

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2018

Findings Date: December 20, 2018

Project Analyst: Bernetta Thorne-Williams

Chief: Martha J. Frisone

Project ID #: J-11571-18

Facility: Carolina Dialysis - Pittsboro

FID #: 981038

County: Chatham

Applicant(s): Carolina Dialysis, LLC

Project: Relocate the entire facility, develop a home training and support program and add one dialysis station for a total of 13 dialysis stations upon completion of this project and Project I.D. # J-11469-18 (add 2 stations)

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 is Carolina Dialysis, LLC (CD) d/b/a Carolina Dialysis - Pittsboro (CD - Pittsboro). The parents are The University of North Carolina Hospitals and Renal Research Institute, LLC, an affiliate 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, develop a home training and support program for home hemodialysis and peritoneal dialysis patients and add one dialysis station for

a total of 13 certified dialysis stations at CD - Pittsboro upon completion of this project and Project I.D. # J-11469-18 (add 2 dialysis stations).

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 deficit of eight dialysis stations in Chatham County. Therefore, the July 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. 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 - Pittsboro in the July 2018 SDR is 3.6000 patients per station per week, or 90.00% ($3.6000 / 4 \text{ patients per station} = 0.9$). This utilization rate was calculated based on 36 in-center dialysis patients and 10 certified dialysis stations ($36 \text{ patients} / 10 \text{ stations} = 3.6 \text{ patients per station per week}$).

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

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		90.0%
Certified Stations		10
Pending Stations		2
Total Existing and Pending Stations		12
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		36
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		33
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.1818
(ii)	Divide the result of Step (i) by 12	0.0152
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.1818
(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	42.5455
(v)	Divide the result of Step (iv) by 3.2 patients per station	13.2955
	and subtract the number of certified and pending stations to determine the number of stations needed	1.2955

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 to relocate the facility and develop a home training and support program for both home hemodialysis (HHD) and peritoneal dialysis (PD) patients. The existing facility located at 480 Hillsboro Street in Pittsboro will be relocated to Powell Place Lane, in Pittsboro which is roughly 1.7 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 Chatham County. The relocation of the facility does not change the number of dialysis stations in Chatham 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 47, Section N.1, page 59, Section O, pages 60-64, 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 16-17, Section L, pages 52-57, Section N.1, page 59, 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 14-17, Section F, pages 26-34, Section K, pages 45-46, Section N, page 59, 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-P is very cognizant of the need to provide services while maintaining energy efficiency.*” On page 13, the applicant identifies the energy efficiency and water conservation components of the project. In Section K, pages 45-46, 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.

The applicant adequately demonstrates that the proposed project is consistent with Policy ESRD-2, Policy GEN-3, and Policy GEN-4, therefore, the application is consistent with criterion.

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.

The applicant proposes to relocate the entire facility, develop a home training and support program for home hemodialysis and peritoneal dialysis patients and add one dialysis station for a total of 13 certified dialysis stations at CD - Pittsboro upon completion of this project and Project I.D. # J-11469-18 (add 2 stations).

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 20, the applicant provides the projected patient origin, as illustrated in the tables below.

DIALYSIS PATIENTS AS OF JUNE 30, 2018		
	IN-CENTER PATIENTS	% OF TOTAL
Chatham	34.0	97.1%
Wake	1.0	2.9%
TOTAL	35.0	100.0%

	OPERATING YEAR 1 2021			OPERATING YEAR 2 2022			COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER PATIENTS	HOME HEMO PATIENTS	PERITONEAL PATIENTS	IN-CENTER PATIENTS	HOME HEMO PATIENTS	PERITONEAL PATIENTS	YEAR 1	YEAR 2
Chatham	46.6	1.0	1.0	49.6	2.1	2.1	98.0%	98.2%
Wake	1.0	0.0	0.0	1.0	0.0	0.0	2.0%	1.8%
TOTAL	47.0	1.0	1.0	50.0	2.0	2.0	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 47 in-center patients by the end of CY1 and 50 in-center patients by the end of CY2. In Section C, pages 14-17, 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, page 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 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 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 Facility Need Methodology calculates a growth rate of 18.18%.

