina Dialysis Mebane for CY2020, as summarized in the following table:

CD-Mebane: Historical- Last Full FY (CY2020)

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Alamance	43	59.72%	2	50.00%	7	77.78%
Orange	27	37.50%	0	0.00%	1	1.11%
Caswell	1	1.39%	0	0.00%	0	0.00%
Chatham	1	1.39%	0	0.00%	0	0.00%
Guilford	0	0.00%	1	25.00%	0	0.00%
Person	0	0.00%	1	25.00%	0	0.00%
Total	72	100.00%	4	100.0%	9	100.0%

In Section C.2, page 25, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Carolina Dialysis Carrboro for the second full fiscal year (CY2024), as summarized in the following table:

CD-Carrboro: Projected- Second Full FY (CY2024)

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Orange	103.35	79.31%	0	0.00%	0	0.00%
Durham	11.00	8.43%	0	0.00%	0	0.00%
Chatham	8.00	6.13%	0	0.00%	0	0.00%
Wake	3	2.30%	0	0.00%	0	0.00%
Alamance	1	0.77%	0	0.00%	0	0.00%
Bladen	1	0.77%	0	0.00%	0	0.00%
Lincoln	1	0.77%	0	0.00%	0	0.00%
Sampson	1	0.77%	0	0.00%	0	0.00%
Vance	1	0.77%	0	0.00%	0	0.00%
Total	130.52	100.00%	0	100.00%	0	0.00%

In Section C.3, pages 25-28, the applicant provides the assumptions and methodology used to project its patient origin. On page 18, the applicant begins with the patient origin for existing in-center dialysis patients for Carolina Dialysis Carrboro as of December 31, 2020. The applicant’s assumptions are reasonable and adequately supported because it is based on the historical patient origin for in-center dialysis patients for Carolina Dialysis Carrboro as of June 30, 2020.

Analysis of Need

In Section C.3, pages 24-27, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the December 31, 2020 census data. The applicant states that it assumes the patients from Orange County dialyzing at CD-Carrboro on December 31, 2020 will continue to dialyze there and will increase at a rate equal to the Orange County Five Year Average Annual Change Rate (AACR) of 6.0% as published in the 2021 SMFP.
- The applicant assumes the 27 existing patients who reside outside of Orange County will continue to dialyze at CD-Carrboro but does not assume any growth in patients from those counties.
- The project is scheduled for completion on December 31, 2022. Therefore, Operating Year (OY) 1 is calendar year (CY) 2023, January 1-December 31, 2023 and OY2 is CY2024, January 1-December 31, 2024.

The information is reasonable and adequately supported based on the following:

- According to the 2021 SMFP, Table 9A, as of December 31, 2019, CD-Carrboro was operating at a rate of 2.97 in-center patients per station per week, or at a utilization rate of 74.39 percent [122 patients / 41 stations = 2.9756; 4. 2.9756/ 4 = 0.7439 or 74.39%].
- The applicant utilized the Orange County Five Year AACR to project patient growth.
- Pursuant to Project ID# J-11995-20, which was approved on February 22, 2021, four dialysis stations from CD-Carrboro will be relocated to Carolina Dialysis Orange

County Home Dialysis with a project completion date of December 31, 2021. Assuming no patient growth (the Five-Year AACR for Orange County is 6.0%) the utilization rate at CD-Carrboro after the relocation of four stations would be 82.43% or 3.297 in-center patients per station per week [$122 \text{ patients} / 37 \text{ stations} = 3.297$. $3.297 / 4 = 0.82425$ or 82.43%].

Projected Utilization

In Section C.3, page 27, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Orange County in-center patients as of December 31, 2020.	82
The applicant projects the Orange County in-center patients forward one year to December 31, 2021 using the Orange County AACR.	$82 \times 1.06 = 86.9$
The applicant projects the Orange County in-center patients forward one year to December 31, 2022 using the Orange County AACR.	$86.9 \times 1.06 = 92.1$
The applicant projects the Orange County in-center patients forward one year to December 31, 2023 using the Orange County AACR.	$92.1 \times 1.06 = 97.7$
The applicant adds the 27 patients who reside outside of Orange County. This is the projected ending census for Operating Year 1 .	$97.7 + 27 = 124.7$
The applicant projects the Orange County in-center patients forward one year to December 31, 2023 using the Orange County AACR.	$97.7 \times 1.06 = 103.5$
The applicant adds the 27 patients who reside outside of Orange County. This is the projected ending census for Operating Year 2 .	$103.5 + 27 = 130.5$

Projected patients for OY1 and OY2 are rounded to the nearest whole number. The applicant projects to serve 124 in-center patients in OY1 and 130 in-center patients in OY2.

