

## **ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

### **FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 22, 2021

Findings Date: February 22, 2021

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11995-20

Facility: Carolina Dialysis Orange County Home Dialysis

FID #: 200890

County: Orange

Applicant: Carolina Dialysis, LLC

Project: 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

### **REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

N.C. Gen. Stat. §131E-183(a) The Agency 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 referred to as “the applicant” or Carolina Dialysis), proposes to 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.

## **Need Determination**

Chapter 9 of the 2020 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 9D, page 170, the county need methodology shows there is a county need determination for additional dialysis stations in Orange County. However, the applicant is not proposing to develop four new dialysis stations; therefore, neither the county nor the facility need methodologies are applicable to this proposal. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

## **Policies**

There is one policy in the 2020 SMFP that is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. 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 within Orange County, pursuant to Policy ESRD-2. 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 proposal does not change the dialysis station inventory in Orange County.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to 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. In Section C.1, pages 16-18, the applicant states,

*“Carolina Dialysis proposes to relocate the entire home therapies program (including four dialysis stations dedicated to home hemodialysis training) from Carolina Dialysis Carrboro to develop a new, free standing Kidney Treatment Center in Hillsborough, Orange County. The facility will provide exclusively home dialysis training and support services for residents of Orange County and other counties where the patients may reside.”*

The following table, summarized from data on page 7 of the application, shows the projected number of stations at Carolina Dialysis Orange County Home Dialysis upon project completion. Carolina Dialysis Carrboro is currently certified for 41 dialysis stations and will be certified for 37 dialysis stations upon project completion.

<b>Carolina Dialysis Orange County Home Dialysis</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
+4	Stations to be added as part of this project	J-11995-20
4	Total stations upon completion of proposed project and previously approved projects	

## **Patient Origin**

On page 113, the 2020 SMFP defines the service area dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located 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.

This proposal is to develop a new dialysis facility, Carolina Dialysis Orange County Home Dialysis, dedicated to home hemodialysis and peritoneal dialysis training and support services by relocating no more than four dialysis stations from Carolina Dialysis Carrboro in Orange County; therefore, there is no historical utilization data.

In Section C.3, page 20, the applicant provides the projected home hemodialysis (HH) and peritoneal dialysis (PD) patient origin for Carolina Dialysis for the second full operating year following project completion, January 1, 2023 – December 31, 2023 (CY2023), as summarized in the following table:

County	Home Hemodialysis		Peritoneal Dialysis	
	HH Patients	% of Total	PD Patients	% of Total
Orange	6.2	60.68%	9.1	50.15%
Chatham	0.0	0.00%	3.0	16.62%
Cumberland	1.0	9.79%	0.0	0.00%
Durham	1.0	9.79%	2.0	11.08%
New Hanover	0.0	0.00%	2.0	11.08%
Northampton	1.0	9.79%	0.0	0.00%
Wake	1.0	9.79%	2.0	11.08%
<b>Total</b>	<b>10.2</b>	<b>100.00%</b>	<b>18.1</b>	<b>100.00%</b>

In Section C.3, pages 20-22, the applicant provides the assumptions and methodology used to project its patient origin. On page 20, the applicant begins with the patient origin for existing home dialysis patients for Carolina Dialysis Carrboro as of June 30, 2020. The applicant’s assumptions are reasonable and adequately supported because it is based on the historical patient origin for home dialysis patients for Carolina Dialysis Carrboro as of June 30, 2020.

## **Analysis of Need**

In Section C.4, pages 24-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- The project will enhance patient training opportunities and allow more Carolina Dialysis patients to dialyze at home.

- Dialysis settings which are not convenient for the patient will adversely affect patient compliance and led to missed treatments. Home dialysis affords patients with maximum convenience and improves compliance.

The information is reasonable and adequately supported because the applicant demonstrates that home dialysis provides patients with more convenient schedules and settings will reduce missed treatment and improve patient compliance.

