

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2019

Findings Date: December 18, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: Q-11783-19

Facility: Greenville Dialysis Center

FID #: 944657

County: Pitt

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Add no more than 4 dialysis stations for a total of no more than 51 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (BMA), the applicant, proposes to add four dialysis stations to Greenville Dialysis Center (Greenville Dialysis) for a total of 51 dialysis stations at the facility upon completion of this project. Greenville Dialysis currently offers both a peritoneal dialysis (PD) and a home hemodialysis (HHD) program. The parent company of BMA is Fresenius Medical Care Holdings (Fresenius).

Need Determination

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2019 Semiannual Dialysis Report (SDR), Table D, page 63, there is no county need

determination for Pitt County. 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 percent. The utilization rate reported for Greenville Dialysis in the July 2019 SDR is 3.3529 patients per station per week, or 83.82 percent, based on 171 in-center dialysis patients and 51 certified dialysis stations [$171 / 51 = 3.3529 / 4 = 0.8382$ or 83.82%]. Application of the facility need methodology indicates that up to a potential maximum of 11 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 12/31/18		83.820%
Certified Stations		51
Pending Stations		0
Total Existing and Pending Stations		51
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		171
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		159
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	12
	Multiply the difference by 2 for the projected net in-center change	24
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1509
(ii)	Divide the result of Step (i) by 12	0.0126
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.1509
(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	196.8113
(v)	Divide the result of Step (iv) by 3.2 patients per station	61.5035
	and subtract the number of certified and pending stations to determine the number of stations needed	10.5035

Note: In the facility need table in Section B, page 9, the applicant listed 3 stations as “pending stations” which resulted in there being a facility need determination of 7.5 (which by rule rounds up to 8) stations at Greenville Dialysis. This is incorrect. There are no pending stations for Greenville Dialysis. The facility need table above showing a facility need for 11 dialysis stations is correct.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eleven stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. 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 four new stations and is therefore consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 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 will promote safety and quality in Section B, page 11; Section N, pages 56-58; Section O, pages 59-62; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 11-12; Section C, pages 24-25; Section L, pages 51-54; Section N, pages 56-58; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 12-13; Section C, pages 17-23; Section F, pages 32-36; Section K, pages 47-49; Section N, pages 56-58; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates 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.

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 four dialysis stations to Greenville Dialysis for a total of 51 dialysis stations at the facility upon completion of this project.

Patient Origin

On page 369, the 2019 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.*” Greenville Dialysis is in Pitt County. Thus, the service area for this review is Pitt County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC) patients, HHD patients and PD patients.

COUNTY	CURRENT YEAR CY2018			OPERATING YEAR 2 CY2022			COUNTY PATIENTS AS % OF TOTAL	
	IC	HHD	PD	IC	HHD	PD	CURRENT YEAR CY2018	OY 2 CY2020
Pitt	149.00	13.00	21.00	153.50	17.44	31.40	82.43%	84.19%
Beaufort	3.00	1.00	0.00	3.00	0.00	0.00	1.80%	1.26%
Bertie	0.00	2.00	2.00	0.00	2.00	2.00	1.80%	1.67%
Chowan	0.00	1.00	0.00	0.00	1.00	0.00	0.45%	0.42%
Craven	0.00	0.00	1.00	0.00	0.00	0.00	0.45%	0.00%
Duplin	1.00	0.00	0.00	1.00	0.00	0.00	0.45%	0.42%
Edgecombe	2.00	1.00	1.00	1.00	4.00	0.00	1.80%	2.09%
Greene	2.00	1.00	0.00	2.00	1.00	0.00	1.35%	1.26%
Hertford	1.00	0.00	0.00	0.00	0.00	0.0	0.45%	0.00%
Lenoir	0.00	1.00	0.00	1.00	0.00	0.00	0.45%	0.42%
Martin	5.00	1.00	1.00	5.00	1.00	1.00	3.15%	2.93%
Nash	0.00	0.00	0.00	1.00	0.00	0.00	0.00%	0.42%
Tyrell	0.00	0.00	1.00	0.00	0.00	1.00	0.45%	0.42%
Washington	0.00	0.00	0.00	1.00	0.00	0.00	0.00%	0.42%
Wake	1.00	0.00	0.00	0.00	0.00	0.00	0.45%	0.00%
Wayne	1.00	0.00	1.00	1.00	0.00	1.00	0.90%	0.84%
Wilson	2.00	1.00	1.00	3.00	3.00	2.00	1.80%	3.35%
Georgia	1.00	0.00	0.00	0.00	0.00	0.00	0.45%	0.00%
South Carolina	1.00	0.00	0.00	0.00	0.00	0.00	0.45%	0.00%
Other States	2.00	0.00	0.00	0.00	0.00	0.00	0.90%	0.00%
Totals	171.00	22.00	29.00	172.50	29.44	38.40		

Source: Tables on pages 16-17 of the application.