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.”

Projected Utilization

On pages 14-15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant starts with the number of Chatham County patients (34), as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Chatham County as published in the July 2018 SDR (10.7%) to project the Chatham County patients forward.
- The applicant does not project an increase in the number of Wake County patients using the facility.
- The applicant proposes to develop a home training and support program. The applicant projects two patients in OY1 (1 HHD and 1 PD) and four patients in OY2 (2 HHD and 2 PD).
- 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.

Carolina Dialysis - Pittsboro
J-11571-18
Page 9

The applicant begins with the Chatham County in-center patients as of June 30, 2018.	34
The applicant projects the Chatham County patients forward 6 months to December 31, 2018 using one half the Chatham County 5-year AACR, which is 5.35%.	$34 \times 1.0535 = 35.8$
The applicant projects the Chatham County in-center patients forward one year to December 31, 2019 at the 5-year AACR, which is 10.7%.	$35.8 \times 1.107 = 39.7$
The applicant projects the Chatham County in-center patients forward one year to December 31, 2020 at the 5-year AACR, which is 10.7%.	$39.7 \times 1.107 = 43.9$
The applicant projects the Chatham County in-center patients forward one year to December 31, 2021 at the 5-year AACR, which is 10.7%.	$43.9 \times 1.107 = 48.6$
The applicant subtracts two patients projected to change to home therapies.	$48.6 - 2 = 46.6$
The applicant adds the 1 Wake County in-center patient. This is the projected ending census for Operating Year 1 (12/ 31/ 2021).	$46.6 + 1 = 47.6$
The applicant projects Chatham County in-center patients forward one year to December 31, 2022 at the 5-year AACR.	$46.6 \times 1.107 = 51.6$
The applicant subtracts two patients projected to change to home therapies.	$51.6 - 2 = 49.6$
The applicant adds the 1 Wake County in-center patient. This is the projected ending census for Operating Year 2 (12/ 31/ 2022).	$49.6 + 1 = 50.6$

The applicant projects to serve 47 in-center patients at the end of CY1 and 50 in-center patients at the end of CY2. Thus, the applicant projects that CD - Pittsboro will have a utilization rate of 90.38% or 3.6 patients per station per week ($47 \text{ patients} / 13 \text{ stations} = 3.6153 / 4 = 0.9038$ or 90.38%) at the end of 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 with the existing in-center patients,
- the applicant grows the Chatham County in-center patients using the Chatham County 5-year AACR (10.7%) and holds the Wake County in-center patient constant,
- the growth rate for CD - Pittsboro was 18.2% as measured between 6/30/17 and 12/31/17, and
- the utilization rate by the end of OY1 is above the minimum standard of 3.2 patients per station per week.

Access

In Section L-1(a), page 52, 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 53, the applicant provides the projected payor mix during OY2, as illustrated below.

Projected Payor Mix OY2

Payment Source	Percent of Total Revenue	Percent of In-Center Revenue	Percent of HHD Revenue	Percent of PD Revenue
Self Pay/ Indigent/ Charity	0.0%	0.0%	0.10%	0.10%
Medicare	70.37%	68.15%	71.03%	71.03%
Medicaid	5.56%	5.86%	3.34%	3.34%
Commercial Insurance	5.56%	4.98%	12.65%	12.65%
Medicare / Commercial	16.67%	18.05%	4.25%	4.25%
Misc. (VA)	1.85%	2.96%	8.62%	8.62%
Total	100.00%	100.00%	100.00%	100.00%

As shown in the table above during OY2, the applicant projects 87.04% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial) and 5.56% to Medicaid patients.

On pages 53-54, 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 - Pittsboro.

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.

