

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 10, 2019

Findings Date: May 10, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: H-11670-19

Facility: FMC of Anson County

FID #: 061094

County: Anson

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

Project: Add one dialysis station for a total of 18 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. (the applicant) proposes to add one dialysis station to Fresenius Medical Care Anson County (FMC Anson County), an existing facility, for a total of 18 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 in the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Anson County; thus the applicant cannot apply to add any additional stations based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations in its existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for

FMC Anson County in the January 2019 SDR is 3.5 patients per station per week, or 87.50%, based on 56 in-center dialysis patients and 16 certified dialysis stations [$56 / 16 = 3.5$; $3.5 / 4 = 0.8750$ or 87.50%]. The applicant received a certificate of need on June 21, 2018 to add one dialysis station to the facility, which would bring the total number of stations to 17. That station was certified on February 4, 2019. However, as of the date the information was submitted to the Agency for the January 2019 SDR, that one station had not yet been certified.

Application of the facility need methodology indicates up to one additional station is needed at this facility, as illustrated in the following the table:

FMC of Anson County		
APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		87.50%
Certified Stations		16
Pending Stations		1
Total Existing and Pending Stations		17
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		56
In-Center Patients as of 12/31/18 (July 2018 SDR) (SDR1)		55
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	1
	Multiply the difference by 2 for the projected net in-center change	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.0364
(ii)	Divide the result of step (i) by 12	0.0030
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0182
(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	57.0182
(v)	Divide the result of step (iv) by 3.2 patients per station	17.8182
	and subtract the number of certified and pending stations to determine the number of stations needed	0.8182

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Anson County is one, 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 one new station; therefore, the application is 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.4 (a and d), pages 9 and 11 – 12, respectively; Section N.1, page 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.4 (b and d), pages 10 - 12; Section C.3, page 17; Section L, pages 51 - 54; Section N.1, page 57; 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.4 (c and d), pages 11 - 12; Section F, page 28; Section K, pages 45 - 46; Section N.1, page 57; 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 one dialysis station to the existing facility for a total of 18 dialysis stations upon project completion.

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

In Section C.8, page 19, the applicant provides the patient origin for FMC Anson County patients as of December 31, 2018, as shown in the table below.

**FMC Anson County
Historical Patient Origin**

COUNTY	# OF PATIENTS
Anson	58
Total	58

The following table illustrates projected patient origin for the first two years of operation following project completion, as provided in Section C, page 15.

**FMC Anson County
 Projected Patient Origin**

COUNTY	OPERATING YEAR 1 CY 2021		OPERATING YEAR 2 CY 2022	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Anson	71.1	100.0%	76.0	100.0%
Total	71	100.0%	76	100.0%

In Section C, pages 15 - 17, 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

The applicant proposes to add one dialysis station to the existing FMC Anson County, for a total of 18 dialysis stations upon project completion. In Section C.1, on pages 15 - 17, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility, summarized as follows:

- The applicant states FMC Anson County serves only in-center dialysis patients as it is not certified to provide home training. BMA patients who are candidates for home training are referred to FMC Charlotte for training and support.
- The applicant begins projections of future patients with the facility patient census as of December 31, 2018, as submitted to the Agency on the ESRD data collection forms submitted in February 2019.
- As of December 31, 2018, the in-center patient census of Anson County residents at FMC Anson County was 58 patients.
- The applicant utilizes the 7.0% Anson County Five Year Average Annual Change Rate (AACR) as published in the January 2019 SDR.
- The applicant projects this project will be complete on December 31, 2020.
- The applicant states there are two “interim years” from January 1, 2019 – December 31, 2019 and January 1, 2020 – December 31, 2020.
- The first Operating Year (OY) for this project is thus calendar year (CY) 2021, January 1, 2021 – December 31, 2021. The second OY is CY 2022, January 1, 2022 – December 31, 2022.

Projected Utilization

In Section C, page 16, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the following table.

FMC ANSON COUNTY IN-CENTER PATIENTS	
Begin with 58 Anson County in-center dialysis patients as of December 31, 2018.	58
Project this population forward one year to December 31, 2019, using the Anson County Five Year AACR of 7.0%	$58 \times 1.07 = 62.1$
Project this population forward one year to December 31, 2020, using the Anson County Five Year AACR of 7.0%	$62.1 \times 1.07 = 66.4$
Project this population forward one year to December 31, 2021, using the Anson County Five Year AACR of 7.0%	$66.4 \times 1.07 = 71.1$
Project this population forward one year to December 31, 2022, using the Anson County Five Year AACR of 7.0%	$71.1 \times 1.07 = 76.1$

Source: Table in Section C, page 16

Projected patients for OY 1 and OY 2 are rounded down to the nearest whole number. Therefore, at the end of OY 1 (CY 2021) FMC Anson County is projected to serve 71 in-center patients on 18 stations; and at the end of OY 2 (CY 2022) the facility is projected to serve 76 in-center patients on 18 stations.

