

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 12, 2018

Findings Date: June 12, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11469-18

Facility: Carolina Dialysis - Pittsboro

FID #: 981038

County: Chatham

Applicant(s): Carolina Dialysis, LLC

Project: Add one dialysis station and relocate one dialysis station from Carolina Dialysis - Sanford for a total of 12 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.

C

The applicant, Carolina Dialysis, LLC (CD) d/b/a Carolina Dialysis - Pittsboro (CD - Pittsboro), whose parent company is The University of North Carolina Hospitals and Renal Research Institute, LLC is an affiliated company of Bio-Medical Applications of North Carolina, Inc. Fresenius Medical Care Holdings, Inc, is the parent company of Bio-Medical Applications of North Carolina, Inc. The applicant proposes to add one dialysis station and to relocate one dialysis station from Carolina Dialysis - Sanford (CD - Sanford) for a total of 12 certified dialysis stations at CD - Pittsboro upon project completion. CD - Sanford will have 33 certified dialysis

stations upon completion of this project and Project I.D. # M-11448-18 (relocate 2 dialysis stations to FMC Lillington).

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 January 2018 Semiannual Dialysis Report (SDR) the county need methodology shows there is a deficit of three dialysis stations in Chatham County. Therefore, the January 2018 SDR does not indicate a need for additional stations in Chatham County based on the county need methodology, which states that the county deficit must be ten or greater to establish a need for additional stations. 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 - Pittsboro in the January 2018 SDR is 3.3000 patients per station per week, or 82.5% ($3.3000 / 4 \text{ patients per station} = 0.825$). This utilization rate was calculated based on 33 in-center dialysis patients and 10 certified dialysis stations ($33 \text{ patients} / 10 \text{ stations} = 3.3 \text{ patients per station per week}$).

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

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		82.50%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 6/30/17 (SDR2)		33
In-Center Patients as of 12/31/16 (SDR1)		31
Step	Description	Result
	Difference (SDR2 - SDR1)	2
(i)	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.1290
(ii)	Divide the result of step (i) by 12	0.0108
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0645
(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	35.1290
(v)	Divide the result of step (iv) by 3.2 patients per station	10.9778
	and subtract the number of certified and pending stations to determine the number of stations needed	1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. 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 one new station, therefore the application is consistent with the facility need determination for dialysis stations.

The applicant also proposes the relocation of one dialysis station from CD – Sanford in Lee County to CD - Pittsboro. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of three dialysis station in Chatham County and a surplus of 12 dialysis stations in Lee County. Thus, the proposed relocation of one station from Lee County to Chatham County would reduce the surplus of stations in Lee County as well as reduce the deficit in Chatham County by one station.

Policies

There are two policies in the 2018 SMFP which are applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-3: Basic Principles.* *Policy ESRD-2* on page 27 of the 2018 SMFP is applicable to this review because the applicant proposes to relocate one dialysis station from Lee County to Chatham County. *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.*

On page 8, the applicant states that the proposed project, *“does not create a deficit of stations in Lee County, nor does this proposal create a surplus of stations in Chatham County.”* Additionally, Lee County is a contiguous county to Chatham County. On page 21, the applicant states that as of December 31, 2017, four Chatham County residents were receiving services at CD – Sanford in Lee County. The applicant adequately demonstrates that the proposed relocation of one from Lee County to Chatham County 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 44, Section N.1, page 54, Section O, pages 55-59, 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, page 10, Section C, pages 16-17, Section L, pages 48-49, Section N.1, page 54, 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 14-16, Section F, pages 24-32, Section K, pages 42-44, Section N, page 54, 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 that the proposed project is consistent with Policy ESRD-2 and 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 also consistent with Policy GEN-3.

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 add one dialysis station pursuant to the facility need determination and to relocate one dialysis station pursuant to Policy ESRD-2 from CD - Sanford for a total of 12 certified dialysis stations at CD - Pittsboro upon project completion. CD - Sanford will have 33 certified dialysis stations upon completion of this project and Project I.D. # M-11448-18 (relocate 2 dialysis stations to FMC Lillington).

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 Chatham County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 14 and Section C.8, page 18, the applicant provides the projected and historical patient origin for CD - Pittsboro, as illustrated in the table below.