### **Projected Utilization**

#### *Home Therapies Projected Utilization*

In Section C.3, pages 22-24, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- The applicant starts with home hemodialysis (HH) and peritoneal dialysis (PD) patient census for Carolina Dialysis Carrboro on June 30, 2020, as shown in the table below.

<b>County</b>	<b>HH</b>	<b>PD</b>
Orange	0	8
Chatham	0	3
Cumberland	1	0
Durham	1	2
New Hanover	0	2
Northampton	1	0
Wake	1	2
<b>Total</b>	<b>4</b>	<b>17</b>

- The applicant assumes two in-center dialysis patients will change to home hemodialysis each year, beginning in 2021.
- The applicant uses the 2020 SMFP Orange County Five-Year Annual Average Change Rate (AACR) of 3.6% for Orange County patient utilization growth for home hemodialysis and peritoneal dialysis patients.

The table below summarizes the beginning patient census for home hemodialysis (HD) and peritoneal dialysis (PD) patients on June 30, 2020 and their growth through the ending patient census on December 31, 2023.

<b>Carolina Dialysis Orange County Home Dialysis</b>	<b>HH</b>	<b>PD</b>
The applicant begins with the Orange County HH and PD patients as of June 30, 2020.	0	8
The applicant projects the Orange County patient population forward six months to December 31, 2020 based on one half the Orange County Five Year Average Annual Change Rate (AACR).	0	$8 \times 1.018 = 8.1$
The applicant adds patients from outside Orange County for a projected census for December 31, 2020.	$0 + 4 = 4$	$8.1 + 9 = 17.1$
The applicant projects the Orange County HH and PD patients forward one year to December 31, 2021 based on the Orange County AACR.	0	$8.1 \times 1.036 = 8.4$
The applicant adds two patients projected to change from in-center to home hemodialysis.	$0 + 2 = 2$	8.4
The applicant adds patients from outside Orange County for a projected census for December 31, 2021.	$2 + 4 = 6$	$8.4 + 9 = 17.4$
The applicant projects the Orange County HH and PD patients forward one year to December 31, 2022 based on the Orange County AACR.	$2 \times 1.036 = 2.1$	$8.4 \times 1.036 = 8.7$
The applicant adds two patients projected to change from in-center to home hemodialysis.	$2.1 + 2 = 4.1$	8.7
The applicant adds patients from outside Orange County. This is the projected ending census for <b>Operating Year 1.</b>	$4.1 + 4 = 8.1$	$8.7 + 9 = 17.7$
The applicant projects the Orange County HH and PD patients forward one year to December 31, 2023 based on the Orange County AACR.	$4.1 \times 1.036 = 4.2$	$8.7 \times 1.036 = 9.1$
The applicant adds two patients projected to change from in-center to home hemodialysis.	$4.2 + 2 = 6.2$	9.1
The applicant adds patients from outside Orange County. This is the projected ending census for <b>Operating Year 2.</b>	$6.2 + 4 = 10.2$	$9.1 + 9 = 18.1$

As the table above shows, the applicant projects 10 home hemodialysis and 18 peritoneal dialysis patients by the end of the second operating year.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant bases the beginning HH and PD patient census on existing Carolina Dialysis Carrboro patients as June 30, 2020.
- The applicant projects the growth of the Orange County patient census using the Orange County Five-Year AACR of 3.6 percent, as reported in the 2020 SMFP.

**Access**

In Section C.7, page 28, the applicant states:

*“The applicant, and the Fresenius Medical Care related facilities in North Carolina, have a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of these facilities has a patient population which includes low-income, racial and ethnic minorities, women, handicapped persons, elderly and other traditionally underserved persons.”*

In Section C.7, page 28, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as summarized in the following table.