Thus, the applicant projects that CD-Carrboro will have a utilization rate of 79.5% or 3.179 patients per station per week ($124 \text{ patients} / 39 \text{ stations} = 3.179 / 4 = 0.795$ or 79.5%) in OY1.

In Section C, pages 24-27 and Section Q, Form C, the applicant provides the assumptions and methodology used to project IC utilization, which is summarized below.

- The applicant projects the first two full operating years of the project will be CY2023 and CY2024.
- The applicant begins its projections with the facility census as of December 31, 2020. This information is reported in the ESRD Data Collection forms submitted to the Agency. The facility reported 110 in-center patients receiving dialysis services at CD-Carrboro. Of the 110 patients, 82 resided in Orange County, 27 resided in North Carolina but not in Orange County and 1 resided out of state in South Carolina.
- The applicant assumed the patient from South Carolina was transient and did not project this patient to continue to receive dialysis at CD-Carrboro.

- The applicant projects that the 27 North Carolina patients residing outside of the Orange County service area will continue to dialyze at CD-Carrboro but does not project any growth for this segment of the patient population.
- The applicant used the Five-Year Orange County AACR to project patient growth.

The projected utilization of 3.179 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant begins the projections with the existing Orange County CD-Carrboro patient census as of December 31, 2020.
- The applicant projects the Orange County patient census at CD-Carrboro will increase by the Orange County Five Year AACR of 6.0 percent, as reported in the 2021 SMFP.
- The applicant does not project growth for its IC patients who do not reside in Orange County.
- The applicant does not project the one IC out-of-state patient continuing to dialyze at CD-Carrboro.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In C.6, page 32 the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	27.66%
Racial and ethnic minorities	69.50%
Women	31.91%
Persons with Disabilities	22.70%
The elderly	50.35%
Medicare beneficiaries	37.59%
Medicaid recipients	27.66%

Source: Table on page 32 of the application.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

CD-Mebane will be certified for 25 dialysis stations upon completion of this project.

In Section D, page 39, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced will be adequately met following completion of the project. On page 39, the applicant states:

“The Applicant projects Carolina Dialysis of Mebane to serve 78.1 in-center patients as of the date the stations are projected to be relocated. Utilization by 78.1 patients on 25

stations is calculated to be 3.12 patients per station. No patients will be adversely impacted by this relocation of stations.”

On page 39, the applicant provides a table which shows projected CD-Carrboro utilization assuming the relocation of 2 stations to the CD-Carrboro facility, which is summarized below:

	Alamance	Orange
The applicant begins with the respective county in-center patients as of December 31, 2020.	43	27
Project the IC patient population forward one year to December 31, 2021 using the respective county Five Year AACR.	$43 \times 1.03 = 44.3$	$27 \times 1.06 = 28.6$
Project the IC patient population forward one year to December 31, 2022 using the respective county Five Year AACR.	$44.3 \times 1.03 = 45.6$	$28.6 \times 1.06 = 30.3$
Add the patients from Alamance and Orange Counties as well as the patients from Caldwell (1) and Chatham (1) Counties. This is the projected ending census for December 31, 2022. This is the date the 2 stations are projected to be relocated from CD-Mebane to CD-Carrboro.	$45.6 + 30.3 + 2 = 77.9$ or 78	

CD-Mebane has 27 dialysis stations prior to December 31, 2022. Then two stations will be relocated to CD-Carrboro pursuant to this application leaving CD-Mebane with 25 dialysis stations.

As shown in the table above, CD-Mebane will have a utilization rate of 78.0% or 3.12 patients per station per week ($78 \text{ patients} / 25 \text{ stations} = 3.12 / 4 = 0.78$ or 78.0%) at the time the 2 stations will be relocated and certified at CD-Carrboro.