	CD - Pittsboro					
	CURRENT AS OF 12/31/2017		OPERATING YEAR 1 CY2019	OPERATING YEAR 2 CY2020	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	% OF TOTAL	IN-CENTER	IN-CENTER	YEAR 1	YEAR 2
Chatham	35.0	97.2%	40.5	42.5	97.6%	97.7%
Wake	1.0	2.8%	1.0	1.0	2.4%	2.3%
TOTAL	36.0	100.0%	41.5	43.5	100.0%	100.0%

In the table on page 14, the applicant rounds down to the nearest whole patient for calendar year (CY) 1 and 2, therefore, the applicant projects to serve 41 in-center patients in CY1 and 43 in-center patients in CY2. In Section C, pages 15-16, 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 15-16, 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 January 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 16, the applicant states,

“The Carolina Dialysis - Pittsboro facility census has been increasing at a rate greater than the Five Year Average Annual Change Rate of Chatham County. ... The patient population projected to utilize the Carolina Dialysis - Pittsboro 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.”

On pages 15-16, the applicant states:

- The applicant begins the projections for the future patient population of CD - Pittsboro by using the ending in-center patient census of 35 patients for Chatham County, as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Chatham County which is 4.8% to project the Chatham County patient population forward. The applicant calculates a growth rate of 6.45% for CD - Pittsboro based on its historical facility utilization. The applicant states on page 15, this utilization is confirmed through the facility need methodology.
- The applicant provides letters of support from two patients currently dialyzing at CD - Sanford expressing a willing to transfer their care to CD - Pittsboro. The letters state CD - Pittsboro would be closer to those patients residence and more convenient than CD - Sanford. See Exhibit C.1.
- The applicant does not project an increase in the patient population for Wake County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2019
Operating Year 2 (OY2) = Calendar Year (CY) 2020

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

- the applicant begins its projections of the patient population to be served with the existing patient census of CD - Pittsboro on December 31, 2017;
- the applicant grows the Chatham County patient population by the January 2018 SDR Chatham County five-year AACR of 4.8% and holds utilization constant for patients from outside Chatham County, and,

- the utilization rate of the in-center patients projected to be dialyzing at CD - Pittsboro by the end of the first year is above the 3.2 minimum standard of patients per station per week.

Projected Utilization

In Section C, page 15, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Chatham County patients dialyzing at CD - Pittsboro as of December 31, 2017.	35
Project the Chatham County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Chatham County of 4.8%	$35 \times 1.048 = 36.7$
Add two Chatham County patients projected to transfer their care from CD – Sanford.	$36.7 + 2 = 38.7$
Add in one patient from Wake County. This is the starting census for the project.	$38.7 + 1 = 39.7$
Project the Chatham County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Chatham County of 4.8%.	$39.7 \times 1.048 = 41.5$
OY1: Add in one patient from Wake County. This is the projected census for OY 1.	$41.5 + 1 = 42.5$
Project the Chatham County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Chatham County of 4.8%.	$42.5 \times 1.048 = 44.5$
OY2: Add one patient from Wake County. This is the projected census for OY 2.	$44.5 + 1 = 45.5^*$

*Note: The actual calculation is 43.4 patients for OY2 instead of 43.5 patients as reported by the applicant on page 15. As the applicant rounds down to the nearest whole number to 43 patients this small difference is inconsequential.

The applicant provides the assumptions for the projected in-center utilization on pages 14-16, as summarized below:

- Beginning census, December 31, 2017, is as listed in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in February 2018.
- OY1 is the period from January 1 through December 31, 2019.
- OY2 is the period from January 1 through December 31, 2020.
- The applicant include letters of support in Exhibit C.1 from two patients currently dialyzing at CD - Sanford who have expressed a willingness to consider transferring their dialysis care to CD - Pittsboro.

- The 35 in-center patients from Chatham County and the one patient from Wake County will continue to dialyze at CD - Pittsboro.
- The Chatham County patient census will grow at the Chatham County AACR of 4.8%, as reported in the January 2018 SDR, and the Wake County census will be held constant.

In Section C.2, page 16, the applicant states:

“In this application, CD-P has projected a patient population of 41.5 rounded down to 41 in-center patients, to be dialyzing at the Carolina Dialysis - Pittsboro facility at the end of the first year. Failure to add the station will lead to higher utilization rates at the facility. Utilization by 41 patients on 12 dialysis stations is calculated to be 3.42 patients per station, or 85.42% utilization.”