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 480 Hillsboro Street in Pittsboro to Powell Place Lane in Pittsboro. In Section C.13, page 21, 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 21, the applicant states:

“The existing facility for Carolina Dialysis - Pittsboro is small, and can not [sic] be expanded. Further, the lease is expiring. The expiring lease presents Carolina Dialysis with an opportunity to relocate the facility and add home therapies in a newer, larger dialysis facility.

Currently there is not a home therapies program at either the Carolina Dialysis facilities in Chatham County. Patients who might be candidates for home dialysis must travel to either Sanford or Carrboro for home training. The existing facility does not have space to accommodate a home training program.”

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

“It is Fresenius and CD-P 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 21, the applicant states the proposed new location is within close proximity to the existing facility and near the center of Chatham County. 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, develop a home training and support program for HHD and PD patients and add one dialysis station for a total of 13 dialysis stations upon completion of this project and Project I.D. # J-11469-18 (add 2 stations).

In Section E.1, pages 24-25, 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, the current facility does not have sufficient room to expand and the existing location would not support the development of a home training and support program. Therefore, this alternative was rejected.
- Not develop a home training and support program - The applicant states that not developing a home training and support program would control costs because the facility would not need the additional space. However, the applicant determined this was not an effective alternative because home patients generally have comparable outcomes to in-center dialysis patients and they have much more freedom and flexibility. Therefore, this alternative was rejected.
- Not apply for one additional station - The applicant states that not adding the additional station ignores the growing patient population at CD - Pittsboro which increased 18.18% between 6/30/17 and 12/31/17. 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 one additional station at the facility, and
- to maintain the status quo does not address the need for the additional station 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 - Pittsboro 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 one additional dialysis station for a total of no more than 13 certified stations at Carolina Dialysis - Pittsboro upon completion of this project and Project I.D. # J-11469-18 (add two stations) which shall include any home hemodialysis training or isolation stations.**
 - 3. Pursuant to Policy ESRD-2, Carolina Dialysis, LLC d/b/a Carolina Dialysis - Pittsboro shall relocate the entire facility to a new site in Chatham County.**
 - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Pittsboro shall develop home dialysis training and support programs for home hemodialysis and peritoneal dialysis patients.**
 - 5. Carolina Dialysis, LLC d/b/a Carolina Dialysis - Pittsboro shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station, which shall include any isolation or home hemodialysis training stations.**
 - 6. 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.

The applicant proposes to relocate the entire facility, develop a home training and support program for HHD and PD patients and add one dialysis station for a total of 13 certified dialysis stations at CD - Pittsboro upon completion of this project and Project I.D. # J-11469-18 (add 2 stations).

Capital and Working Capital Costs

In Section F, pages 27, the applicant projects the total capital cost of the project, as shown in the table below.

Miscellaneous Costs:	
Construction Contract Costs	\$1,736,626
Dialysis Machines	\$15,000
Water Treatment Equipment	\$250,000
Other Equipment/Furniture	\$164,769
Miscellaneous Costs	\$507,742
Total	\$2,674,138

In Section F, page 30, 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 28, 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 *	\$2,674,138	\$2,674,138
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing **	\$2,674,138	\$2,674,138

* 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 \$2,674,138 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 \$2,674,138 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.

	Operating Year 1 CY2021	Operating Year 2 CY2022
Total Treatments	7,261	7,705
Total Gross Revenues (Charges)	\$28,366,644	\$31,317,764
Total Net Revenue	\$2,545,408	\$2,842,212
Average Net Revenue per Treatment	\$350.56	\$368.88
Total Operating Expenses (Costs)	\$2,444,258	\$2,686,336
Average Operating Expense per Treatment	\$336.63	\$348.65
Net Income	\$101,151	\$155,876

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 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, develop a home training and support program for HHD and PD patients and add one dialysis station for a total of 13 certified dialysis stations at CD - Pittsboro upon completion of this project and Project I.D. # J-11469-18 (add 2 stations).

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 July 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 CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility	Certified Stations 12/31/17	# In-center Patients 12/31/17	Percent Utilization 12/31/17	Patients per Station 12/31/17
CD – Pittsboro*	10	36	90.00%	3.6000
CD - Siler City**	22	77	87.50%	3.5000
Total	32	113	88.28%	3.5312

Source: July 2018 SDR.