In Section, page 25 and Section D, pages 38-39, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the facility census as of December 31, 2020. This information is reported in the ESRD Data Collection forms submitted to the Agency. The facility reported 72 IC patients receiving dialysis services at CD-Mebane. Of the 72 IC patients, 43 resided in Alamance County, 27 resided in Orange County, and a total of 2 resided in Caswell and Chatham counties.
- The applicant states that it projects patients forward from the December 31, 2020 census data. The applicant states that it assumes all the IC patients dialyzing at CD-Mebane will continue to dialyze at the facility.
- The applicant projects that the IC patients from Alamance County will increase at a rate equal to the Alamance County Five Year AACR of 3.0% as published in the 2021 SMFP and the IC patients from Orange County will increase at a rate equal to the Orange County Five Year AACR of 6.0% as published in the 2021 SMFP.

- The applicant projects that the 2 patients from Caswell and Chatham counties will continue to dialyze at CD-Mebane but does not project any growth for this segment of the patient population.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant begins the projections with the existing CD-Mebane patient census as of December 31, 2020.
- The applicant projects the Alamance and Orange County patient census at CD-Mebane will increase by the Alamance and Orange County Five Year AACRs, as reported in the 2021 SMFP.
- The applicant does not project growth for its IC patients who do not reside in either Alamance or Orange County.
- The utilization rate, calculated as of the date the 2 stations are projected to be relocated to CD-Carrboro, and based on the number of stations at CD-Carrboro after the 2 stations are relocated, is less than 80%.

Access to Medically Underserved Groups

In Section D, page 40, the applicant states:

“All Carolina Dialysis and Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. The Form O identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. ... Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

In Section D.3, page 40, the applicant states the relocation of two stations from CD-Mebane to CD-Carrboro will not have any impact on the access to services by low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare beneficiaries or Medicaid recipients.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

In Section E.2, page 43, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because CD-Carrboro is highly utilized and there is an eight-station deficit in Orange County. Failure to add stations would lead to higher utilization and potentially interrupts patient admissions. Therefore, the applicant determined this is not the most effective alternative.
- *Relocate fewer than two stations* – The applicant states that relocating fewer than two stations is less effective because CD-Carrboro is highly utilized and failure to add stations potentially interrupts patient admissions. Therefore, the applicant determined this is not the most effective alternative.
- *Relocate up to eight stations* – The applicant states that relocating more than two stations is not cost-effective because the CD-Carrboro facility does not have adequate capacity to accommodate more than two stations and would require a physical plant expansion and thus significant capital expenditure to develop additional space. Therefore, the applicant determined this is not the least costly nor most effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

- The applicant is taking advantage of space being vacated by the home therapies program and will redevelop the space to provide in-center dialysis care through transitional care.
- The applicant can address high utilization rates and avoid possible patient admission interruptions while avoiding the capital expense of a physical plant expansion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Carolina Dialysis, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, the certificate holder shall relocate no more than two stations from Carolina Dialysis-Mebane to Carolina Dialysis-Carrboro for a total of no more than 39 in-center and home hemodialysis stations at Carolina Dialysis-Carrboro upon completion of this project and Project ID# J-11995-20 (relocate four dialysis stations).**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify two stations at Carolina Dialysis-Mebane for a total of no more than 25 in-center and home hemodialysis stations upon completion of this project and Project ID #G-11403-17 (add seven dialysis stations).**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.**

5. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$433,500
Miscellaneous Costs	\$76,500
Total	\$510,000

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Section Q the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the information on projected capital costs provided by the applicant in Form F.1a of the application.

In Section F, page 47, the applicant states there will be no working capital cost because CD-Carrboro is an operational facility.

Availability of Funds

In Section F, page 45, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Carolina Dialysis, LLC	Total
Loans	\$	\$
Accumulated reserves or OE *	\$510,000	\$510,000
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$510,000	\$510,000

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- In Exhibit F-1, the applicant provides a letter dated May 17, 2021, from a Carolina Dialysis, LLC Board Member, documenting its commitment to fund the capital and costs of the project. Exhibit F-2 contains a balance sheet for Carolina Dialysis, LLC as of March 31, 2021, showing that applicant had \$29.1 million in cash and cash equivalents and \$53.4 million in total assets.
- The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Exhibit F-1 and Exhibit F-2, as described above.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	18,041	18,884
Total Gross Revenues (Charges)	\$113,496,496	\$118,797,956
Total Net Revenue	\$7,650,750	\$9,168,562
Average Net Revenue per Treatment	\$424	\$486
Total Operating Expenses (Costs)	\$4,925,300	\$5,075,563
Average Operating Expense per Treatment	\$273	\$269
Net Income	\$2,725,451	\$4,093,000

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Contractual adjustments are calculated by payor class and modality for each year.
- Salary expenses are projected to increase at a rate of 2.5% annually.
- The employer pays 36% of the staff expense.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

On page 113, the 2021 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” CD-Carrboro is in Orange County. Thus, the service area for this application is Orange County. Facilities may serve residents of counties not included in their service area.

