

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 31, 2019

Findings Date: December 31, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: M-11772-19

Facility: Fresenius Medical Care Angier Dialysis

FID #: 100969

County: Harnett

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

Project: Add no more than 2 dialysis stations for a total of no more than 12 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. (hereinafter referred to as “the applicant” or BMA) proposes to add two dialysis stations to Fresenius Medical Care Angier Dialysis (FMC Angier), an existing dialysis facility, for a total of 14 dialysis stations upon project completion.

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of eight stations in Harnett County, but because there are facilities with a reported utilization of less than 80% in Table B of the 2019 SDR and the county deficit is less than ten stations, there is no county need determination for new dialysis stations for Harnett County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for that dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Fresenius Medical Care Angier Dialysis in the July 2019 SDR is 3.6 patients per station per week, or 90.0%, based on 36 in-center dialysis patients and 10 certified dialysis stations [$36 / 10 = 3.6$; $3.6 / 4 = 0.90$]. Therefore, Fresenius Medical Care Angier Dialysis is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to three additional stations may be needed at this facility, as illustrated in the following the table:

Fresenius Medical Care Angier Dialysis		
OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		90%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		36
In-Center Patients as of 6/30/18 (Jan 2019 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 6/30/18	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 12/31/17 until 12/31/18)	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	3.2955

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Fresenius Medical Care Angier Dialysis is three, based on rounding allowed in Step (v). 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 two new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles is the only Policy in the 2019 SMFP which is applicable to this review.

Policy GEN-3, on page 31 of the 2019 SMFP, 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.3 (a and d), pages 12 and 14, respectively; Sections N.1 and N.2(b), pages 51 - 52; Section O, pages 54 - 57; 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.3, pages 12 - 13; Section N.2(c), page 52; 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.3, pages 13 - 14; Section F, pages 29 – 33; Sections N.1 and N.2(a), pages 51 - 52; 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, and
- 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 two dialysis stations to FMC Angier for a total of 12 dialysis stations upon project completion. FMC Angier does not provide home dialysis training and support at this facility.

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.” Thus, the service area for this facility is Harnett County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 17, the applicant provides the patient origin for FMC Angier in-center (IC) patients as of December 31, 2018, as illustrated in the table below:

**FMC Angier Historical Patient Origin
January 1, 2018 – December 31, 2018**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Harnett	26	72.2%
Forsyth	1	2.8%
Johnston	2	5.6%
Wake	6	16.7%
Wayne	1	2.8%
Total	36	100.0%

Totals may not sum due to rounding

The applicant projects patient origin for the second full year of operation, calendar year (CY) 2022 in Section C, page 17, as illustrated in the following table:

**FMC Angier Projected Patient Origin
 January 1, 2022 – December 31, 2022**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Harnett	33.9	77.0%
Johnston	4.0	9.0%
Wake	6.0	14.0%
Total	43.9	100.0%

Totals may not sum due to rounding

In Section C, pages 18 - 19, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 19 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, stating that dialysis treatment is necessary for patients with End Stage Renal Disease.

In Section C, pages 18 – 19 and Section Q, pages 66 - 67, the applicant provides the assumptions and methodology for projecting in-center patient utilization, summarized as follows:

- The applicant provides a table on pages 18 and 66 that shows the facility in-center census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC ANGIER
 IN-CENTER PATIENTS**

COUNTY	12/31/2018	6/30/2019
Harnett	26	25
Forsyth	1	0
Johnston	2	4
Wake	6	6
Wayne	1	0
Total	36	35

- The applicant states that it will begin its analysis with the FMC Angier patient census as of June 30, 2019, which was submitted to the Agency on the ESRD Data Collection form in August 2019 and is shown in the table above.
- The applicant projects growth of the Harnett County patient population based on the 9.1% Harnett County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.
- The applicant does not project growth of the patient population residing in Johnston and Wake counties, but assumes those patients are dialyzing at FMC Angier by choice. The applicant states it will add those patients to the census at appropriate points in time.

- The applicant projects project completion by December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1 - December 31, 2021 and OY 2 is CY 2022, January 1 - December 31, 2022.

