

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 15, 2023

Findings Date: September 15, 2023

Project Analyst: Julie M. Faenza

Co-signer: Gloria C. Hale

Project ID #: J-12386-23

Facility: Carolina Dialysis-Carrboro

FID #: 956088

County: Orange

Applicant: Carolina Dialysis, LLC

Project: Relocate no more than 2 dialysis stations from Carolina Dialysis Siler City, no more than 2 dialysis stations from FMC Dialysis Center West Pettigrew, and no more than 1 dialysis station from Carolina Dialysis Pittsboro for a total of no more than 46 stations upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 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 referred to as “Carolina Dialysis” or “the applicant”) proposes to relocate two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

Project ID #J-11995-20 originally approved the relocation of the entire home training program at Carolina Dialysis-Carrboro and four in-center dialysis stations. However, pursuant to a

material compliance request approved by the Agency on September 21, 2021, the applicant is only relocating two in-center stations as part of Project ID #J-11995-20.

### **Need Determination**

The applicant does not propose to add any dialysis stations pursuant to either the county need methodology or the facility need methodology. Therefore, there are no need determinations applicable to this review.

### **Policies**

There is one policy in the 2023 SMFP which is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations*, on page 22 of the 2023 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.”*

In Section B, pages 20-21, the applicant explains why it believes its application is consistent with Policy ESRD-2, as described below.

### **Chatham County**

- CD-Siler City and CD-Pittsboro are both located in Chatham County.
- Chatham County is contiguous to Orange County.
- On pages 20-21, the applicant states both the Patient Origin Report for the 2023 SMFP and the ESRD Data Collection Form submitted for the year ending December 31, 2022 shows Carolina Dialysis-Siler City (CD-Siler City) was serving one Orange County dialysis patient.

- On page 20, the applicant states that the Patient Origin Report for the 2023 SMFP shows Carolina Dialysis-Pittsboro (CD-Pittsboro) was serving three Orange County dialysis patients. On page 21, the applicant states that the ESRD Data Collection Form submitted for the year ending December 31, 2022 shows CD-Pittsboro was serving five Orange County dialysis patients.
- According to Table 9B on page 131 of the 2023 SMFP, there is a surplus of six dialysis stations in Chatham County. The applicant proposes to relocate a total of three stations from Chatham County to Orange County.

### Durham County

- FMC West Pettigrew is located in Durham County.
- Durham County is contiguous to Orange County.
- On page 20, the applicant states that the Patient Origin Report for the 2023 SMFP shows FMC West Pettigrew was serving three Orange County dialysis patients. On page 21, the applicant states that the ESRD Data Collection Form submitted for the year ending December 31, 2022 shows FMC West Pettigrew was serving two Orange County dialysis patients.
- According to Table 9B on page 132 of the 2023 SMFP, there is a surplus of 62 dialysis stations in Durham County. The applicant proposes to relocate a total of two stations from Durham County to Orange County.

The applicant adequately demonstrates the proposed project is conforming to Policy ESRD-2 based on the following:

- The applicant's facilities in Chatham County are serving Orange County residents, Chatham County has a surplus of dialysis stations, and the proposed project will not create a deficit of dialysis stations in Chatham County.
- The applicant's facility in Durham County is serving Orange County residents, Durham County has a surplus of dialysis stations, and the proposed project will not create a deficit of dialysis stations in Durham County.
- According to Table 9B on page 133 of the 2023 SMFP, Orange County has a deficit of seven dialysis stations, and the proposed project will not create a surplus of dialysis stations in Orange 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 application is conforming to this criterion because the application is conforming to Policy ESRD-2.

- (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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

In Section A, page 15, the applicant states that, pursuant to the certificate of need issued for Project ID #J-11995-20, the home dialysis program currently located at CD-Carrboro will be relocated to a new facility and CD-Carrboro will not offer home dialysis training and support after Project ID #J-11995-20 is complete.

### **Patient Origin**

On page 113, the 2023 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Orange County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

<b>CD-Carrboro Current* &amp; Projected Patient Origin</b>				
	<b>Current (CY 2022)</b>		<b>Projected (CY 2027)</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Orange	86.0	84.3%	115.9	86.6%
Durham	8.0	7.8%	10.0	7.5%
Johnston	1.0	1.0%	1.0	0.7%
Northampton	1.0	1.0%	1.0	0.7%
Sampson	1.0	1.0%	1.0	0.7%
Wake	5.0	4.9%	5.0	3.9%
<b>Total</b>	<b>102.0</b>	<b>100.0%</b>	<b>133.9</b>	<b>100.0%</b>

**Source:** Section C, pages 25 and 27

**Note:** Table may not foot due to rounding.

\*Because the applicant has already been approved to relocate its home training program as part of Project ID #J-11995-20, the current home training patients are not included for purposes of illustrating current patient origin.