In Section C, pages 17-19, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B, pages 9-10, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP.

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The facility need methodology shows a need for up to eight dialysis stations at the existing Greenville Dialysis facility. However, the Project Analyst determined the facility need methodology shows the applicant has a need for eleven dialysis stations. The applicant is seeking to add four dialysis stations.
- As of December 31, 2018, based on 51 certified stations, Greenville Dialysis was operating at 83.82% utilization.

- A certificate of need was issued on March 23, 2019 to relocate four dialysis stations from Greenville Dialysis to FMC Farmville (Project I.D. #Q-11636-18). This project was certified on April 15, 2019 which reduced the number of certified stations at Greenville Dialysis from 51 stations to 47 stations.
- The applicant projects the first full operating year of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year will be January 1, 2022 – December 31, 2022 (CY2022).
- As part of Project I.D. #Q-11304-17 (develop a new 12 station facility- FKC Captains Cove), BMA states it projected 19 Pitt County patients to transfer their care to the new facility. The new facility was certified on August 30, 2019; however, BMA will show those transfers effective as of June 30, 2019 for this application.
- The applicant projects future patient populations for the facility starting as of June 30, 2019.
- The applicant calculates projected utilization by growing IC Pitt County patients at 4.4%, the Five-Year Average Annual Change Rate (AACR) for Pitt County, as shown in Table D in the July 2019 SDR.
- As of June 30, 2019, there were also four IC patients from other states dialyzing at the facility. BMA does not project any patients from other states as part of the facility's future patient population. BMA assumes these patients were transient.

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

- According to the July 2019 SDR, as of December 31, 2018, Greenville Dialysis was operating at a rate of 3.3529 patients per station per week, or 83.82 percent utilization.
- The applicant demonstrates a need to add eleven dialysis stations to its facility via the facility need methodology and is proposing to only add four dialysis stations. The discussion regarding the facility need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In-Center Patients

In Section C, pages 17-19, and Section Q, the applicant provides projected utilization as summarized in the following table.

Greenville Dialysis	In-Center Patients
As of June 30, 2019, there were 151 Pitt County IC patients dialyzing at Greenville Dialysis.	151
Subtract the 19 Pitt County patients projected to transfer their care to FKC Captains Cove (Project ID #Q-11304-17.)	$151 - 19 = 132$
Project the Pitt County IC patients forward six months to December 31, 2019, using one half of the Five-Year AACR for Pitt County which is 4.4%.	$132 \times 1.022 = 134.9$
Project the Pitt County IC patients forward one year to December 31, 2020, using the Five-Year AACR for Pitt County which is 4.4%.	$134.9 \times 1.044 = 140.8$
Project the Pitt County IC patients forward one year to December 31, 2021, using the Five-Year AACR for Pitt County which is 4.4%.	$140.8 \times 1.044 = 147$
Add the 19 patients from outside Pitt County. This is the ending patient census as of December 31, 2021. This is the IC patient census at the end of OY1.	$147 + 19 = 166$
Project the Pitt County IC patients forward one year to December 31, 2022, using the Five-Year AACR for Pitt County which is 4.4%.	$147 \times 1.044 = 153.5$
Add the 19 patients from outside Pitt County. This is the ending patient census as of December 31, 2022. This is the IC patient census at the end of OY2.	$153.5 + 19 = 172.5$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 166 and 172 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.2549 patients per station per week, or 81.37% ($166 \text{ patients} / 51 \text{ stations} = 3.2549 / 4 = 0.8137$ or 81.37%).
- OY2: 4.0689 patients per station per week, or 101.7% ($172 \text{ patients} / 51 \text{ stations} = 3.3725 / 4 = .8431$ or 84.31%).

The projected utilization of 3.2549 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 projects future utilization based on historical utilization.
- The applicant starts with the 151 existing Pitt County patients and accounts for the 19 Pitt County IC patients projected to transfer their care to the FKC Captains Cove facility.
- The Pitt County patients are projected to increase based on 4.4% per year which is the Five-Year AACR for Pitt County as reported in Table D of the July 2019 SDR.
- The applicant projects no growth for patients who utilize the facility and live in other counties.