On page 14, the applicant rounds down to the nearest whole patient for calendar year (CY) 1 and 2, therefore, the applicant projects to serve 41 in-center patients in CY1 and 43 in-center patients in CY2. Thus, the applicant projects that CD - Pittsboro will have a utilization rate of 85.4% or 3.4 patients per station per week (41 patients / 12 stations = 3.4166 / 4 = 0.854 or 85.4%) in CY1. The projected utilization of 3.4 patients per station per week at the end of OY1 exceeds 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 its utilization projection with the existing patients of CD - Pittsboro,
- the applicant grows the Chatham County patient population by the January 2018 SDR Chatham County AACR and holds the patient population from outside Chatham County constant, and
- the resulting utilization rate at CD - Pittsboro by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

On page 14, the applicant states CD - Pittsboro does not currently provide home hemodialysis (HH) or peritoneal dialysis (PD) training nor does the applicant propose adding a home training program in the proposed application. On page 37, the applicant states that those patients who desire HH and PD training will be referred to either CD - Sanford or CD - Carrboro.

Access

In Section L-1(a), pages 48-49, the applicant states that each of FMC's 112 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.7, page 52, the applicant provides the historical payor mix calendar year (CY) 2017 for CD - Pittsboro, as illustrated below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.00%
Medicare	71.27%
Medicaid	5.45%
Commercial Insurance	4.49%
Medicare / Commercial	15.73%
Misc. (VA)	3.06%
Total	100.0%

As illustrated in the table above, in CY2017 92.5% of all CD - Pittsboro patients were Medicare or Medicaid recipients. On page 49, the applicant states it projects no change in its payor mix, thus the applicant projects to serve the same number of Medicare or Medicaid recipients in project year (PY) 2 as served in CY2017.

The projected payor mix is reasonable and adequately supported.

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 one dialysis station from CD - Sanford to CD - Pittsboro. On page 21, the applicant states that CD - Sanford is currently licensed for 36 dialysis stations. In Project I.D. # M-11448-18 FMC was approved to relocate 2 stations to FMC Lillington. Thus, upon completion of Project I.D. # M-11448-18 and this project, CD - Sanford will have 33 dialysis stations ($36 - 2 = 34 - 1 = 33$).

In Section D, page 21, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On pages 21-22, the applicant states:

- The applicant identifies an in-center patient population that consist of patients from Lee, Chatham, Harnett, Hoke and Moore counties. (page 21)
- Two patients who currently dialyze at CD - Sanford and reside in Chatham County will transfer their care to CD - Pittsboro. (page 21)
- The applicant projects the Lee County patient population forward using the Five-Year Average Annual Change Rate for Lee County of 1.3%. (page 22)
- The applicant does not project growth in the patient population from Chatham, Harnett, Hoke or Moore County. (page 22)

In Section D, page 22, the applicant projects to serve 116 patients on 33 dialysis stations CY2019 (OY1) of the proposed project, as illustrated below.

Begin with Lee County patients dialyzing at CD - Sanford as of December 31, 2017.	98
Project the Lee County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Lee County of 1.3%	$98 \times 1.03 = 100.9^*$
Add the 19 patients from other counties. This is the starting census for the project.	$100.9 + 19 = 119.9$
Subtract two Chatham County residents projected to transfer their care to CD-Pittsboro.	$119.9 - 2 = 117.9$

*The applicant calculates $98 \times 1.03 = 99.3$. This was assumed to be a typographical error on page 22 of the application as $98 \times 1.03 = 100.9$.

Thus, the applicant projects that CD - Sanford will serve a total of 118 in-center patients at the end of OY1 for a utilization rate of 89.3% or 3.6 (rounded) patients per station per week (118 patients / 33 stations = 3.575 / 4 = 0.893 or 89.3%).

In Section D, page 22, the applicant states,

“This relocation of one station will not alter or affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.

Those patients dialyzing with Carolina Dialysis - Sanford will continue to have access to dialysis care.”

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

- the applicant begins its utilization projection with the existing patients of CD - Sanford,
- the applicant grows the Lee County patient population by the January 2018 SDR Lee County AACR and holds the patient population from outside Lee County constant, and
- the resulting utilization rate at CD - Sanford by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Conclusion

The Agency reviewed the:

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

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

- The needs of the population currently using the services to be reduced, eliminated or 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 add one dialysis station and to relocate one dialysis station from CD - Sanford for a total of 12 certified dialysis stations upon project completion.

In Section E.1, page 23, 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 utilization at CD - Pittsboro will be greater than 80% by the end of OY1. Therefore, this alternative was rejected.
- Relocate stations from CD - Siler City – The applicant reports that the utilization for CD - Siler City has increased its utilization since the January 2018 SDR (utilization as of June 30, 2017) which reported a utilization rate of 78.41%. The applicant reports that as of December 31, 2017, CD - Siler City had a utilization of 87.5%. Therefore, it would not have been in the best interest of those patients to relocate stations from the CD - Siler City facility.