In Section C, pages 30-32, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant clearly explains the growth projections for the Orange County and Durham County patient populations.
- The applicant did not project growth in the patient population dialyzing at CD-Carrboro and who live outside of Orange and Durham counties.

**Analysis of Need**

In Section C, pages 27-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 34, the applicant states:

*“As the ESRD patient population of the county increases, more dialysis stations are needed. Approval of this application to relocate five dialysis stations to Carolina Dialysis Carrboro will reduce the Orange County station deficit, as well as serving to reduce the station surpluses in Chatham and Durham County.*

*Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. Patients will normally receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will generally dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient's demise.*

*The need that this population has for the proposed services is a function of the individual patient's need for dialysis care and treatment.”*

The information is reasonable and adequately supported for the following reasons:

- On page 29, the applicant states that the number of in-center dialysis patients residing in Orange County increased by 5.3% and the number of Orange County in-center dialysis patients at CD-Carrboro increased by 4.9% between December 31, 2021 and December 31, 2022.
- On page 33, the applicant states CD-Carrboro is the only dialysis facility operating in Orange County and that most Orange County dialysis patients are choosing in-center dialysis treatment.
- In Exhibit C-3, the applicant provides 10 letters of support from patients (eight Orange County residents and two Durham County residents) that each state CD-Carrboro is closer to their residence than the location where they currently receive dialysis, and they will consider transferring their care to CD-Carrboro upon project completion.

Projected Utilization

In Section C, pages 25 and 27, and on Form C in Section Q, the applicant provides historical and projected utilization, as shown in the tables below.

<b>CD-Pittsboro Historical* &amp; Projected Utilization</b>				
	<b>Historical (CY 2022)</b>		<b>Projected (CY 2027)</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Orange	86.0	84.3%	115.9	86.6%
Durham	8.0	7.8%	10.0	7.5%
Johnston	1.0	1.0%	1.0	0.7%
Northampton	1.0	1.0%	1.0	0.7%
Sampson	1.0	1.0%	1.0	0.7%
Wake	5.0	4.9%	5.0	3.9%
<b>Total</b>	<b>102.0</b>	<b>100.0%</b>	<b>133.9</b>	<b>100.0%</b>

**Note:** Table may not foot due to rounding.

\*Excluding home training patients that will be moving to a new location upon completion of Project ID #J-11995-20.

In Section C, pages 30-32, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census at CD-Carrboro on December 31, 2022. The applicant states that on December 31, 2022, its patient census was comprised of 86 Orange County patients, 8 Durham County patients, 5 Wake County patients, and 1 patient each from Johnston, Northampton, and Sampson counties.
- The applicant projects growth in the Orange County patient population using a 4.5% annual growth rate. The applicant states that while the projected growth rate is higher than the 5-

year Average Annual Change Rate (AACR) for Orange County as published in the 2023 SMFP, other factors justify use of a higher growth rate:

- The number of Orange County in-center dialysis patients increased by 5.3% between December 31, 2021 and December 31, 2022.
- The number of Orange County patients at CD-Carrboro increased by 4.9% between December 31, 2021 and December 31, 2022.
- The applicant assumes the eight Orange County dialysis patients and two Durham County dialysis patients that wrote letters of support indicating they would consider switching their care to CD-Carrboro will do so. The applicant assumes those patients will shift to CD-Carrboro once the relocated stations are operational.
- The applicant assumes no other population growth for the patients residing in counties other than Orange County but assumes the patients will continue to dialyze at CD-Carrboro and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2026. OY1 is CY 2026. OY2 is CY 2027.

In Section C, pages 31-32, and immediately following Form C in Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

<b>CD-Carrboro Projected Utilization</b>	
Starting point of calculations is Orange County patients dialyzing at CD-Carrboro on December 31, 2022.	86
Orange County patient population is projected forward by one year to December 31, 2023, using the 4.5% projected annual growth rate.	$86 \times 1.045 = 89.9$
Orange County patient population is projected forward by one year to December 31, 2024, using the 4.5% projected annual growth rate.	$89.9 \times 1.045 = 93.9$
Orange County patient population is projected forward by one year to December 31, 2025, using the 4.5% projected annual growth rate.	$93.9 \times 1.045 = 98.1$
The 8 Orange County patients who wrote letters of support and are projected to switch care to CD-Carrboro are added.	$98.1 + 8 = 106.1$
The 2 Durham County patients who wrote letters of support and are projected to switch care to CD-Carrboro are added.	$106.1 + 2 = 108.1$
The patients dialyzing at CD-Carrboro from other counties are added. This is the projected starting patient census on January 1, 2026.	$108.1 + 16 = 124.1$
Orange County patient population is projected forward by one year to December 31, 2026, using the 4.5% projected annual growth rate.	$106.1 \times 1.045 = 110.9$
The patients dialyzing at CD-Carrboro from other counties are added. This is the projected census on December 31, 2026 (OY1).	$110.9 + 18 = 128.9$
Orange County patient population is projected forward by one year to December 31, 2027, using the 4.5% projected annual growth rate.	$110.9 \times 1.045 = 115.9$
The patients dialyzing at CD-Carrboro from other counties are added. This is the projected census on December 31, 2027 (OY2).	$115.9 + 18 = 133.9$

