

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 11, 2019

Findings Date: January 11, 2019

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria Hale

Project ID #: J-11578-18

Facility: Carolina Dialysis - Sanford

FID #: 955801

County: Lee

Applicant(s): Carolina Dialysis, LLC

Project: Relocate the entire facility and add six dialysis stations for a total of 39 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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.

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The applicant is Carolina Dialysis, LLC (CD) d/b/a Carolina Dialysis - Sanford (CD - Sanford). The parent companies are The University of North Carolina Hospitals and Renal Research Institute, LLC, an affiliate company of Bio-Medical Applications of North Carolina, Inc. (BMA). Fresenius Medical Care Holdings, Inc, is the parent company of BMA.

The applicant proposes to relocate the entire facility and add six dialysis stations for a total of 39 certified dialysis stations at CD - Sanford upon project completion.

#### **Need Determination**

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the July 2018 Semiannual Dialysis Report (SDR) the county need methodology shows there is a surplus of two dialysis stations in Lee County. Therefore, the July 2018 SDR does not indicate a need for additional stations in Lee County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for CD - Sanford in the July 2018 SDR is 3.2500 patients per station per week, or 81.25% (3.2500 / 4 patients per station = 0.8125). This utilization rate was calculated based on 117 in-center dialysis patients and 36 certified dialysis stations (117 patients / 36 stations = 3.25 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		81.3%
Certified Stations		36
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>36</b>
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		117
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		109
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.1468
(ii)	Divide the result of Step (i) by 12	0.0122
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.1468
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	134.1743
(v)	Divide the result of Step (iv) by 3.2 patients per station	41.9295
	and subtract the number of certified and pending stations to determine the number of stations needed	5.9295

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six stations. Step (C) of the facility need methodology states, *“The facility may apply to expand to meet the need established ..., up to a maximum of*

*ten stations.”* The applicant proposes to add six new stations, therefore the application is consistent with the facility need determination for dialysis stations.

The applicant also proposes to relocate the existing facility from 1922 K.M. Wicker Memorial Drive in Sanford to Central Drive, in Sanford which is roughly 0.5 miles away from the existing site.

### **Policies**

There are three policies in the 2018 SMFP which are applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

*Policy ESRD-2* on page 27 of the 2018 SMFP is applicable to this review because the applicant proposes to relocate existing dialysis stations. *Policy ESRD-2* 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 Semiannual Dialysis Report, 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 Semiannual Dialysis Report.*

The applicant proposes to relocate an entire existing dialysis facility within Lee County. The relocation of the facility does not change the number of dialysis stations in Lee County. Therefore, the application is consistent with Policy ESRD-2.

*Policy GEN-3* on page 33 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. *Policy GEN-3* states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the*

*delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 9-10, Section K.1(g), page 50, Section N.1, page 61, Section O, pages 62-65, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, pages 10-11, Section C, pages 15-19, Section L, pages 55-59, Section N.1, page 61, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, pages 11-12, Section C.1, pages 15-19, Section F, pages 28-34, Section K, pages 48-52, Section N, page 61, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

*Policy GEN-4* on page 33 of the 2018 SMFP is applicable to this review because the applicant proposes a capital expenditure greater than \$2 million. *Policy GEN-4* states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The capital expenditure for the proposed project is greater than \$2 million, but less than \$5 million. In Section B.4, page 13, the applicant states, "CD-S is very cognizant of the need to provide services while maintaining energy efficiency." On pages 13-14, the applicant identifies the energy efficiency and water conservation components of the project. In Section K, pages 48-49, the applicant provides additional information about their plans for energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement to assure improved energy efficiency and water conservation for the proposed replacement facility. Therefore, the application is consistent with Policy GEN-4.

### **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.

- (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 relocate the entire facility and add six dialysis stations for a total of 39 certified dialysis stations at CD - Sanford upon project completion.

**Patient Origin**

On page 365, the 2018 SMFP defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Lee County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 15 and Section C.8, page 23, the applicant provides the historical and projected patient origin, as illustrated in the tables below.