Estimated Percentages of Patients by Group		
a	Low income persons	71.43%
b	Racial and ethnic minorities	50.00%
c	Women	53.57%
d	Handicapped persons	32.14%
e	The elderly	50.00%
f	Medicare beneficiaries	78.57%
g	Medicaid recipients	21.43%

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 the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to 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. Carolina Dialysis Carrboro is currently certified for 41 dialysis stations and will be certified for 37 dialysis stations upon project completion. In Section D.2, pages 31-36, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 31, the applicant states,

*“Relocation of the stations to the new Carolina Dialysis Orange County Home will not have any effect upon the in-center dialysis patients of Carolina Dialysis Carroboro. The relocated stations will continue to be available to the patients choosing home hemodialysis. ... The Carolina Dialysis Carrboro facility is currently certified for 41 dialysis stations. Those stations include 37 in-center stations and four stations used exclusively for home hemodialysis training and support services.”*

On page 35, the applicant provides a table which shows projected Carolina Dialysis Carrboro utilization assuming the relocation of four stations to the proposed facility, Carolina Dialysis Orange County Dialysis, which is summarized below:



<b>Carolina Dialysis Carrboro</b>	<b>In-Center</b>
The applicant begins with the Orange County in-center patients as of June 30, 2020.	90
The applicant projects the Orange County patient population forward six months to December 31, 2020 based on one half the Orange County Five Year Average Annual Change Rate (AACR).	$90 \times 1.018 = 91.6$
The applicant adds patients from outside Orange County for a projected census for December 31, 2020.	$91.6 + 29 = 120.6$
The applicant projects the Orange County in-center patients forward one year to December 31, 2021 based on the Orange County AACR.	$91.6 \times 1.036 = 94.9$
The applicant subtracts two patients projected to change from in-center to home hemodialysis.	$94.9 - 2 = 92.9$
The applicant adds patients from outside Orange County for a projected census for December 31, 2021.	$92.9 + 29 = 121.9$
The applicant projects the Orange County in-center patients forward one year to December 31, 2022 based on the Orange County AACR.	$92.9 \times 1.036 = 96.3$
The applicant subtracts two patients projected to change from in-center to home hemodialysis.	$96.3 - 2 = 94.3$
The applicant adds patients from outside Orange County. This is the projected ending census for <b>Operating Year 1.</b>	$94.3 + 29 = 123.3$
The applicant projects the Orange County in-center patients forward one year to December 31, 2023 based on the Orange County AACR.	$94.3 \times 1.036 = 97.7$
The applicant subtracts two patients projected to change from in-center to home hemodialysis.	$97.7 - 2 = 95.7$
The applicant adds patients from outside Orange County. This is the projected ending census for <b>Operating Year 2.</b>	$95.7 + 29 = 124.7$

As shown in the table above, Carolina Dialysis Carrboro is projected to have a utilization rate of 3.3 patients per station per week or 82.4% ( $122 \text{ patients} / 37 \text{ stations} = 3.3 / 4 = 0.82$ ) at the time of the proposed relocation of stations on December 31, 2021. The applicant states that the population presently served at Carolina Dialysis Carrboro will continue to have their needs adequately met by the remaining dialysis stations.

In Section D.3, page 36, the applicant states the relocation of the home program from Carolina Dialysis Carrboro will not have any effect access 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

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

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 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.

In Section E.1, page 38, the applicant states it believes there are no alternatives less costly or more effective than the alternative proposed in this application to meet the identified need.

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.

#### **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 develop a new kidney disease treatment center to be known as Carolina Dialysis Orange County Home Dialysis by relocating no more than four home hemodialysis stations from Carolina Dialysis Carrboro.**
  - 3. The certificate holder shall install plumbing and electrical wiring through the walls for no more than four home hemodialysis stations.**
  - 4. Upon completion of this project, the certificate holder shall take the necessary steps to decertify four stations at Carolina Dialysis Carrboro for a total of no more than 37 in-center and home hemodialysis stations upon completion of the project.**
  - 5. 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 fourth month. The first progress report shall be due on August 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**
  - 6. 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 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.

**Capital and Working Capital Costs**

In Section Q, Form F.1a Capital Cost, the applicant projects the total capital cost for the project as summarized below.