The applicant projects to serve 128.9 patients on 46 stations, which is 2.8 patients per station per week ( $128.9 \text{ patients} / 46 \text{ stations} = 2.80$ ), by the end of OY1 and 133.9 patients on 46 stations, which is 2.91 patients per station per week ( $133.9 \text{ patients} / 46 \text{ stations} = 2.91$ ), by the end of OY2. This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- While the projected growth rate for Orange County patients is higher than the 5-Year AACR for Orange County as published in the 2023 SMFP, the applicant relies on recent and verifiable historical data to project utilization.
- The applicant relies on letters of support from patients expressing an interest in transferring their care in projecting utilization.
- The applicant projects no growth for the patients residing outside of Orange County and the patients from Durham County who provided letters expressing an interest in transferring their care.

**Access to Medically Underserved Groups**

In Section C, page 36, the applicant states:

*“.... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [people aged 65 and older], 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 Medical Care and its 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, [disability], age or any other grouping/category or basis for being an underserved person.”*

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Estimated % of Total Patients in FY 2</b>
Low income persons	48.9%
Racial and ethnic minorities	84.8%
Women	32.6%
Persons with disabilities	20.7%
Persons 65 and older	44.6%
Medicare beneficiaries	71.7%
Medicaid recipients	48.9%

**Source:** Section C, page 37

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 based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

### **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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

**Two Stations Being Relocated from CD-Siler City**

In Section D, pages 43-45, 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. The applicant notes the 5-Year AACR for Chatham County is -2.3%, and despite projecting utilization at a growth rate of 3.7%, CD-Siler City will still only be utilized at a rate of 68.2%, even after stations are relocated.

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

- The applicant’s utilization projections show available capacity for existing patients, even when using a higher growth rate than the 5-Year AACR for Chatham County.
- The applicant states that while there is no facility need for CD-Siler City in the 2023 SMFP, the facility will apply for additional stations in the future as needed.

On Form D in Section Q and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides projected utilization, as illustrated in the following table.

<b>CD-Siler City Historical &amp; Projected Utilization – December 2022-2025</b>								
	<b>December 31, 2022</b>		<b>December 31, 2023</b>		<b>December 31, 2024</b>		<b>December 31, 2025</b>	
	<b># Patients</b>	<b>% Patients</b>						
Chatham	56.0	94.9%	58.1	95.1%	60.2	95.3%	62.4	95.4%
Alamance	1.0	1.7%	1.0	1.6%	1.0	1.6%	1.0	1.5%
Orange	1.0	1.7%	1.0	1.6%	1.0	1.6%	1.0	1.5%
Randolph	1.0	1.7%	1.0	1.6%	1.0	1.6%	1.0	1.5%
<b>Total</b>	<b>59.0</b>	<b>100.0%</b>	<b>61.1</b>	<b>100.0%</b>	<b>63.2</b>	<b>100.0%</b>	<b>65.4</b>	<b>100.0%</b>

In Section D, pages 43-45, and immediately following Form D in Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the in-center patient census on December 31, 2022. The applicant states that on December 31, 2022, the in-center patient census at CD-Siler City was comprised of 56 Chatham County patients and one patient each from Alamance, Orange, and Randolph counties.
- The applicant notes that the 5-Year AACR for Chatham County is -2.3% but projects growth at a rate of 3.7% per year. The applicant states the Chatham County patient population at CD-Siler City increased by 3.7% during the last year.
- The applicant assumes the patients from Alamance, Orange, and Randolph counties will continue to dialyze at CD-Siler City and projects no growth in those patient populations but adds those patients to the projections where appropriate.

In Section D, page 44, and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides the calculations used to project the patient census at CD-Siler City through December 2025, as shown in the table below.

<b>CD-Siler City Projected Utilization</b>	
Starting point of calculations is Chatham County patients dialyzing at CD-Siler City on December 31, 2022.	56
Chatham County patient population is projected forward by one year to December 31, 2023, using the 3.7% projected growth rate.	$56 \times 1.037 = 58.1$
Chatham County patient population is projected forward by one year to December 31, 2024, using the 3.7% projected growth rate.	$58.1 \times 1.037 = 60.2$
Chatham County patient population is projected forward by one year to December 31, 2025, using the 3.7% projected growth rate.	$60.2 \times 1.037 = 62.4$
The patients from other counties are added. This is the projected census on December 31, 2025 (starting point for proposed project).	$62.4 + 3 = 65.4$

The applicant projects to serve 65.4 patients on 24 stations, which is 2.7 patients per station per week ( $65.4 \text{ patients} / 24 \text{ stations} = 2.73$ , which is rounded to 2.7, and is 67.5% of capacity), by the end of CY 2025, when the proposed project is projected to become operational.