<b>DIALYSIS PATIENTS AS OF JUNE 30, 2018</b>				
<b>COUNTY</b>	<b>IN-CENTER PATIENTS</b>	<b>PERITONEAL PATIENTS</b>	<b>HOME HEMO PATIENTS</b>	<b>% OF TOTAL</b>
Lee	93.0	8.0	2.0	71.0%
Chatham	4.0	1.0	0.0	3.5%
Cumberland	1.0	6.0	0.0	4.8%
Harnett	11.0	7.0	1.0	13.1%
Hoke	1.0	2.0	0.0	2.1%
Moore	3.0	3.0	0.0	4.1%
Other States	2.0	0.0	0.0	1.4%
<b>TOTAL</b>	<b>115.0</b>	<b>27.0</b>	<b>3.0</b>	<b>100.0%</b>

	OPERATING YEAR 1 2021			OPERATING YEAR 2 2022*			PERCENT OF TOTAL PATIENTS	
	IN- CENTER PATIENTS	PERITONEAL PATIENTS	HOME HEMO PATIENTS	IN- CENTER PATIENTS	PERITONEAL PATIENTS	HOME HEMO PATIENTS	YEAR 1	YEAR 2
Lee	110.2	9.5	2.4	115.9	9.9	2.5	77.2% [77.8%]	78.1% [79.2%]
Chatham	2.0	1.0	0.0	2.0	1.0	0.0	1.9%	1.8% [1.9%]
Cumberland	1.0	6.0	0.0	1.0	6.0	0.0	4.4% [4.5%]	4.3%
Harnett	9.0	7.0	1.0	9.0	7.0	1.0	10.8%	10.3% [10.5%]
Hoke	1.0	2.0	0.0	1.0	2.0	0.0	1.9%	1.8% [1.9%]
Moore	3.0	3.0	0.0	3.0	3.0	0.0	3.8%	3.7%
<b>TOTAL</b>	126.0	28.0	3.0	131.0	28.0	3.0	100.0%	100.0%

\*For OY2 it was assumed based on historical utilization that the applicant transposed the columns for peritoneal and home hemodialysis patients on page 15 of the application. In the above table, the Project Analyst illustrates the number of peritoneal and home hemodialysis patients according to its correct historical utilization.

In the table on page 15, the applicant rounds down to the nearest whole patient for calendar year (CY) 1 and 2, therefore, the applicant projects to serve 126 in-center patients by the end of CY1 and 131 in-center patients by the end of CY2. In Section C, pages 15-19, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 18-19, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the July 2018 SDR. The applicant further states on page 8, that the application is also being filed pursuant to Policy ESRD-2, relocation of dialysis stations.

On page 19, the applicant states,

*“The Carolina Dialysis - Sanford facility census has been increasing at a rate greater than the Five Year Average Annual Change Rate of Lee County. The Facility Need Methodology calculates a growth rate of 14.68%.*

*The patient population projected to utilize the Carolina Dialysis - Sanford facility indeed has a need for the stations at this location. The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”*

### Projected Utilization

On pages 16-19, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant starts with the number of Lee County patients (93), as of August 31, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Lee County as published in the July 2018 SDR (5.2%) to project the Lee County patients forward.
- The applicant does not project an increase in the number of Chatham, Cumberland, Harnett, Hoke or Moore counties patients using the facility.
- The applicant projected in Project I.D. # J-11448-18 that two Harnett County patients would transfer their care from CD - Sanford to FMC Lillington as of December 31, 2018. This project is certified and two patients from Harnett County will be subtracted from the facility's census as of December 31, 2018.
- The applicant projected in Project I.D. # J-11469-18 that two Chatham County patients would transfer their care from CD - Sanford to Carolina Dialysis - Pittsboro (CD-Pittsboro) as of December 31, 2018. This project is certified and two patients from Chatham County will be subtracted from the facility's census as of December 31, 2018.
- The applicant projects that HHD and PD patients who receive home training and support services will also grow at the Five-Year AACR for Lee County as published in the July 2018 SDR (5.2%).
- Operating Year 1 (OY1) = Calendar Year (CY) 2021.  
Operating Year 2 (OY2) = Calendar Year (CY) 2022.