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 applicant's need methodology indicates a need for additional stations at the facility,
- to maintain the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions, and
- applying for less than one station pursuant to the facility need methodology and relocating less than one station for a total of two additional stations at CD - Pittsboro would result in a higher utilization than 4.1 patients per station.

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 - Pittsboro shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to the facility need determination in the January 2018 SDR and Policy ESRD-2, Carolina Dialysis, LLC shall develop no more than one additional dialysis station and relocate no more than one dialysis station from Carolina Dialysis - Sanford for a total of no more than 12 certified stations at Carolina Dialysis - Pittsboro upon project completion which shall include any home hemodialysis training or isolation stations.
 3. Upon completion of this project, Carolina Dialysis, LLC shall take the necessary steps to decertify one dialysis station at Carolina Dialysis - Sanford for a total of no more than thirty-three dialysis stations at Carolina Dialysis - Sanford upon completion of this project and Project I.D. # M-11448-18 (relocate two dialysis station to FMC Lillington).
 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Pittsboro shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations, which shall include any isolation or home hemodialysis training stations.
 5. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Pittsboro 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 add one dialysis station and to relocate one dialysis station from CD - Sanford for a total of 12 certified dialysis stations at CD - Pittsboro upon project completion.

Capital and Working Capital Costs

In Section F, pages 25, the applicant projects the total capital cost of the project as shown in the table below.

Miscellaneous Costs:	
Dialysis Machines	\$30,000
Water Treatment Equipment	\$1,500
Other Equipment/Furniture	\$6,000
Total	\$37,500

In Section R, the applicant provides the assumptions used to project the capital cost. In Section F, page 28, the applicant states that there will be no start-up costs or initial operating expenses associated with the proposed project as CD - Pittsboro is an existing facility.

Availability of Funds

In Section F, page 26, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Carolina Dialysis, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$37,500	\$37,500
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing **	\$37,500	\$37,500

* OE = Owner's Equity

Exhibit F.1 contains a letter dated March 15, 2018, from the member Board of Managers, President of UNC Health Care Networks Hospital and Executive VP and CFO of UNC Hospitals at Chapel Hill, which states,

“As a member of the Board of Managers ... I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$37,500 as may be needed for this project.”

Exhibit F.2 contains the Balance Sheet for Carolina Dialysis, LLC which indicates that it had \$23,627,675 in cash and investments as of December 31, 2017, \$38,680,436 in total assets and \$34,831,752 in retained earnings (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, should there be a need.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (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.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	5,928	6,224
Total Gross Revenues (Charges)	\$23,640,864	\$24,821,312
Total Net Revenue	\$2,155,473	\$2,263,102
Average Net Revenue per Treatment	\$363.61	\$363.61
Total Operating Expenses (Costs)	\$2,028,622	\$2,107,647
Average Operating Expense per Treatment	\$342.21	\$338.63
Net Income	\$126,851	\$155,454

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
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the capital costs 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 add one dialysis station and to relocate one dialysis station from CD - Sanford for a total of 12 certified dialysis stations at CD - Pittsboro 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 Chatham County. Facilities may serve residents of counties not included in their service area.

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

CHATHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility	Certified Stations 6/30/17	# In-center Patients	Percent Utilization	Patients per Station
CD - Pittsboro	10	33	82.50%	3.3000
CD - Siler City	22	69	78.41%	3.1364
Total	32	102	79.68%	3.1875

Source: January 2018 SDR.

As shown in the table above, CD-Pittsboro operated with the highest utilization rate of 82.50%. With regard to the utilization at CD - Siler City, on page 33 the applicant states, *“The utilization rate at both Carolina Dialysis facilities in Chatham County has significantly changed in the six months between June 30 and December 31, 2017.”*

On page 33, the applicant provides the following table to show the increase in utilization at the two facilities.

		As of June 30, 2017		As of December 31, 2017	
		# of Stations	# of Patients	Percent Utilization	# of Patients
CD - Pittsboro	10	33	82.50%	36	90.0%
CD - Siler City	22	69	78.41%	77	87.8%
Total	32	102	79.68%	113	88.3%

As illustrated above, the applicant reports that CD - Pittsboro had a utilization of 90.0% and CD-Siler City had a utilization of 87.8% as of December 31, 2017. The overall the utilization for those two facilities as of December 31, 2017 was 88.3%, thus the facilities in Chatham County are well utilized.