Projected Utilization

In Section C, page 19 and Section Q, page 67, the applicant provides the methodology it used to project utilization, based on its stated assumptions, as illustrated in the following table:

FMC ANGIER IN-CENTER PATIENTS	
Begin with Harnett County patient population as of June 30, 2019.	25
Project forward six months to December 31, 2019 using one-half of the Harnett County Five Year AACR in the July 2019 SDR of 9.1%.	$25 \times 1.0455 = 26.1$
Project forward one year to December 31, 2020 using Harnett County Five Year AACR of 9.1%.	$26.1 \times 1.091 = 28.5$
Add patients from Johnston and Wake counties. This is beginning census for OY 1.	$28.5 + 10 = 38.5$
Project Harnett County population forward one year to December 31, 2021, using Harnett County Five Year AACR of 9.1%.	$28.5 \times 1.091 = 31.1$
Add patients from Johnston and Wake counties. This is ending census for OY 1.	$31.1 + 10 = 41.1$
Project Harnett County population forward one year to December 31, 2022, using Harnett County Five Year AACR of 9.1%.	$31.1 \times 1.091 = 33.9$
Add patients from Johnston and Wake counties. This is ending census for OY 2.	$33.9 + 10 = 43.9$

Source: Tables in Sections C and Q, pages 19 and 67, respectively.

At the end of OY 1 (CY 2021), FMC Angier projects to serve 41 in-center patients on 12 stations, for a utilization rate of 85.4%; and at the end of OY 2 (CY 2022) the facility is projected to serve 44 in-center patients on 12 stations, for a utilization rate of 91.7%.

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

- OY 1: 3.4 patients per station per week, or 85.4% utilization: $41 / 12 = 3.42$; $3.42 / 4 = 0.854$.
- OY 2: 3.7 patients per station per week, or 91.7% utilization: $44 \text{ patients} / 12 \text{ stations} = 3.67$; $3.67 / 4 = 0.917$.

The projected utilization of 3.4 patients per station per week at the end of OY 1 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:

- FMC Angier was operating at 90.0% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects future patient utilization based on historical utilization.
- The applicant projects growth of the Harnett County patient population using the Harnett County AACR of 9.1%.
- Projected utilization at the end of OY 1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C.7, page 21, 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.

...

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

FMC Angier Projected Payor Mix, CY 2022

PAYOR SOURCE	# OF PATIENTS	% OF TOTAL
Self Pay	2.17	4.95%
Insurance*	1.68	3.83%
Medicare*	33.01	75.13%
Medicaid*	1.01	2.29%
Medicare / Commercial	5.68	12.93%
Miscellaneous (includes VA)	0.38	0.87%
Total	43.94	100.00%

Totals may not sum due to rounding

*Includes any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and

- 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 two dialysis stations to FMC Angier for a total of 12 dialysis stations upon project completion.

In Section E, page 27, the applicant states it considered the following alternatives related to serving the needs of the dialysis patients in the service area:

1. 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 service area of FMC Angier. The applicant states it projects to serve 43.9 in-center patients at the end of OY 2, and failure to add stations will result in higher facility utilization rates and fewer opportunities for admission.
2. Relocate stations from another BMA facility in Harnett County – the applicant states it considered relocating stations from one of its other three dialysis facilities in Harnett County, as follows:

- a. Dunn Kidney Center – the applicant states this facility was operating at 75.71%, but Project ID #M-11663-19 authorized the relocation of three stations from that facility. Relocating additional stations out of this facility would not be appropriate.
- b. Fresenius Medical Care Lillington – the applicant states utilization at this facility is increasing [62.5% at the end of 2018 and 71.88% in June 2019]. Therefore, census growth warrants retention of the stations at this facility.
- c. Fresenius Medical Care Anderson Creek – the applicant states this facility was operating at 85.71%, cannot lose stations, and applied for additional stations in this review cycle pursuant to the Facility Need Methodology.

On page 28, the applicant states that it elected to add two 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 FMC Angier.

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 provided 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, and
- information publicly available during the review and used by the Agency.

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

- 1. 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 two additional dialysis stations at Fresenius Medical Care Angier Dialysis for a total of no more than 12 dialysis stations, 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 two dialysis stations to FMC Angier for a total of 12 dialysis stations upon completion of this project.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects the total capital cost of the project as summarized in the table below.

Non-Medical Equipment	\$1,500
Furniture	\$6,000
Total	\$7,500

In Section Q, page 71, the applicant provides the assumptions used to project the capital cost.

In Sections F.3, page 30, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 29, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC.	TOTAL
Loans	0	0
Accumulated reserves or OE *	\$7,500	\$7,500
Bonds	0	0
Other (Specify)	0	0
Total Financing	\$7,500	\$7,500

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, the applicant projects that revenues will not exceed operating expenses in the first two operating years of the project, as summarized in the table below.