The applicant's methodology is illustrated in the following table.



The applicant begins with the Lee County in-center patients as of August 31, 2018.	93
The applicant projects the Lee County patients forward 4 months to December 31, 2018 using one third of the Lee County 5-year AACR, which is 1.733%.	$93 \times 1.01733 = 94.6$
The applicant projects the Lee County in-center patients forward one year to December 31, 2019 at the 5-year AACR, which is 5.2%.	$94.3 \times 1.052 = 99.5$
The applicant projects the Lee County in-center patients forward one year to December 31, 2020 at the 5-year AACR, which is 5.2%.	$99.5 \times 1.052 = 104.7$
The applicant projects the Lee County in-center patients forward one year to December 31, 2021 at the 5-year AACR, which is 5.2%.	$104.7 \times 1.052 = 110.2$
The applicant adds the 16 in-center patients from other counties instead of 20 in-center patients because four patients (2 from Harnett County and 2 from Chatham County) are projected to transfer their care to FMC Lillington and CD - Pittsboro, respectively. This is the projected ending census for <b>Operating Year 1</b> (12/ 31/ 2021).	$110.2 + 16 = 126.2$
The applicant projects Lee County in-center patients forward one year to December 31, 2022 at the 5-year AACR, which is 5.2%.	$110.2 \times 1.052 = 115.9$
The applicant adds the 16 in-center patients from other counties. This is the projected ending census for <b>Operating Year 2</b> (12/ 31/ 2022).	$115.9 + 16 = 131.9$

The applicant projects to serve 126 in-center patients at the end of CY1 and 131 in-center patients at the end of CY2. Thus, the applicant projects that CD - Sanford will have a utilization rate of 80.77% or 3.2 patients per station per week ( $126 \text{ patients} / 39 \text{ stations} = 3.230 / 4 = 0.80769$  or 80.77%) at the end of CY1. The projected utilization of 3.2 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- the applicant begins with the existing in-center patients,
- the applicant grows the Lee County in-center patients using the Lee County 5-year AACR (5.2%) and holds the in-center patient population from other counties constant,
- the growth rate for CD - Sanford was 14.68% as measured between 6/30/17 and 12/31/17, and
- the utilization rate by the end of OY1 meets the minimum standard of 3.2 patients per station per week.

*Home Hemodialysis and Peritoneal Dialysis*

The applicant currently provides training and support for HHD and PD patients. On page 16, the applicant states CD - Sanford will project its home patient population in the same manner as its in-center patient population, increasing these populations by applying the 5-year AACR for Lee County (5.2%) each year. On pages 17 - 18, the applicant provides tables that demonstrate the

projected growth in its HHD and PD training and support programs. At the end of OY1 and OY2, the applicant projects to serve 28 PD patients and 3 HHD patients.

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

- the applicant begins with the existing HHD and PD patients, all of whom are from Lee County, and
- the applicant grows the HHD and PD patients by the Lee County 5-year AACR (5.2%).

**Access**

In Section L-1(a), page 55, the applicant states that each of FMC’s 114 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.1, page 56, the applicant provides the projected payor mix during OY2, as illustrated below.

**Projected Payor Mix OY2**

<b>Payment Source</b>	<b>Percent of Total Revenue</b>	<b>Percent of In-Center Revenue</b>	<b>Percent of HHD Revenue</b>	<b>Percent of PD Revenue</b>
Self Pay/ Indigent/ Charity	3.03%	3.05%	0.10%	0.10%
Medicare	69.09%	69.78%	71.03%	71.03%
Medicaid	12.12%	14.41%	3.34%	3.34%
Commercial Insurance	4.85%	2.48%	12.65%	12.65%
Medicare / Commercial	8.48%	9.77%	4.25%	4.25%
Misc. (VA)	2.42%	0.51%	8.62%	8.62%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

As shown in the table above, OY2, the applicant projects 77.57% of total services will be provided to Medicare (includes Medicare and Medicare/Commercial) and 12.12% to Medicaid patients.

On pages 56-57, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at CD - Sanford.