In Section G, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Pittsboro. The applicant states, *“CD-P is actually taking a proactive step to ensure adequate access to care by the patients of the area who choose to dialyze at the facility.”*

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 two dialysis stations at CD - Pittsboro is needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H, page 34, the applicant provides current and projected staffing for the proposed services. The applicant does not project a change in the staffing of CD - Pittsboro with the addition of the two stations, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES OY2
Registered Nurse	2.00	2.00
Technician (PCT))	4.00	4.00
Dietician	0.45	0.45
Social Worker	0.45	0.45
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.15	0.15
In-Service	0.15	0.15
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	0.75	0.75
Total	10.10	10.10

The assumptions and methodology used to project staffing are provided in Section H and Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 64, which is found in Section R. In Section H, pages 34-35, 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 her interest in continuing to serve as the medical director of CD - Pittsboro.

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
- 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.

- (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 37, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

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

The applicant provides supporting documentation in Exhibit I.1-5. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training services with CD - Carrboro, Spectra for laboratories services, UNC Hospitals for transfer agreement and 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
- 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.

- (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.

NA

The applicant does not propose to construct new space nor renovate the existing space. Therefore, Criterion (12) is not applicable to this review.

(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 52, the applicant provides the historical payor mix during January 1 to December 31, 2017 for the proposed services during CY 2017, as shown in the table below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.00%
Medicare	71.27%
Medicaid	5.45%
Commercial Insurance	4.49%
Medicare / Commercial	15.73%
Misc. (VA)	3.06%
Total	100.0%

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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Chatham	26%	52%	28%	12%	8%	15%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

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 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

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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 51, the applicant states:

“CD-P 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 51, 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
- 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.

- (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 49, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.00%
Medicare	71.27%
Medicaid	5.45%
Commercial Insurance	4.49%
Medicare / Commercial	15.73%
Misc. (VA)	3.06%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects the same payor source as CY2017 which consist of 87% Medicare patients (includes Medicare and Medicare/Commercial) and 5.45% Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at CD - Pittsboro.

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.

- (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 51, 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
- 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.

- (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 53, 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
- Information which was publicly available during the review and used by the Agency.

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 add one dialysis station and to relocate one dialysis station from CD - Sanford for a total of 12 certified dialysis stations at CD - Pittsboro 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 Chatham County. Facilities may serve residents of counties not included in their service area.

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

CHATHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility	Certified Stations 6/30/17	# In-center Patients	Percent Utilization	Patients per Station
CD - Pittsboro	10	33	82.50%	3.3000
CD - Siler City	22	69	78.41%	3.1364
Total	32	102	79.68%	3.1875

Source: January 2018 SDR.

As shown in the table above, CD-Pittsboro operated with the highest utilization rate of 82.50%. With regard to the utilization at CD - Siler City, on page 33 the applicant states, *“The utilization rate at both Carolina Dialysis facilities in Chatham County has significantly changed in the six months between June 30 and December 31, 2017.”*

On page 33, the applicant provides the following table to show the increase in utilization at the two facilities.

	# of Stations	As of June 30, 2017		As of December 31, 2017	
		# of Patients	Percent Utilization	# of Patients	Percent Utilization
CD - Pittsboro	10	33	82.50%	36	90.0%
CD - Siler City	22	69	78.41%	77	87.8%
Total	32	102	79.68%	113	88.3%

As illustrated above, the applicant reports that CD - Pittsboro had a utilization of 90.0% and CD-Siler City had a utilization of 87.8% as of December 31, 2017. The overall the utilization for those two facilities as of December 31, 2017 was 88.3%, thus the facilities in Chatham County are well utilized.

In Section N.1, page 54, 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 54, the applicant states:

“CD-P does not expect this proposal to have effect on the competitive climate in Chatham County. At the present time, there are two operational facilities to serve the ESRD patients in Chatham County, both are operated by Carolina Dialysis, LLC. CD-P 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 4, 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, pages 58-59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities (BMA East Rocky Mount). The applicant states that all of the problems have been corrected as documented in Exhibit O-3. 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

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

.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 - Pittsboro 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 14-16, the applicant demonstrates that CD - Pittsboro will serve a total of 41 in-center patients at the end of OY1 for a utilization rate of 85.4% or 3.4 patients per station per week ($41 \text{ patients} / 12 \text{ stations} = 3.4 / 4 = 0.854$ or 85.4%). 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 14-16, 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.