- The utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.
- Based on the facility need methodology the Greenville Dialysis facility has a need for eleven dialysis stations and the applicant is only proposing to add four dialysis stations.

Home Therapies

In Section C.4, page 22, the applicant states that the need the proposed population has for the proposed services is a function of the individual patient need for dialysis care and treatment.

In Section C, page 20-22, and Section Q, pages 73-74, the applicant describes its need methodology and assumptions for projecting home training dialysis utilization at Greenville Dialysis, summarized as follows:

- The applicant states that it will begin utilization with the Greenville Dialysis patient census as of June 30, 2019, which was submitted to the Agency on the ESRD Data Collection form in August 2019. The applicant provides its historical and projected utilization for home therapy patients as summarized below.

**Greenville Dialysis
Home Therapy Patients**

COUNTY	12/31/2018		6/30/2019	
	HHD	PD	HHD	PD
Pitt	13	21	15	27
Beaufort	1	0	0	0
Bertie	2	2	2	2
Chowan	1	0	1	0
Craven	0	1	0	0
Edgecombe	1	1	4	0
Green	1	0	1	0
Lenoir	1	0	0	0
Martin	1	1	1	1
Tyrrell	0	1	0	1
Wayne	0	1	0	1
Wilson	1	1	3	2
Total	22	29	27	34

Source: Table on page 20 of the application.

- The applicant projects growth based on Pitt County’s Five-Year AACR published in the July 2019 SDR of 4.4%.
- The applicant assumes the patients from outside Pitt County will continue to dialyze at Greenville Dialysis by patient choice but with no growth.
- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

Home Therapy Projected Utilization

In Section C, page 21 and Section Q, page 74, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the following table.

GREENVILLE DIALYSIS HOME THERAPY PATIENTS		
	HHD	PD
Begin with the Pitt County home patients as of June 30, 2019.	15	27
Project this population forward six months to December 31, 2019, using the Pitt County AACR of 4.4% (2.2% for six months).	$15 \times 1.022 = 15.3$	$27 \times 1.022 = 27.59$
Project Pit County patients forward one year to December 31, 2020, using the Pitt County AACR of 4.4%	$15.3 \times 1.044 = 16$	$27.59 \times 1.044 = 28.81$
Project this population forward one year to December 31, 2021, using the Pitt County Five Year AACR of 4.4%.	$16 \times 1.044 = 16.71$	$28.81 \times 1.044 = 30.08$
Add the patients from outside of Pitt County projected to continue to dialyze at Greenville Dialysis. This is the ending patient census for OY1.	$16.71 + 12 = \mathbf{28.71}$	$30.08 + 7 = \mathbf{37.08}$
Project Pitt County patients forward one year to December 31, 2022, using the Pitt County Five Year AACR of 4.4%.	$16.71 \times 1.044 = 17.44$	$30.08 \times 1.044 = 31.40$
Add the patients from outside of Pitt County projected to continue to dialyze at Greenville Dialysis. This is the ending patient census for OY2.	$17.44 + 12 = \mathbf{29.44}$	$31.40 + 7 = \mathbf{38.40}$

Source: Table in Section C, page 21 and Section Q, page 74

At the end of OY1 (CY2021) Greenville Dialysis is projected to serve 28 HHD patients and 37 PD patients; and at the end of OY2 (CY2022) the facility is projected to serve 29 HHD patients and 38 PD patients.

Projected utilization of the home training program is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for home training services in Pitt County.
- The applicant projects HHD and PD patients based on its historical utilization.
- The applicant projects growth in the Pitt County patient population using the Pitt County Five Year AACR of 4.4%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Pitt County.

Projected utilization of the total proposed IC, HHD, and PD program at Greenville Dialysis is reasonable and adequately supported for the reasons stated above.

Access

In Section C, page 24, the applicant states,

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 53, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	IC Patients		HHD Patients		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Medicaid*	7.46	4.32%	0.00	0.00%	0.23	0.60%
Medicare*	125.61	72.81%	17.30	58.77%	25.56	66.57%
Insurance*	7.49	4.34%	6.60	22.42%	6.04	15.74%
Self-Pay	1.94	1.12%	0.31	1.04%	0.60	1.56%
Other: Medicare/Commercial	26.37	15.29%	2.53	8.58%	4.34	11.29%
Other: Misc. (Includes VA)	3.64	2.11%	2.71	9.19%	1.63	4.24%
Total	172.51	100.00%	29.44	100.00%	38.40	100.00%

*Including any managed care plans.

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.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(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 four dialysis stations to Greenville Dialysis for a total of 51 dialysis stations at the facility upon completion of this project.