**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 (payor mix) 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 relocate the entire facility from its current location at 1922 K.M. Wicker Memorial Drive in Sanford to Central Drive, in Sanford which is roughly 0.5 miles away from the existing site. In Section C.13, page 24, 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 24, the applicant states:

*“The existing facility for Carolina Dialysis - Sanford is in need of significant upgrades which cannot be accomplished while continuing patient care. Further, the lease is expiring. ...*

*The relocated facility is to be developed in close proximity to the existing facility, and is not being developed in another area of the county.”*

In Section C.3, page 17, the applicant states:

*“It is Fresenius and CD-S policy to provide all services to all patients regardless of income, race/ethnic origin, gender, physical or mental conditions, age, ability to pay or other factor that would classify a patient as underserved.”*

In Section C.13, page 24, the applicant states the proposed new location is within close proximity to the existing facility. Thus, the facility will still be accessible to the same population presently served, including medically underserved groups.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- 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 relocate the entire facility and add six dialysis stations for a total of 39 certified dialysis stations at CD - Sanford upon project completion.

In Section E.1, page 27, 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 that maintaining the status quo is not an effective alternative because the lease is expiring and the current facility needs “*significant*” upgrades which cannot be accomplished while continuing to provide care. Therefore, this alternative was rejected.
- Apply for fewer stations - The applicant states that applying for fewer stations ignores the growing patient population at CD - Sanford which increased by 14.68% between 6/30/17 and 12/31/17. Therefore, this alternative was rejected.
- Relocate some stations from CD – Lee County - The applicant states the facility’s census increased by four patients in six months ended December 31, 2017 and by another two patients by June 30, 2018. Based on this growth it would not be appropriate to relocate stations to another facility. Therefore, this alternative was rejected.

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 facility is operating above 80% capacity,
- the facility need methodology indicates a need for six additional stations at the facility, and
- to maintain the status quo does not address the need for the additional stations at the facility and would result in higher utilization and potentially restrict patient admissions.

### **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. Therefore, the application is approved subject to the following conditions:

- 1. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Sanford shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2018 SDR, the applicant shall develop six additional dialysis stations for a total of no more than 39 certified stations at Carolina Dialysis - Sanford upon project completion which shall include any home hemodialysis training or isolation stations.**
  - 3. Pursuant to Policy ESRD-2, Carolina Dialysis, LLC d/b/a Carolina Dialysis - Sanford shall relocate the entire facility to a new site in Lee County.**
  - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Sanford shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
  - 5. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Sanford 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 the entire facility and add six dialysis stations for a total of 39 certified dialysis stations at CD - Sanford upon project completion.

**Capital and Working Capital Costs**

In Section F, pages 29, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Miscellaneous Costs:</b>	
Construction Contract Costs	\$2,353,011
Dialysis Machines	\$90,000
Water Treatment Equipment	\$275,000
Other Equipment/Furniture	\$219,718
Miscellaneous Costs	\$617,528
<b>Total</b>	<b>\$3,555,257</b>

In Section F, page 32, the applicant states that there will be no start-up costs or initial operating expenses associated with the proposed project as CD - Sanford is an existing facility.

**Availability of Funds**

In Section F, page 30, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

<b>Type</b>	<b>Carolina Dialysis, LLC</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,555,257	\$3,555,257
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$3,555,257</b>	<b>\$3,555,257</b>

\* OE = Owner's Equity

Exhibit F.1 contains a letter dated September 17, 2018, from the Chairman of the Board of Managers for Carolina Dialysis, which states,

*“This project calls for a capital expenditure of \$3,555,527 on behalf of Carolina Dialysis, LLC.*

*As Chairman of the Board of Managers, I am authorized and do hereby authorize ... and commit cash reserves for the capital cost of \$3,555,257 as may be needed for this project.”*

Exhibit F.2 contains a balance sheet for Carolina Dialysis, LLC which indicates that, as of June 30, 2018, it had \$23,046,729 in cash and investments, \$41,798,706 in total assets and \$37,917,505 in retained earnings (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, for the capital needs of the project.