	OY 1 CY 2021	OY 2 CY 2022
Total Treatments	5,892.40	6,293.92
Total Gross Revenue (charges)	\$37,069,068	\$39,595,081
Total Net Revenue	\$1,490,614	\$1,592,189
Average Net Revenue per Treatment	\$252.97	\$252.97
Total Operating Expenses (costs)	\$1,694,546	\$1,764,466
Average Operating Expense per Treatment	\$287.58	\$280.34
Net Income / Profit (loss)	(\$203,932)	(\$172,277)

In Section Q, on Form F.2, the applicant states:

“This facility has been operating at a loss, and is forecast to operate at a loss at least through the end of Operating Year 2. While this facility has been operating at a financial loss, it is our expectation that it will soon become profitable.”

In the September 16, 2019 letter provided in Exhibit F.2, the Senior Vice President and Treasurer of FMCH states:

“This facility has been operating at a financial loss for several years. We are in hopes that additional capacity will allow the fixed costs to be diluted over a larger patient base, and help this facility to achieve financial success. Fresenius Medical Care is committed to this facility and supporting it through this period of financial uncertainty for the foreseeable future.”

FMCH’s 2018 consolidated balance sheets reflect total assets in excess of \$20 billion, and cash reserves of \$1.8 billion.

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, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add two dialysis stations to FMC Angier for a total of 12 dialysis stations 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.” The facility is located in Harnett County; thus, the service area for this facility consists of Harnett County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, there are four existing and approved dialysis facilities in Harnett County, all of which are owned or operated by the applicant or a related entity, as follows:

Harnett County Dialysis Facilities, July 2019 SDR

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
Dunn Kidney Center	106	35	75.71%
FMC Anderson Creek	48	14	85.71%
Fresenius Medical Care Angier Dialysis	36	10	90.00%
Fresenius Medical Care of Lillington	40	16	62.50%
Total	230	75	78.48%

Per the July 2019 SDR, as of December 31, 2018, Fresenius related entities own and operate all four of the existing dialysis facilities in Harnett County with a total of 75 certified stations. As stated by the applicant in Section E, page 28, Fresenius Medical Care of Lillington recently reported a 71.88% utilization, and Dunn Kidney Center was recently approved to relocate stations from that facility. The remaining facility, FMC Anderson Creek, was operating at 85.71% utilization.

The applicant provides the same data as above in Section G, page 34, and also provides the updated data for its facilities as submitted on the ESRD Data Collection Forms in August 2019. That data shows an increase in the number of patients, as shown in the following table:

Harnett County Dialysis Facilities as of June 30, 2019

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
Dunn Kidney Center	105	35	75.00%
FMC Anderson Creek	48	14	85.71%
Fresenius Medical Care Angier Dialysis	35	10	87.50%
Fresenius Medical Care of Lillington	46	16	71.88%
Total	234	75	78.00%

Source: Application page 34, reflecting data submitted to the Agency in August 2019.

In Section G, page 35, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Harnett County based on the utilization as of June 30, 2019. The applicant states:

“This is an application to add two dialysis stations to FMC Angier.

The July 2019 SDR does report a deficit of eight stations in Harnett County. Additional stations are needed by the dialysis patient population of the county.

Approval of this application does not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists fo [sic] the ESRD patient population of the county.”

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

- There is a facility need determination for up to three additional dialysis stations at FMC Angier, as calculated using the methodology in the July 2019 SDR.
- The applicant does not propose to develop more dialysis stations than are shown to be needed in the service area.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and

- 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.

- (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 Form H Staffing, in Section Q, page 81, the applicant provides a table illustrating current and projected OY 2 staffing in full time equivalents (FTEs) for FMC Angier, as summarized below.

FMC ANGIER CURRENT AND PROJECTED STAFFING

POSITION	FTE POSITIONS AS OF 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	1.00	1.00	1.00
Patient Care Technician	3.00	4.00	4.00
Dietician	0.40	0.40	0.40
Social Worker	0.40	0.40	0.40
Equipment Technician	0.33	0.33	0.33
Administration	0.50	0.50	0.50
FMC Director Operations	0.15	0.15	0.15
In-Service	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
Total	7.08	8.08	8.08

Source: Section Q Form H

The applicant projects to hire one new Patient Care Technician as a result of this project. The assumptions and methodology used to project existing staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 37, the applicant identifies the current medical director for the facility as Dr. Lee. In Exhibit H-4, the applicant provides a letter from Dr. Lee confirming his intent to continue to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- application, and
- 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 39, 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:

FMC ANGIER ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Refer to BMA Fuquay Varina Kidney Center, BMA Dunn
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Refer to BMA Fuquay Varina Kidney Center, BMA Dunn
Psychological counseling	Day Mark Recovery, Carolina Counseling, DHHS
Isolation – hepatitis	On Site by Applicant
Nutritional counseling	On Site by Applicant
Social Work services	On Site by Applicant
Acute dialysis in an acute care setting	Referral to WakeMed
Emergency care	Provided by facility staff until ambulance arrives
Blood bank services	Referral to WakeMed, Rex Hospital, Harnett Health
Diagnostic and evaluation services	Referral to WakeMed, Rex Hospital, Harnett Health
X-ray services	Referral to WakeMed, Rex Hospital, Harnett Health
Laboratory services	On Site by Applicant
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Referral to Rex Vascular, Raleigh Access Center, WakeMed Vascular, Triangle Vascular
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & Counseling	NC DHHS Vocational Rehab
Transportation	HARTS, H2Go

Source: Application page 39

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

Conclusion

The Agency reviewed the:

- application, and
- 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 proposes to add two dialysis stations to FMC Angier for a total of 12 dialysis stations upon project completion.

In Section K, page 42, the applicant states that the proposed project will install and add two dialysis stations into existing space, and no new construction nor renovation is required as part of this project.

The applicant does not propose to

- construct any new space
- 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 47, the applicant provides the historical payor mix during CY 2018 for its existing services at FMC Angier, as summarized in the table below.

**FMC ANGIER
 HISTORICAL PAYOR MIX CY 2018**

Payor Source	In-Center Patients	
	# of Patients	% of Total
Self-pay	1.78	4.95%
Insurance*	1.38	3.83%
Medicare*	27.05	75.13%
Medicaid*	0.83	2.29%
Medicare/Commercial	4.66	12.93%
Miscellaneous (Incl. VA)	0.31	0.87%
Total	36.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 46, the applicant compares demographical information on FMC Angier patients and the service area population during CY 2018, as summarized below:

	PERCENTAGE OF TOTAL FMC ANGIER PATIENTS SERVED DURING THE LAST FULL OY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	47.1%	51.3%
Male	52.9%	48.7%
Unknown		
64 and Younger	61.8%	88.4%
65 and Older	38.2%	11.6%
American Indian	0.0	0.8%
Asian	67.6%	7.5%
Black or African-American	0.0%	21.0%
Native Hawaiian or Pacific Islander	26.5%	0.1%
White or Caucasian	5.9%	59.8%
Other Race	67.6%	10.8%
Declined / Unavailable	0.0%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information 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, page 47, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities or handicapped persons under any federal regulations.

In Section L, page 48, 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, and
- 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 48, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**FMC ANGIER
PROJECTED PAYOR MIX CY 2021**

Payor Source	In-Center Patients	
	# of Patients	% of Total
Self-pay	2.17	4.95%
Insurance*	1.68	3.83%
Medicare*	33.01	75.13%
Medicaid*	1.01	2.29%
Medicare/Commercial	5.68	12.93%
Miscellaneous (Incl. VA)	0.38	0.87%
Total	43.94	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 4.95% of total in-center services will be provided to self-pay patients, 88.06% to Medicare patients (includes Medicare and Medicare/Commercial), and 2.29% to Medicaid patients.

On pages 48 - 49, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of FMC Angier.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- 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 50, 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.

Conclusion

The Agency reviewed the:

- application, and
- 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 two dialysis stations to FMC Angier for a total of 12 dialysis stations 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.” The facility is located in Harnett County; thus, the service area for this facility consists of Harnett County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, there are four existing and approved dialysis facilities in Harnett County, all of which are owned or operated by the applicant or a related entity, as follows:

Harnett County Dialysis Facilities, July 2019 SDR

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
Dunn Kidney Center	106	35	75.71%
FMC Anderson Creek	48	14	85.71%
Fresenius Medical Care Angier Dialysis	36	10	90.00%
Fresenius Medical Care of Lillington	40	16	62.50%
Total	230	75	78.48%

In Section N, pages 51 - 53, 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 Harnett County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Angier facility begins with current patient population.

There are currently four Fresenius related dialysis facilities within Harnett County. With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area... .

Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.

...

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.”

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, and
- 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 Facilities, 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 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius 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- FMC Angier is an existing facility.

(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 and Section Q Form C, page 65, the applicant projects that FMC Angier will serve 41.1 in-center patients on 12 stations, or a rate of 3.4 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patient per station per week. 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 18 - 19 and Section Q, pages 66 - 67, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.