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

- The applicant uses a higher projected growth rate than the 5-Year AACR for Chatham County; if the actual growth rate turns out to be lower than the projected growth rate, the result would be even more capacity for additional patients at CD-Siler City.
- The applicant projects growth in the Chatham County patient population based on its recent facility experience.

Access to Medically Underserved Groups

In Section D, pages 49-51, the applicant states that the relocation of two stations from CD-Siler City will not have any effect on the ability of any members of underserved groups to

receive care at CD-Siler City and offers projected estimates of percentages of patients that fall into medically underserved groups on page 50.

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use in-center dialysis services at CD-Siler City will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- The applicant provides a projected estimate of the percentage of patients in medically underserved groups it anticipates serving.

**One Station Being Relocated from CD-Pittsboro**

In Section D, pages 45-47, 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. The applicant notes the 5-Year AACR for Chatham County is -2.3%, and despite projecting utilization at a growth rate of 3.7%, CD-Pittsboro will still only be utilized at a rate of 73%, even after stations are relocated. The applicant also states that it intends to apply for one additional station based on a facility need determination and plans to file that application on November 15, 2023.

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

- The applicant’s utilization projections show available capacity for existing patients, even when using a higher growth rate than the 5-Year AACR for Chatham County.
- The applicant states it will apply for an additional station based on facility need and provides the date it will file that application.

On Form D in Section Q and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides projected utilization, as illustrated in the following table.

<b>CD-Pittsboro Historical &amp; Projected Utilization – May 2023 – December 2025</b>								
	<b>May 2, 2023</b>		<b>December 31, 2023</b>		<b>December 31, 2024</b>		<b>December 31, 2025</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Chatham	31.0	88.6%	31.7	88.8%	32.8	89.1%	34.1	97.2%
Alamance	1.0	2.9%	1.0	2.8%	1.0	2.7%	1.0	2.8%
Orange	2.0	5.7%	2.0	5.6%	2.0	5.4%	0.0	0.0%
Durham	1.0	2.9%	1.0	2.8%	1.0	2.7%	0.0	0.0%
<b>Total</b>	<b>35.0</b>	<b>100.0%</b>	<b>35.7</b>	<b>100.0%</b>	<b>36.8</b>	<b>100.0%</b>	<b>35.1</b>	<b>100.0%</b>

In Section D, pages 45-47, and immediately following Form D in Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the in-center patient census on May 2, 2023. The applicant states that on May 2, 2023, the in-center patient census at CD-Pittsboro was comprised of 31 Chatham County patients, two Durham County patients, and one patient each from Alamance and Orange counties.
- The applicant notes that the 5-Year AACR for Chatham County is -2.3% but projects growth at a rate of 3.7% per year. The applicant states the Chatham County patient population at CD-Pittsboro increased by 14.8% during the last four months prior to submission of the application, which is an annualized growth rate of 44.4%, but chose to use the 3.7% growth rate to be consistent with projections for CD-Siler City.
- The applicant assumes the patients from Alamance, Orange, and Durham counties will continue to dialyze at CD-Pittsboro and projects no growth in those patient populations but adds those patients to the projections where appropriate.
- The applicant assumes the two patients from Durham County and the patient from Orange County who submitted letters of support stating they would consider switching their care to CD-Carrboro will do so, consistent with the applicant’s projections for CD-Carrboro, and projects those patients will shift as of January 1, 2026, the projected completion date for the proposed project.

In Section D, page 46, and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides the calculations used to project the patient census at CD-Pittsboro through December 2025, as shown in the table below.

<b>CD-Pittsboro Projected Utilization</b>	
Starting point of calculations is Chatham County patients dialyzing at CD-Pittsboro on May 2, 2023.	31
Chatham County patient population is projected forward by seven months to December 31, 2023, using the 3.7% projected growth rate.	$31 \times [(0.037 / 12) \times 7] + 31 = 31.7$
Chatham County patient population is projected forward by one year to December 31, 2024, using the 3.7% projected growth rate.	$31.7 \times 1.037 = 32.8$
Chatham County patient population is projected forward by one year to December 31, 2025, using the 3.7% projected growth rate.	$32.8 \times 1.037 = 34.1$
The patients from Durham and Orange counties projected to transfer care to CD-Carrboro are subtracted from the total number of patients from other counties.	$4 - 3 = 1$
The patient from Alamance County is added. This is the projected census on December 31, 2025 (starting point for proposed project).	$34.1 + 1 = 35.1$

The applicant projects to serve 35.1 patients on 12 stations, which is 2.9 patients per station per week (35.1 patients / 12 stations = 2.93, which is rounded to 2.9, and is 72.5% of capacity), by the end of CY 2025, when the proposed project is projected to become operational.