### **Financial Feasibility**

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

	<b>Operating Year 1 CY2021</b>	<b>Operating Year 2 CY2022</b>
Total Treatments	22,080	22,821
Total Gross Revenues (Charges)	\$88,055,040	\$91,010,148
Total Net Revenue	\$6,570,991	\$6,756,376
Average Net Revenue per Treatment	\$298	\$296
Total Operating Expenses (Costs)	\$5,263,902	\$5,429,483
Average Operating Expense per Treatment	\$238	\$238
Net Income	\$1,307,090	\$1,326,893

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 cost are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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 relocate the entire facility and add six dialysis stations for a total of 39 certified dialysis stations at CD - Sanford upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Lee County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently two dialysis facilities in Lee County, both of which are operated by Carolina Dialysis, LLC, as illustrated below.

<b>LEE COUNTY DIALYSIS FACILITIES CERTIFIED STATIONS &amp; UTILIZATION as of December 31, 2017</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 12/31/17</b>	<b># In-center Patients 12/31/17</b>	<b>Percent Utilization 12/31/17</b>	<b>Patients per Station 12/31/17</b>
CD - Lee County	17	53	77.94%	3.1176
CD - Sanford	36	117	81.25%	3.2500
<b>Total / Average</b>	<b>53</b>	<b>170</b>	<b>80.18%</b>	<b>3.2075</b>

Source: July 2018 SDR.

As illustrated in the table above, the existing facilities in Lee County are well utilized with an average utilization of 3.20 patients per station per week [170/53=3.20] or 80.2% [3.20/4=0.8018].

In Section G, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Lee County. The applicant states, *“the Carolina Dialysis - Lee County [sic] facility growth rate exceeds the growth rate of Lee County...”*

*This application will not create un-necessary duplication.”*



The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of one dialysis station at CD - Sanford is needed in addition to the existing and approved dialysis stations.

**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.

- (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

In Section H, page 38, the applicant provides current and projected staffing for the proposed services. The applicant projects no change in the staffing of CD - Sanford with the relocation of the facility and the addition of six stations, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES OY2
Registered Nurse	6.00	6.00
Home Training Nurse	2.00	2.00
LPN	1.00	1.00
Patient Care Tech (PCT))	13.00	13.00
Dietician	1.25	1.25
Social Worker	1.25	1.25
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.15	0.15
In-Service	0.25	0.25
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	0.85	0.85
<b>Total</b>	<b>27.90</b>	<b>27.90</b>

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 70, which is found in Section R. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and

continuing education programs. In Exhibit I.5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of CD - Sanford.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 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.

### C

In Section I, page 42, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>CD - Sanford Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	CD - Sanford (on site)
Self-care training (in-center)	CD - Sanford (on site)
Home training HH PD Accessible follow-up program	CD - Sanford (on site)
Psychological counseling	UNC Hospitals
Isolation – hepatitis	CD - Sanford (on site)
Nutritional counseling	CD - Sanford (on site)
Social Work services	CD - Sanford (on site)
Acute dialysis in an acute care setting	Central Carolina Hospital or UNC Hospitals
Emergency care	Central Carolina Hospital or UNC Hospitals
Blood bank services	Central Carolina Hospital
Diagnostic and evaluation services	Central Carolina Hospital
X-ray services	Central Carolina Hospital
Laboratory services	Spectra
Pediatric nephrology	UNC Hospitals
Vascular surgery	UNC Hospital or Pinehurst Surgical
Transplantation services	UNC Hospitals
Vocational rehabilitation & counseling	Lee County Vocational Rehab.
Transportation	County of Lee Transit System (COLTS)

In Section I.3, pages 43-45, the applicant describes its existing and proposed relationships with other local healthcare and social service providers. The applicant provides supporting documentation in Exhibit I.2-5. Exhibits I-2 through I-4, respectively, contain copies of agreements with Spectra for laboratories services, Central Carolina Hospital and UNC Hospitals for transfer agreement and UNC Hospitals transplant services.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

**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.

- (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

In Section K, page 50, the applicant states that the project involves up fitting 8,671 square feet of leased space. Line drawings are provided in Exhibit K.1. On pages 48-49, the applicant identifies the applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.1.

On pages 51-52, 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.