<b>Projected Capital Costs</b>	
	<b>Total Costs</b>
Construction Costs	\$1,013,075
Architect/Engineering Fees	\$91,177
Nonmedical Equipment	\$27,957
Furniture	\$102,533
Other: Contingency	\$55,213
<b>Total Capital Costs</b>	<b>\$1,289,594</b>

In Section Q, page 87, 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 on page 87 of the application.

In Section F, pages 40-41, the applicant projects that start-up costs will be \$92,514 and initial operating expenses will be \$632,359 for a total working capital of \$724,872. On page 41, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information regarding projected start-up costs and initial operating expenses provided on page 41 of the application.

**Availability of Funds**

In Section F, pages 39 and 42, the applicant states that the capital and working capital cost, respectively, will be funded by Carolina Dialysis, LLC, as shown in the tables below.

<b>Sources of Capital Financing</b>	
<b>Type</b>	<b>Carolina Dialysis, LLC</b>
Loans	
Accumulated reserves or OE *	\$1,289,594
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$1,289,594</b>

\* OE = Owner's Equity

**Sources of Working Capital Financing**

Type	Carolina Dialysis, LLC
Loans	
Accumulated reserves or OE *	\$724,872
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$724,872</b>

\* OE = Owner's Equity

In Exhibit F-1, the applicant provides a letter dated November 15, 2020, from a UNC Health, Carolina Dialysis, LLC Board Member, documenting its commitment to fund the capital and working capital costs of the project. Exhibit F-2 contains a balance sheet for Carolina Dialysis for fiscal year ended September 30, 2020, showing that applicant had \$28.5 million in cash and cash equivalents and \$48.7 million in total assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working 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 provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

<b>Carolina Dialysis Orange County Home Dialysis Revenue and Expenses</b>		
	<b>CY2022</b>	<b>CY2023</b>
Treatments	3,644	4,002
Gross Patient Revenue	\$22,927,599	\$25,179,389
Net Patient Revenue	\$2,179,702	\$2,322,639
Average Net Revenue per Treatment	\$598	\$580
Total Operating Expenses	\$1,264,717	\$1,297,456
Average Operating Expense per Treatment	\$347	\$324
Net Income	\$914,985	\$1,025,183

Totals may not sum due to rounding

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:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.

- 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 and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - 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 costs and charges.
- (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 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.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located 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.

The applicant operates the only existing dialysis center in Orange County; Carolina Dialysis Carrboro. Table 9B, page 161 of the 2020 SMFP shows that Carolina Dialysis Carrboro had 41 certified stations and 122 in-center patients as of December 31, 2018 for a utilization rate of 74.39 percent.

In Section G.2, page 45, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Orange County. The applicant states:

*“The project involves the complete relocation of an existing home dialysis program to develop the new Carolina Dialysis Orange County Home Dialysis facility. The project does not create new dialysis stations or additional services within the service area. In short, nothing is being duplicated. The home training program of Carolina Dialysis Carrboro will be relocated.”*

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

- 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 four stations for the development of a new facility is needed in addition to the operational facility 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 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 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.

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

POSITION	PROJECTED FTE POSITIONS CY2022	PROJECTED FTE POSITIONS CY2023
Administrator	1.00	1.00
Home Training Nurse	3.00	3.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.15	0.15
Administrative/Business Office	0.75	0.75
FMC Director Operations	0.15	0.15
In-Service	0.15	0.15
Chief Technician	0.05	0.05
<b>Total</b>	<b>6.25</b>	<b>6.25</b>

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs 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, page 46, 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 46-47, and in Section Q, Form H, 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 the reasons stated 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.



The applicant proposes to 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.

### **Ancillary and Support Services**

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 48, 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 information provided in Section I.1 and Exhibit I, as described above.

### **Coordination**

In Section I.2, page 49, 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 information provided in Section I.2 and Exhibit I, 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.

- (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 not 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 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.

In Section K.1, page 51, the applicant states that the project involves renovation of 4,647 square feet of leased space. Line drawings are provided in Exhibit K-2.