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

- The applicant uses a higher projected growth rate than the 5-Year AACR for Chatham County but which is lower than the facility's recent experience.
- The applicant states it plans to apply for an additional station based on facility need on November 15, 2023.
- The applicant subtracts patients who provided letters of support for this application and who the applicant assumes will switch care to CD-Carrboro upon project completion.

#### Access to Medically Underserved Groups

In Section D, pages 49-51, the applicant states that the relocation of one station from CD-Pittsboro will not have any effect on the ability of any members of underserved groups to receive care at CD-Pittsboro and offers projected estimates of percentages of patients that fall into medically underserved groups on page 50.

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use in-center dialysis services at CD-Pittsboro will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- The applicant provides a projected estimate of the percentage of patients in medically underserved groups it anticipates serving.

#### **Two Stations Being Relocated from FMC West Pettigrew**

In Section D, pages 47-49, 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. The applicant projects growth in the Durham County patient population based on the 5-Year AACR of 0.3% for Durham County as published in the 2023 SMFP and also projects a decline of six patients from its current patient census. After all utilization projections, the facility will only be utilized at a rate of approximately 52.7%, even after the stations are relocated.

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

- The applicant's utilization projections show available capacity for existing patients.
- The applicant states that while there is no facility need for FMC West Pettigrew in the 2023 SMFP, the facility will apply for additional stations in the future as needed.

On Form D in Section Q and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides projected utilization, as illustrated in the following table.

<b>FMC West Pettigrew Historical &amp; Projected Utilization – December 2022-2025</b>								
	<b>December 31, 2022</b>		<b>December 31, 2023</b>		<b>December 31, 2024</b>		<b>December 31, 2025</b>	
	<b># Patients</b>	<b>% Patients</b>						
Durham	42.0	80.8%	42.1	87.5%	42.3	87.6%	42.4	91.4%
Granville	1.0	1.9%	1.0	2.1%	1.0	2.1%	1.0	2.2%
Orange	2.0	3.9%	2.0	4.2%	2.0	4.1%	0.0	0.0%
Wake	3.0	5.8%	3.0	6.2%	3.0	6.2%	3.0	6.5%
Other States	4.0	7.7%	0.0	0.0%	0.0	0.0%	0.0	0.0%
<b>Total</b>	<b>52.0</b>	<b>100.0%</b>	<b>48.1</b>	<b>100.0%</b>	<b>48.3</b>	<b>100.0%</b>	<b>46.4</b>	<b>100.0%</b>

In Section D, pages 47-49, and immediately following Form D in Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the in-center patient census on December 31, 2022. The applicant states that on December 31, 2022, the in-center patient census at FMC West Pettigrew was comprised of 42 Durham County patients, three patients from Wake County, two patients from Orange County, one patient from Granville County, and four patients from other states.
- The applicant projects growth in the Durham County patient population at an annual rate of 0.3%, which is the 5-Year AACR for Durham County as published in the 2023 SMFP.
- The applicant assumes the four patients from other states are transient patients who will not continue dialyzing with the facility and does not include them in the facility census.
- The applicant assumes the patients from Wake, Orange, and Granville counties will continue to dialyze at FMC West Pettigrew and projects no growth in those patient populations but adds those patients to the projections where appropriate.
- The applicant assumes the two patients from Orange County who submitted letters of support stating they would consider switching their care to CD-Carrboro will do so, consistent with the applicant’s projections for CD-Carrboro, and projects those patients will shift as of January 1, 2026, the projected completion date for the proposed project.

In Section D, page 48, and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides the calculations used to project the patient census at FMC West Pettigrew through December 2025, as shown in the table below.

<b>FMC West Pettigrew Projected Utilization</b>	
Starting point of calculations is Durham County patients dialyzing at FMC West Pettigrew on December 31, 2022.	42
Durham County patient population is projected forward by one year to December 31, 2023, using the 5-Year AACR of 0.3% for Durham County.	$42 \times 1.003 = 42.1$
Durham County patient population is projected forward by one year to December 31, 2024, using the 5-Year AACR of 0.3% for Durham County.	$42.1 \times 1.003 = 42.3$
Durham County patient population is projected forward by one year to December 31, 2025, using the 5-Year AACR of 0.3% for Durham County.	$42.3 \times 1.003 = 42.4$
The patients from Orange County projected to transfer care to CD-Carrboro are subtracted from the total number of patients from other counties.	$6 - 2 = 4$
The patients from other counties are added. This is the projected census on December 31, 2025 (starting point for proposed project).	$42.4 + 4 = 46.4$

The applicant projects to serve 46.4 patients on 22 stations, which is 2.1 patients per station per week (46.4 patients / 22 stations = 2.11, which is rounded to 2.1, and is 52.5% of capacity), by the end of CY 2025, when the proposed project is projected to become operational.

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

- The applicant uses the 5-Year AACR for Durham County as published in the 2023 SMFP to project growth in the Durham County patient population.
- The applicant does not project growth in the patient population from outside of Durham County and removes out-of-state patients from projections.
- The applicant subtracts patients who provided letters of support for this application and who the applicant assumes will switch care to CD-Carrboro upon project completion.