*approved to add 2 stations

**approved to add 1 station

As illustrated in the table above, the existing facilities in Chatham County are well utilized. Even with the three approved stations, the average utilization rate would be 3.22 patients per station per week [$113/35=3.22$] or 80.7% [$3.22/4=0.807$].

In Section G, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Chatham County. The applicant states, *“Based solely on the growth of the census within the Carolina Dialysis facilities in both Pittsboro and Siler City, the applicant suggests that adding one station is not duplicating existing capacity.”*

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 - Pittsboro 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 36, the applicant provides current and projected staffing for the proposed services. The applicant projects a change in the staffing of CD - Pittsboro with the relocation of the facility, the addition of one station and the development of a home training and support program, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES OY2
Registered Nurse	2.00	2.50
Home Training Nurse	0.00	0.50
Technician (PCT))	4.00	4.50
Dietician	0.45	0.50
Social Worker	0.45	0.50
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.15	0.15
In-Service	0.15	0.25
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	0.75	0.85
Total	10.10	11.90

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 69, which is found in Section R. In Section H, page 37, 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

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 40, 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 The applicant proposes to add home training and support services - in the future this service will be performed on site.
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

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 47, the applicant states that the project involves up fitting 4,498 square feet of leased space. Line drawings are provided in Exhibit K.1. On pages 45-46, 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 page 48-49, 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 57, 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	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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Chatham	24%	52%	28%	12%	10%	14%
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 25-26¹) 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:

¹ <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 55, 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 56, 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 53, the applicant projects the following payor mix for the proposed services during OY2, as shown in the table below.

Projected Payor Mix OY2

Payment Source	Percent of Total Revenue	Percent of In-Center Revenue	Percent of HHD Revenue	Percent of PD Revenue
Self Pay/ Indigent/ Charity	0.0%	0.0%	0.10%	0.10%
Medicare	70.37%	68.15%	71.03%	71.03%
Medicaid	5.56%	5.86%	3.34%	3.34%
Commercial Insurance	5.56%	4.98%	12.65%	12.65%
Medicare / Commercial	16.67%	18.05%	4.25%	4.25%
Misc. (VA)	1.85%	2.96%	8.62%	8.62%
Total	100.00%	100.00%	100.00%	100.00%

As shown in the table above during OY2, the applicant projects 87.04% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial) and 5.56% to Medicaid patients.

On pages 53-54, 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 - Pittsboro.

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, pages 55-56, 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 58, 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, develop a home training and support program for HHD and PD patients and add one dialysis station for a total of 13 certified dialysis stations at CD - Pittsboro upon completion of this project and Project I.D. # J-11469-18 (add 2 stations).

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 July 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 CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility	Certified Stations 12/31/17	# In-center Patients 12/31/17	Percent Utilization 12/31/17	Patients per Station 12/31/17
CD – Pittsboro*	10	36	90.00%	3.6000
CD - Siler City**	22	77	87.50%	3.5000
Total	32	113	88.28%	3.5312

Source: July 2018 SDR.

*approved to add 2 stations

**approved to add 1 station

As illustrated in the table above, the existing facilities in Chatham County are well utilized. Even with the three approved stations, the average utilization rate would be 3.22 patients per station per week [113/35=3.22] or 80.7% [3.22/4=0.807].

In Section N.1, page 59, 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-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 of Chatham County, both 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 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, pages 63-64, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in zero of these facilities. In Exhibit O-2, the applicant provides a copy of the most recent survey for CD-Pittsboro. 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 - 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 14-17, the applicant demonstrates that CD - Pittsboro will serve a total of 47 in-center patients at the end of OY1 for a utilization rate of 90.38% or 3.6 patients per station per week ($47 \text{ patients} / 13 \text{ stations} = 3.6153 / 4 = 0.9038$ or 90.38%). 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.