In Section E, page 30, 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 this was not a reasonable alternative because it fails to recognize the growth of the ESRD patient population residing in the area. The applicant states that failure to add stations will result in higher utilization rates at the facility and fewer opportunities for patient admission, therefore this alternative was not the least costly or most effective alternative.
- Apply for fewer than four stations – the applicant states that applying for fewer stations would only serve to increase projected utilization rates at the facility and decrease the possibilities for admission into the facility, therefore this alternative was not the least costly or most effective alternative.
- Relocate stations from another BMA facility in Pitt County – the applicant states that its Pitt County facilities are well utilized with each of the other three operational facilities operating at over 80% utilization as of December 31, 2018. The applicant states that it would not be appropriate to relocate stations from any of the facilities. Therefore, this alternative was not the least costly or most effective alternative.

On page 31, the applicant states that it elected to add four stations pursuant to the facility need methodology because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at Greenville Dialysis.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis stations at Greenville Dialysis Center for a total of no more than 51 certified dialysis stations at Greenville Dialysis Center upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. 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 four dialysis stations to Greenville Dialysis for a total of 51 dialysis stations at the facility upon completion of this project.

Capital and Working Capital Costs

In Section F.1, page 32, the applicant projects no capital costs for the proposed project.

In Section F.3, page 34, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
Greenville Dialysis	Operating Year 1 CY2021	Operating Year 2 CY2022
Total Treatments	33,705	34,940
Total Gross Revenues (Charges)	\$212,038,433	\$219,811,379
Total Net Revenue	\$10,552,390	\$10,932,458
Average Net Revenue per Treatment	\$313.08	\$312.89
Total Operating Expenses (Costs)	\$9,257,872	\$9,535,949
Average Operating Expense per Treatment	\$274.67	\$272.92
Net Income/Profit	\$1,294,518	\$1,396,509

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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 because 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.

The applicant proposes to add four dialysis stations to Greenville Dialysis for a total 51 dialysis stations at the facility upon completion of this project.

On page 369, the 2019 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.” Greenville Dialysis is in Pitt County. Thus, the service area for this review is Pitt County. Facilities may serve residents of counties not included in their service area.

According to the July 2019 SDR, Table B indicates there are five dialysis facilities (four existing and one approved) in Pitt County, as follows:

Dialysis Facility	# of Certified Stations	Percent Utilization	Patients Per Station
FMC Care of Ayden	16	82.81%	3.3125
FMC Dialysis Services of East Carolina	41	81.10%	3.2439
FMC Farmville	10	95.00%	3.8000
Fresenius Kidney Care Captains Cove	0	0.00%	0.0000
Greenville Dialysis Center	51	83.82%	3.3529

Source: July 2019 SDR, Table B.

In Section G, pages 37-39, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Pitt County. On pages 38-39, the applicant states:

“The SDR also reports that the Pitt County ESRD Census for December 31, 2018 was 432, and that this census was increasing at a rate of 4.4%. ... If this growth rate is sustained...Pitt County will need five new dialysis stations each year. ... Approval of this application would not cause unnecessary duplication of services but will ensure an adequate inventory of dialysis stations exists for the ESRD patient population of the county.”

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

- The facility need methodology for Greenville Dialysis shows a need for 11 stations and the project only proposes the addition of four stations.
- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing stations in Pitt County.

Conclusion

The Agency reviewed the:

- Application

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

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

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

C

In Section Q, Form H the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(June 30, 2019)	2nd Full Fiscal Year (CY2022)
RNs	9.00	9.00
PCT	19.00	20.00
Home Training Nurse	4.75	5.75
Dietician	1.90	2.00
Social Worker	1.90	2.00
Administrator-Clinical Manager	1.00	1.00
FMC Dir. Ops	0.20	0.20
In-Service	0.30	0.30
Administrative/Business Office	2.90	2.90
Chief Tech	0.20	0.20
Maintenance-Equipment Tech	1.00	1.00
TOTAL	42.15	44.35

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section Q. In Sections H.2 and H.3, page 41, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 42, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3.1 and H-3.2, the applicant provides supporting documentation.