Access to Medically Underserved Groups

In Section D, pages 49-51, the applicant states that the relocation of two stations from FMC West Pettigrew will not have any effect on the ability of any members of underserved groups to receive care at FMC West Pettigrew and offers projected estimates of percentages of patients that fall into medically underserved groups on page 50.

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use in-center dialysis services at FMC West Pettigrew will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- The applicant provides a projected estimate of the percentage of patients in medically underserved groups it anticipates serving.

## **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 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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

In Section E, page 53, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo would result in a continued deficit of dialysis stations in Orange County, since the applicant is the only facility providing in-center dialysis services in Orange County and would not address the need for additional stations; therefore, this was not an effective alternative.
- Apply to Relocate Fewer Than Five Stations: the applicant states that applying to relocate fewer than five stations would have the same effect as maintaining the status quo; therefore, this is not an effective alternative.
- Apply to Relocate More Than Five Stations: the applicant states that applying to relocate more than five stations is not cost effective because the facility does not have room for more than 46 stations; therefore, this is not an 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 applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **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 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 in the 2023 SMFP, the certificate holder shall relocate no more than two dialysis stations from Carolina Dialysis-Siler City, no more than two dialysis stations from FMC Dialysis Center West Pettigrew, and no more than one dialysis station from Carolina Dialysis-Pittsboro for a total of no more than 46 in-center dialysis stations at Carolina Dialysis-Carrboro upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify two in-center and home hemodialysis stations at Carolina Dialysis-Siler City for a total of no more than 24 in-center and home hemodialysis stations at Carolina Dialysis-Siler City.**
- 4. Upon completion of this project, Fresenius Medical Care Holdings, Inc. shall take the necessary steps to decertify two in-center and home hemodialysis stations at FMC Dialysis Center West Pettigrew for a total of no more than 22 in-center and home hemodialysis stations at FMC Dialysis Center West Pettigrew.**
- 5. Upon completion of this project, the certificate holder shall take the necessary steps to decertify one in-center and home hemodialysis station at Carolina Dialysis-Pittsboro for a total of no more than 12 in-center and home hemodialysis stations at Carolina Dialysis-Pittsboro.**

- 6. Upon completion of the proposed project, Carolina Dialysis-Siler City shall have no more than 24 dialysis stations, FMC Dialysis Center West Pettigrew shall have no more than 22 dialysis stations, and Carolina Dialysis-Pittsboro shall have no more than 12 dialysis stations.**
  - 7. 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. The first progress report shall be due on April 1, 2024.**
  - 8. 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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

**Capital and Working Capital Costs**

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

Construction/Renovation Contracts	\$1,364,000
Architect/Engineering Fees	\$136,400
Non-Medical Equipment	\$250,000
Furniture	\$100,000
<b>Total</b>	<b>\$1,850,400</b>

Immediately following Form F.1a 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:

- The applicant projects construction costs based on a national database utilized by Fresenius, one of the applicant's ultimate parent companies.
- The applicant identifies the items that are included in each category.

In Section F, page 57, the applicant states there are no projected start-up costs or initial operating expenses because CD-Carrboro is an existing and operational facility. This information is reasonable and adequately supported because CD-Carrboro is an existing facility currently offering ESRD services and will continue to offer ESRD services during and after development of the proposed project.

### **Availability of Funds**

In Section F, pages 55-56, the applicant states the projected capital costs will be funded by accumulated reserves.

Exhibit F-1 contains a letter dated May 15, 2023 from a Board Member of Carolina Dialysis, LLC, committing \$1,850,400 to development of the proposed project. Exhibit F-1 also contains a letter dated May 15, 2023 from the Senior Vice President & Treasurer of Fresenius Medical Care Holdings, Inc., one of the ultimate parent companies of the applicant, authorizing the relocation of the stations from CD-Siler City, CD-Pittsboro, and FMC West Pettigrew to CD-Carrboro. In Exhibit F-2, the applicant provides a balance sheet for Carolina Dialysis, LLC, which shows that as of March 2023, Carolina Dialysis, LLC had adequate cash and assets to cover the capital costs of the proposed project.

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

- The applicant provides a letter from a Board Member authorizing the use of funding to develop the proposed project and a letter from a company executive authorizing the relocation.
- The applicant provides documentation to demonstrate the availability of funds for the projected capital costs of the proposed project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, 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.