On page 53, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K. The site appears to be suitable for the proposed facility based on the applicant's representations and supporting documentation.

In Section K.3, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the

information and representations made by the applicant on pages 51-52 of the application.

In Section K.3, 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 information and representations made by the applicant on page 52 of the application.

On pages 52-53, 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 handicapped persons, 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

The applicant proposes to 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. This will be a new facility and therefore has no history. In Section L.1, page 56, the applicant provides the Carolina Dialysis Carrboro's historical payor mix for CY2019, as shown in the table below.

<b>Payor Source</b>	<b>Home Hemodialysis Patients</b>	<b>Peritoneal Dialysis Patients</b>
Insurance	7.84%	26.25%
Medicare	38.86%	43.48%
Medicaid	0.00%	7.36%
Medicare/Commercial	53.30%	22.91%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding

In Section L.1(a), page 55, the applicant provides comparison of the demographical information on Carolina Dialysis Carrboro patients and the service area patients during the last full operating year, as summarized below.

	<b>Percentage of Total Patients Served during the Last Full OY</b>	<b>Percentage of the Population of the Service Area Where the Stations are Located*</b>
Female	53.6%	51.1%
Male	46.4%	48.9%
Unknown	0.0%	0.0%
64 and Younger	50.0%	81.7%
65 and Older	50.0%	18.3%
American Indian	0.0%	0.6%
Asian	3.6%	4.5%
Black or African-American	28.6%	8.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	50.0%	74.9%
Other Race	17.9%	11.0%
Declined / Unavailable	0.0%	0.0%

\* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

### **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 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 handicapped persons 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 56, the applicant states that the facility is not obligated to provide uncompensated care or community service.

In Section L.2, page 57, the applicant states there have been no civil rights access complaints filed against any of the applicant’s facilities within the last five years.

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.3, page 57, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Projected Payor Mix CY2023**

Payment Source	Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total
Insurance*	0.80	7.84%	4.74	26.25%
Medicare*	3.97	38.86%	7.85	43.48%
Medicaid*	0.00	0.00%	1.33	7.36%
Medicare/Commercial	5.45	53.30%	4.14	22.91%
<b>Total</b>	<b>10.22</b>	<b>0.0%</b>	<b>18.06</b>	<b>100.0%</b>

Totals may not sum due to rounding

\*Including any managed care plans

On page 57, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on the historical payor mix for Carolina Dialysis Carroboro.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 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 58, 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 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.

In Section M., 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-2. 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 59, and Exhibit M-2, 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 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.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located 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.

The applicant operates the only existing dialysis center in Orange County; Carolina Dialysis Carrboro. Table 9B, page 161 of the 2020 SMFP shows that Carolina Dialysis Carrboro had 41 certified stations and 122 in-center patients as of December 31, 2018 for a utilization rate of 74.39 percent.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 60, 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 Carolina Dialysis Orange County Home Program facility begins with the current patient population served by the Carolina Dialysis Carrboro facility. The applicant projects growth of that population consistent with the Orange County Five Year Average Annual Change Rate published in the 2020 SMFP.”*

Regarding the impact of the proposal on cost effectiveness, in Section N.2, page 61, the applicant states:

*“This is a proposal to relocate the home training program of Carolina Dialysis Carrboro to develop a new freestanding End Stage Renal Disease Treatment Center focused on home dialysis. The applicant is serving a significant number of dialysis patients residing in the area of the facility. ... Approval of this application 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.2, page 61, the applicant states:

*“Quality of care is always in the forefront at Fresenius related facilities. Quality care is not negotiable. Carolina Dialysis, 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.2, page 61, the applicant states:

*“The Carolina Dialysis facilities and all Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. The Form A 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 A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by Carolina Dialysis or a related entity.

In Section O.2, page 66, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that

resulted in a finding of “*Immediate Jeopardy*” occurred in any Carolina Dialysis or related facility. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Carolina Dialysis and related 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.
- (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.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for home hemodialysis and peritoneal dialysis patients. The applicant does not propose to include any certified in-center stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.