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 44, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

GREENVILLE DIALYSIS CENTER Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On-Site
Self-care training (in-center)	On-Site
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On-Site
Psychological counseling	Referral to: PORT Health Services; ECU Department of Psychiatry and Behavioral Medicine
Isolation – hepatitis	On-Site
Nutritional counseling	On-Site
Social Work services	On-Site
Acute dialysis in an acute care setting	Referral to: Vidant Health System
Emergency care	Provided by facility staff until Ambulance arrival
Blood bank services	Referral to Vidant Health System
Diagnostic and evaluation services	Referral to Vidant Health System; Physicians East Medical Services
X-ray services	Referral to Vidant Health System; Physicians East Medical Services
Laboratory services	On-Site
Pediatric nephrology	Referral to: ECU School of Medicine
Vascular surgery	Referral to: Greenville Surgical, LLC; Azura Vascular Care; ECU School of Medicine
Transplantation services	Vidant Health System; UNC, Duke, UMC
Vocational rehabilitation & counseling	Eastern Carolina Vocation Rehabilitation Center
Transportation	PATS (Pitt Area Transportation System), Med-One Medical Transportation; Care First Medical Transportation

On page 44, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 44, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant provides supporting documentation in Exhibits I-1.2 through I-1.4.

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.

NA

The applicant does not propose to construct any new space or renovate any 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, page 52, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

Payor Source	IC Patients		HHD Patients		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Medicaid	7.39	4.32%	0.00	0.00%	0.17	0.60%
Medicare	124.51	72.81%	12.93	58.77%	19.31	66.57%
Insurance	7.43	4.34%	4.93	22.42%	4.56	15.74%
Self-Pay	1.92	1.12%	0.23	1.04%	0.45	1.56%
Other: Medicare/Commercial	26.14	15.29%	1.89	8.58%	3.27	11.29%
Other: Misc. (Includes VA)	3.61	2.11%	2.02	9.19%	1.23	4.24%
Total	171.00	100.00%	22.00	100.00%	29.00	100.00%

In Section L, page 51, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	43.0%	53.0%
Male	57.0%	47.0%
Unknown	0.0%	0.0%
64 and Younger	59.1%	86.8%
65 and Older	40.9%	13.2%
American Indian	0.0%	0.5%
Asian	0.4%	2.2%
Black or African-American	73.4%	35.7%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	21.5%	54.3%
Other Race	3.0%	7.1%
Declined / Unavailable	0.0%	0.0%

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 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, the applicant states in Section L, pages 52-53, that it has no obligation by any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons under any federal regulations.

In Section L, page 53, 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 the second full fiscal year of operation (CY2022) following completion of the project, as shown in the table below.

Payor Source	IC Patients		HHD Patients		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Medicaid	7.46	4.32%	0.00	0.00%	0.23	0.60%
Medicare	125.61	72.81%	17.30	58.77%	25.56	66.57%
Insurance	7.49	4.34%	6.60	22.42%	6.04	15.74%
Self-Pay	1.94	1.12%	0.31	1.04%	0.60	1.56%
Other: Medicare/Commercial	26.37	15.29%	2.53	8.58%	4.34	11.29%
Other: Misc (Includes VA)	3.64	2.11%	2.71	9.19%	1.63	4.24%
Total	172.51	100.00%	29.44	100.00%	38.40	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that for IC patients 1.12 percent of services will be provided to self-pay patients; 88.1 percent to Medicare (includes Medicare/Commercial) patients; and 4.32 percent to Medicaid patients.

On pages 53-54, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. 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.

- (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.

In Section L, page 54, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 55, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

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 add four dialysis stations to Greenville Dialysis for a total of 51 dialysis stations at the facility upon completion of this project.

On page 369, the 2019 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.*” Greenville Dialysis is in Pitt County. Thus, the service area for this review is Pitt County. Facilities may serve residents of counties not included in their service area.

According to the July 2019 SDR, Table B indicates there are five dialysis facilities (four existing and one approved) in Pitt County, as follows:

Dialysis Facility	# of Certified Stations	Percent Utilization	Patients Per Station
FMC Care of Ayden	16	82.81%	3.3125
FMC Dialysis Services of East Carolina	41	81.10%	3.2439
FMC Farmville	10	95.00%	3.8000
Fresenius Kidney Care Captains Cove	0	0.00%	0.0000
Greenville Dialysis Center	51	83.82%	3.3529

Source: July 2019 SDR, Table B.

In Section N, pages 56-58, 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. The applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Pitt County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population.”

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 B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

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.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 114 dialysis facilities located in North Carolina.

In Section O, page 62, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at the over 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new 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- Greenville Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in 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, page 19, the applicant demonstrates that Greenville Dialysis will serve a total of 166 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 81.37% or 3.2549 patients per station per week ($166 \text{ patients} / 51 \text{ stations} = 3.2549 / 4 = 0.8137$ or 81.37%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 17-22, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.