<b>Projected Revenues and Operating Expenses</b>		
<b>CD-Carrboro</b>	<b>FY 1 – CY 2026</b>	<b>FY 2 – CY 2027</b>
Total Treatments	18,919	19,552
Total Gross Revenues (Charges)	\$117,806,585	\$122,353,716
Total Net Revenue	\$6,385,645	\$6,632,120
Average Net Revenue per Treatment	\$338	\$339
Total Operating Expenses (Costs)	\$4,434,384	\$4,537,377
Average Operating Expense per Treatment	\$234	\$232
<b>Net Revenue/(Loss)</b>	<b>\$1,951,261</b>	<b>\$2,094,744</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- 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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

On page 113, the 2023 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 and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Orange County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2023 SMFP, CD-Carrboro is the only existing or approved dialysis facility serving in-center patients in Orange County. As of December 31, 2021, CD-Carrboro was serving 114 patients on 41 stations, for a utilization rate of 2.78 patients per station per week (69.51%).

In Section G, pages 62-63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Orange County. The applicant states:

*“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations from contiguous counties to Orange County, pursuant to Policy ESRD-2. The 2023 SMFP, Table 9A indicates that Carolina Dialysis Carrboro is the only dialysis facility offering in-center dialysis services in Orange County. The 2023 SMFP Table 9B indicates there is a seven-station deficit in Orange County. Relocating five 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 applicant proposes to relocate existing dialysis stations from counties with a surplus of dialysis stations into Orange County where there is a deficit of dialysis stations.

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations 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 described 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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

On Form H in Section Q, the applicant provides current and projected staffing in full-time equivalent (FTE) positions for CD-Carrboro, as shown in the table below.

<b>CD-Carrboro Current &amp; Projected Staffing (FTEs)</b>		
<b>Position</b>	<b>Current (as of 5/1/2023)</b>	<b>Projected (FYs 1-2; CYs 2026-2027)</b>
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses	3.00	6.00
Patient Care Technicians	9.00	13.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	1.00	1.00
Administration/Business Office	2.00	2.00
FMC Director of Operations	0.13	0.13
FMC Chief Technician	0.13	0.13
FMC In-Service	0.13	0.13
<b>TOTAL</b>	<b>18.39</b>	<b>25.39</b>

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 64-65, 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 following:

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

### **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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

### **Ancillary and Support Services**

In Section I, page 67, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 67-72, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

## **Coordination**

In Section I, page 72, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the facility is an existing facility that has existing relationships with local health care and social service providers.

## **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 relocate two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

In Section K, page 75, the applicant states the proposed project involves renovating approximately 4,000 square feet of existing space. Line drawings are provided in Exhibit K-2.

In Section K, pages 75-76, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states it will renovate existing space to be vacated by home therapy training programs and that renovation is a much more cost-effective approach than adding onto the physical building.
- The applicant states its parent company has extensive experience designing dialysis facilities and incorporating cost-saving measures.

In Section K, page 76, 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 applicant states the costs of the proposed project are the responsibility of the applicant and the costs are not passed on to patients.
- The applicant states the project will not increase costs or charges to the public for the proposed services.

In Section K, pages 76-77, 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 80, the applicant provides the historical payor mix during CY 2022 for its existing services, as shown in the table below.

<b>CD-Carrboro Historical Payor Mix CY 2022</b>				
<b>Payment Source</b>	<b>In-Center</b>		<b>Peritoneal Dialysis*</b>	
	<b># of Patients</b>	<b>% of Patients</b>	<b># of Patients</b>	<b>% of Patients</b>
Self-Pay	6.3	6.19%	0.3	1.40%
Commercial Insurance**	6.2	6.08%	5.0	25.18%
Medicare**	74.9	73.38%	14.4	71.86%
Medicaid**	11.7	11.51%	0.2	1.21%
Misc. (including VA)	2.9	2.83%	0.1	0.34%
<b>Total</b>	<b>102.0</b>	<b>100.00%</b>	<b>20.0</b>	<b>100.00%</b>

\*The facility will not offer peritoneal dialysis training and support upon completion of Project ID #J-11995-20.

\*\*Including any managed care plans

**Note:** Table may not foot due to rounding.

In Section L, pages 80-81, the applicant provides the historical payor mix during CY 2022 for the facilities where stations are being relocated from, as shown in the table below.

Historical Payor Mix* CY 2022 – CD-Siler City, CD-Pittsboro, & FMC West Pettigrew						
Payment Source	CD-Siler City		CD-Pittsboro		FMC West Pettigrew	
	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Self-Pay	1.4	2.40%	0.4	1.23%	3.5	6.74%
Commercial Insurance**	13.9	23.63%	0.7	1.97%	5.2	10.03%
Medicare**	17.7	30.02%	27.7	83.87%	36.2	69.61%
Medicaid**	24.1	40.84%	2.3	6.96%	5.0	9.55%
Misc. (including VA)	1.8	3.11%	2.0	5.97%	2.1	4.08%
<b>Total</b>	<b>59.0</b>	<b>100.00%</b>	<b>33.0</b>	<b>100.00%</b>	<b>52.0</b>	<b>100.00%</b>

\*Only in-center patients are shown in this table.

\*\*Including any managed care plans

**Note:** Table may not foot due to rounding.

In Section L, pages 82-83, the applicant provides the following comparisons.