There are two dialysis centers in Orange County, one existing and one approved but not yet developed, both are owned by the applicant. Table 9A, page 128 of the 2021 SMFP shows that CD-Carrboro had 41 certified stations and 122 in-center patients as of December 31, 2019 for a utilization rate of 74.39 percent. The applicant was issued a Certificate of Need to develop a new dialysis facility in Orange County, CD-Orange County Home Dialysis (Project

ID# J-11995-20, develop a new dialysis facility in Hillsborough dedicated to home hemodialysis and peritoneal dialysis training and support services by relocating the entire home training program of Carolina Dialysis Carrboro and no more than 4 dialysis stations pursuant to Policy ESRD-2) which is expected to start offering services as of December 31, 2021. The 4 in-center dialysis stations that are part of CD-Orange County Home Dialysis are being relocated from CD-Carrboro, thus the 8-station deficit in Orange County is not impacted by Project ID# J-11995-20.

In Section G, page 52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved in-center dialysis services in Orange County. The applicant states:

“The SMFP Table 9B indicates there is an eight station deficit in Orange County. Relocating two stations to Carolina Dialysis Carrboro obviously does not totally satisfy the deficit but does help to ensure additional capacity for the ESRD patients of Orange County. Relocating stations to a county that will continue to have a deficit of stations does not cause unnecessary duplication.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Orange County.
- The applicant adequately demonstrates that the proposed relocation of the two stations is needed in addition to the existing or approved dialysis stations in Orange County.
- Table 9B of the 2021 SMFP shows an eight-station deficit in Orange County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(5/17/2021)	2nd Full Fiscal Year (CY2024)
Administrator	1.00	1.00
Registered Nurse	6.00	7.00
Licensed Practical Nurse	1.00	1.00
Home Training Nurse	3.00	0.00
Technicians	10.00	12.00
Medical Records	1.00	1.00
Dietician	1.50	1.50
Social Worker	1.50	1.50
Maintenance	1.00	1.00
Administrative/Business Office	1.00	1.00
FMC Director of Operations	0.15	0.15
Chief Technician	0.30	0.30
FMC In-Service	0.30	0.30
TOTAL	27.75	27.75

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H.2 and H.3, pages 54-55, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 54-55, and in Section Q, Form H, as described above. following:

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

Ancillary and Support Services

In Section I.1, page 56, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 56-61, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the based on the information provided in Section I.1, and Exhibit I as described above.

Coordination

In I.2, page 61, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the on the information provided in Section I.2 and Exhibit I, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the

services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is no applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to relocate no more than 2 dialysis stations from Carolina Dialysis Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

In Section K, page 64, the applicant states that the project involves renovating 800 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 64, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the project involves the renovation of existing space as opposed to a more costly *“bricks and mortar”* addition to the building.

On page 65 the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The costs of adding stations are not passed on to the patient.
- The proposed addition of two stations is a necessary part of doing business to ensure convenient access to care for the patients of the area.
- Existing space will be renovated rather than constructing new space.

On pages 65-66, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 69, the applicant provides the historical payor mix during & (time frame) for the proposed services, as shown in the table below.

CD-Carrboro
Last Full FY: 1/1/2020 to 12/31/2020

Payor Source	IC		HH		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.20	2.88%	0.00	0.00%	0.00	0.00%
Insurance*	9.20	8.35%	0.80	12.97%	7.20	30.06%
Medicare*	81.80	74.34%	5.20	87.03%	15.80	65.92%
Medicaid*	13.50	12.7%	0.00	0.00%	1.00	4.02%
Other (including VA and Medicare Advantage)	2.40	2.16%	0.00	0.00%	0.00	0.00%
Total	110.00	100.00%	6.00	100.00%	24.00	100.00%

Source: Table on page 69 of the application.
 *Including any managed care plans.

CD- Mebane
Last Full FY: 1/1/2020 to 12/31/2020

Payor Source	IC		HH		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	2.20	3.09%	0.00	0.00%	0.00	0.00%
Insurance*	6.60	9.11%	1.50	36.85%	2.20	24.47%
Medicare*	54.70	75.91%	1.80	44.72%	5.40	59.96%
Medicaid*	6.00	8.35%	0.70	18.43%	1.10	12.63%
Other (including VA and Medicare Advantage)	2.60	3.55%	0.00	0.00%	0.30	2.94%
Total	72.00	100.00%	4.00	100.00%	9.00	100.00%

Source: Table on page 69 of the application.
 *Including any managed care plans.