**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.

- (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

In Section L.7, page 59, the applicant provides the historical payor mix during CY 2017, as shown in the table below.

Payment Source	Percent of Total Revenue
Self Pay/ Indigent/ Charity	2.23%
Medicare	71.95%
Medicaid	13.76%
Commercial Insurance	2.97%
Medicare / Commercial	8.66%
Misc. (VA)	0.44%
<b>Total</b>	<b>100.0%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Lee	16%	52%	42%	17%	10%	15%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>

Latest Data 7/1/17 as of 7/17/18

\* Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

### Conclusion

The Agency reviewed the:

<sup>1</sup> <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, page 58, the applicant states:

*“CD-S does not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all CD-P is obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section L, page 59, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

### **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 56, the applicant projects the following payor mix for the proposed services during OY2, as shown in the table below.

**Projected Payor Mix OY2**

<b>Payment Source</b>	<b>Percent of Total Revenue</b>	<b>Percent of In-Center Revenue</b>	<b>Percent of HHD Revenue</b>	<b>Percent of PD Revenue</b>
Self Pay/ Indigent/ Charity	3.03%	3.05%	0.10%	0.10%
Medicare	69.09%	69.78%	71.03%	71.03%
Medicaid	12.12%	14.41%	3.34%	3.34%
Commercial Insurance	4.85%	2.48%	12.65%	12.65%
Medicare / Commercial	8.48%	9.77%	4.25%	4.25%
Misc. (VA)	2.42%	0.51%	8.62%	8.62%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

As shown in the table above, OY2, the applicant projects 77.57% of total services will be provided to Medicare (includes Medicare and Medicare/Commercial) and 12.12% to Medicaid patients.

On pages 56-57, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at CD - Sanford.

**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.4, 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

In Section M, page 60, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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 the entire facility and add six dialysis stations for a total of 39 certified dialysis stations at CD - Sanford upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Lee County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently two dialysis facilities in Lee County, both of which are operated by Carolina Dialysis, LLC, as illustrated below.

<b>LEE COUNTY DIALYSIS FACILITIES            CERTIFIED STATIONS &amp;            UTILIZATION as of December 31, 2017</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 12/31/17</b>	<b># In-center Patients 12/31/17</b>	<b>Percent Utilization 12/31/17</b>	<b>Patients per Station 12/31/17</b>
CD - Lee County	17	53	77.94%	3.1176
CD - Sanford	36	117	81.25%	3.2500
<b>Total / Average</b>	<b>53</b>	<b>170</b>	<b>80.18%</b>	<b>3.2075</b>

Source: July 2018 SDR.

As illustrated in the table above, the existing facilities in Lee County are well utilized with an average utilization of 3.20 patients per station per week [ $170/53=3.20$ ] or 80.2% [ $3.20/4=0.8018$ ].

In Section N.1, page 61, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 59, the applicant states:

*“CD-S does not expect this proposal to have effect on the competitive climate in Lee County. At the present time, there are two operational facilities to serve the ESRD patients of Lee County, both operated by Carolina Dialysis, LLC. CD-S does not project to serve dialysis patients currently being served by another provider.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **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.

- (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 A.11, page 5, the applicant states that Carolina Dialysis, LLC operates six facilities in North Carolina. In Exhibit A.3, the applicant provides a list of its affiliates which includes Bio-Medical Applications of North Carolina, Inc.

In Section O, page 65, the applicant states that, during the 18 months immediately preceding the submittal of the application, immediate jeopardy incidents related to quality of care occurred in none of these facilities. In Exhibit O-2, the applicant provides a copy of the most recent survey for CD - Sanford. After reviewing and considering information provided by the applicant and considering the quality of care provided at all facilities, including those related or affiliated with

the applicant, the applicant provided 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.

C

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- CD - Sanford is an existing facility.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, pages 15-19, the applicant demonstrates that CD - Sanford will serve a total of 126 in-center patients at the end of OY1 for a utilization rate of 80.77% or 3.23 patients per station per week ( $126 \text{ patients} / 39 \text{ stations} = 3.230 / 4 = 0.80769$  or 80.77%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C.1, pages 15-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.