CD-Carrboro	% of Total Patients Served during CY 2022	% of the Population of Orange County
Female	32.6%	52.3%
Male	67.4%	47.7%
Unknown	0.0%	0.0%
64 and Younger	55.4%	84.3%
65 and Older	44.6%	15.7%
American Indian	0.0%	0.6%
Asian	2.2%	7.9%
Black or African-American	64.1%	11.9%
Native Hawaiian or Pacific Islander	1.1%	0.1%
White or Caucasian	15.2%	69.3%
Other Race	17.4%	11.6%
Declined / Unavailable	0.0%	0.0%

	% of Total Patients Served by CD-Siler City during CY 2022	% of Total Patients Served by CD-Pittsboro during CY 2022	% of the Population of Chatham County
Female	25.0%	21.0%	51.6%
Male	75.0%	79.0%	48.4%
Unknown	0.0%	0.0%	0.0%
64 and Younger	57.6%	58.1%	74.7%
65 and Older	42.4%	41.9%	25.3%
American Indian	0.0%	0.0%	1.3%
Asian	0.0%	1.6%	2.4%
Black or African-American	45.2%	27.4%	12.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.2%
White or Caucasian	54.8%	27.4%	82.2%
Other Race	0.0%	0.0%	14.2%
Declined / Unavailable	0.0%	0.0%	0.0%

<b>FMC West Pettigrew</b>	<b>% of Total Patients Served during CY 2022</b>	<b>% of the Population of Durham County</b>
Female	37.1%	52.2%
Male	62.9%	47.8%
Unknown	0.0%	0.0%
64 and Younger	27.4%	85.7%
65 and Older	72.6%	14.3%
American Indian	0.0%	1.0%
Asian	0.0%	5.6%
Black or African-American	69.4%	35.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	16.1%	54.5%
Other Race	0.0%	16.6%
Declined / Unavailable	0.0%	0.0%

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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, pages 83-84, the applicant states it has no such obligation.

In Section L, page 84, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against CD-Carrboro.

**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.

- (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 84, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>CD-Carrboro Projected Payor Mix CY 2027</b>		
<b>Payment Source</b>	<b># of Patients</b>	<b>% of Patients</b>
Self-Pay	8.3	6.19%
Commercial Insurance*	8.1	6.08%
Medicare*	98.3	73.38%
Medicaid*	15.4	11.51%
Misc. (including VA)	3.8	2.83%
<b>Total</b>	<b>133.9</b>	<b>100.00%</b>

\*Including any managed care plans

**Note:** Table may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 6.19% of services will be provided to self-pay patients; 73.38% of services will be provided to Medicare patients; and 11.51% of services will be provided to Medicaid patients.

On pages 84-85, the applicant provides the assumptions and methodology it uses 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 because it is based on the historical payor mix at CD-Carrboro.

**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.

- (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, page 86, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**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.

- (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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

In Section M, page 87, 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 following:

- In Exhibit M-2, the applicant provides a copy of a letter sent to UNC Chapel Hill offering the facility as a training site for nursing students.
- The applicant states it often receives calls to utilize the facility for health professional training programs and discusses the process for intake when it receives such an inquiry.
- The applicant is a joint venture involving The University of North Carolina Hospitals, which is an academic medical center.

## **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 two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

On page 113, the 2023 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 and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Orange County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2023 SMFP, CD-Carrboro is the only existing or approved dialysis facility serving in-center patients in Orange County. As of December 31, 2021, CD-Carrboro was serving 114 patients on 41 stations, for a utilization rate of 2.78 patients per station per week (69.51%).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Durham [sic] County. The applicant does not project to serve dialysis patients currently being served by another provider.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 89, the applicant states:

*“This is a proposal to relocate five stations from CD-Siler City, CD-Pittsboro and FMC West Pettigrew to the CD-Carrboro facility. The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application 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 89, 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, 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 89-90, the applicant states:

*“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. .... Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [people aged 65 and older], 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 any other factor that would classify a patient as underserved.*

*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, [disability], 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 Sections C, D, and L 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 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 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

The applicant proposes to relocate two dialysis stations from Carolina Dialysis-Siler City (CD-Siler City), two dialysis stations from FMC Dialysis Center West Pettigrew (FMC West Pettigrew), and one dialysis station from Carolina Dialysis-Pittsboro (CD-Pittsboro) for a total of 46 stations at Carolina Dialysis-Carrboro (CD-Carrboro) upon completion of this project, Project ID #J-12080-21 (relocate 2 stations), and Project ID #J-11995-20 (relocate 2 stations).

On Form O in Section Q, 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 a total of 125 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 95, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 125 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

### **10 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 dialysis 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. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- CD-Pittsboro is an existing facility. Therefore, this Rule 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 31-32, and on Form C in Section Q, the applicant projects that CD-Carrboro will serve 128.9 patients on 46 stations, or a rate of 2.8 patients per station per week,

as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 30-32, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.