In Section L, page 70, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	31.9%	52.3%
Male	68.1%	47.7%
Unknown	0.0%	0.0%
64 and Younger	49.6%	85.4%
65 and Older	50.4%	14.6%
American Indian	0.0%	0.6%
Asian	2.8%	8.1%
Black or African-American	52.5%	11.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	27.7%	69.5%
Other Race	17.0%	9.9%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 71, the applicant states that CD-Carrboro is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 71, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against CD-Carrboro.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 72, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CD-Carrboro: Projected Payor Mix
2nd Full FY: 1/1/2023 to 12/31/2023

Payor Source	IC		HH		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.20	2.88%	0.00	0.00%	0.00	0.00%
Insurance*	9.20	8.35%	0.00	0.00%	0.00	0.00%
Medicare*	81.80	74.34%	0.00	0.00%	0.00	0.00%
Medicaid*	13.50	12.7%	0.00	0.00%	0.00	0.00%
Other (including VA and Medicare Advantage)	2.40	2.16%	0.00	0.00%	0.00	0.00%
Total	110.00	100.00%	0.00	100.00%	0.00	100.00%

Source: Table on page 72 of the application.

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.88% of total services will be provided to self-pay patients, 74.34% to Medicare patients and 12.7% to Medicaid patients.

On pages 72-73, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following reasons:

- The applicant includes Medicare Advantage in the Other category, rather than including it in the category of Medicare, as the application directs.
- The applicant bases future payor mix percentages on CY2020 payor mix percentages for treatment volumes.
- The applicant bases payor mix upon treatment volumes rather than patients.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 74, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to relocate no more than 2 dialysis stations from Carolina Dialysis Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

In Section M, page 75, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 75, and Exhibit M.1, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to relocate no more than 2 dialysis stations from CD-Mebane to CD-Carrboro for a total of no more than 39 stations upon completion of this project and Project ID #J-11995-20 (relocate 4).

On page 113, the 2021 SMFP defines the service area for dialysis stations as, “... the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” CD-Carrboro is in Orange County. Thus, the service area for this application is Orange County. Facilities may serve residents of counties not included in their service area.

There are two dialysis centers in Orange County, one existing and one approved but not yet developed, both are owned by the applicant. Table 9A, page 128 of the 2021 SMFP shows that CD-Carrboro had 41 certified stations and 122 in-center patients as of December 31, 2019 for a utilization rate of 74.39 percent. The applicant was issued a Certificate of Need to develop a new dialysis facility in Orange County, CD-Orange County Home Dialysis (Project ID# J-11995-20, develop a new dialysis facility in Hillsborough dedicated to home hemodialysis and peritoneal dialysis training and support services by relocating the entire home training program of Carolina Dialysis Carrboro and no more than 4 dialysis stations pursuant to Policy ESRD-2) which is expected to start offering services as of December 31, 2021. The 4 in-center dialysis stations that are part of CD-Orange County Home Dialysis are being relocated from CD-Carrboro, thus the 8-station deficit in Orange County is not impacted by Project ID# J-11995-20.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Orange County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population and projects growth of that population consistent with the Orange County Five Year Average Annual Change Rate published in the 2021 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, the applicant states:

“This is a proposal to relocate two stations to Carolina Dialysis Carrboro. The applicant is serving a significant number of dialysis patients residing in the area of the facility. ... Approval of this will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 77, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality care is not negotiable. Fresenius Medical Care, a co-parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 77-78, the applicant states:

“All Carolina Dialysis and Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. The Form O identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. ... Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 83, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius Medical Care related facility was found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 The specific criteria are discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

- (b) *An applicant proposing to increase the number of dialysis stations in:*
 - (1) *an existing dialysis facility; or*
 - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;**shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

- C- In Section C, pages 25-28, and Section Q, Form C, the applicant projects that CD-Carrboro will serve 124 in-center patients on 39 dialysis stations. The projected utilization for OY1 of 3.179 patients per station per week or 79.5% utilization (124 patients / 39 stations = 3.179/4 = 0.795 or 79.5%). The projected utilization of 3.179 patients per station per week exceeds the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C, pages 25-28, and Section Q, Form C, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.