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

- OY 1: 3.94 patients per station per week, or 98.6% utilization [$71 / 18 = 3.94$; $3.94 / 4 = 0.9861$].
- OY2: 4.22 patients per station per week, or 105% utilization [$76 \text{ patients} / 18 \text{ stations} = 4.22$; $4.22 / 4 = 1.055\%$]

The projected utilization of 3.94 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 Anson County was operating at 87.5% capacity as of June 30, 2018, as reported in the January 2019 SDR.
- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the patient population using the Anson County Five Year AACR of 7.0%, as published in the January 2019 SDR.
- 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.3, page 17, 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 undeserved 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 undeserved person.”

In Section L, page 52, 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.

**FMC Anson County
Projected Payor Mix CY 2022**

Payment Source	% of Total
Self-pay/Indigent/Charity	0.38%
Medicare	77.32%
Medicaid	2.37%
Commercial Insurance	6.72%
Medicare/Commercial	13.20%
Total	100.00%

Note: numbers may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately 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 one dialysis station to the existing facility for a total of 18 dialysis stations upon project completion.

In Section E, page 23, the applicant states the only alternative it considered was to add one station to this facility pursuant to the facility need methodology, because doing so addresses the needs of this facility and these patients.

In Section E, page 23, the applicant states that its proposal is the most cost effective alternative because of its modest capital expenditure and meeting the growing needs of patients choosing to dialyze at FMC Anson County.

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

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 and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
 2. **Pursuant to the facility need determination in the January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station at Fresenius Medical Care of Anson County for a total of no more than 18 certified stations 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 one dialysis station to the existing facility for a total of 18 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 25, and in supplemental information provided at the Agency's request, the applicant projects the total capital cost of the project as shown in the following table:

ITEM	COST
Construction Contract	\$222,481
RO Water Treatment Equipment	\$35,000
Other Equipment / Furniture	\$15,014
Architect / Engineering Fees	\$15,574
Contingency	\$35,664
Total	\$323,733

In Sections F.10 and F.11, pages 28, 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 26, the applicant states that the parent company of the applicant will fund the entire capital cost of the proposed project with accumulated reserves as shown in the table below.

Sources of Capital Cost Financing

TYPE	BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC.	TOTAL
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$323,733	\$323,733
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$323,733	\$323,733

* OE = Owner's Equity

Exhibit F-1 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 contains a copy of the Consolidated Balance Statements from Fresenius Medical Care Holdings, Inc. and subsidiaries, which showed that as of December 31, 2017 Fresenius Medical Care Holdings, Inc. had \$569,818,000 in cash and equivalents, \$19,822,127,000 in total assets and \$10,542,494,000 in net assets (total assets less total liabilities).

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 B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

FMC Anson County Projected Revenue and Operating Expenses

	OY 1 CY 2021	OY 2 CY 2022
Total Treatments	10,077	10,818
Total Gross Revenue (charges)	\$40,187,076	\$43,142,184
Total Net Revenue	\$2,607,570	\$2,799,314
Average Net Revenue per Treatment	\$258.76	\$258.76
Total Operating Expenses (costs)	\$2,552,159	\$2,673,087
Average Operating Expense per Treatment	\$253.26	\$247.10
Net Income / Profit	\$55,411	\$126,227

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add one dialysis station to the existing facility for a total of 18 dialysis stations upon project completion.

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

There are two dialysis providers in Anson County, and two existing facilities. DaVita operates the other dialysis facility and received a certificate of need on November 6, 2018 to relocate the entire facility to a new location in the same town, within Anson County. See the following table that shows the two dialysis facilities in Anson County, from Table B of the January 2019 SDR:

FACILITY	PROVIDER	LOCATION	# STATIONS	UTILIZATION
Fresenius Medical Care of Anson County	BMA	Wadesboro	16	87.50%
Dialysis Care of Anson County	DaVita	Wadesboro	15	41.67%

In Section G, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Anson County. The applicant states:

“BMA is not creating unnecessary duplication of existing or approved health services. Rather this application seeks to ensure that adequate dialysis resources are available for the patient population choosing to dialyze at the FMC Anson County facility.”

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 at FMC Anson County, as calculated using the methodology in the January 2019 SDR, for the proposed additional dialysis station.
- 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
- Information which was publicly available during the review and used by the Agency

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

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

C

In Section H.1, page 35, the applicant provides current and projected staffing in full time equivalents (FTEs) for FMC Anson County. The applicant proposes to add 0.50 FTE equivalents for RN and patient care technician positions associated with the proposed project, which is a net increase of one FTE position. The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Exhibit H-2, the applicant provides an outline of its continuing education programs. In Section I.3, page 40, the applicant identifies the current medical director for the facility. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing 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
- 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 ANSON COUNTY – ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	BMA on site
Self-care training (in-center)	Referral to FMC Charlotte
Home training HH PD Accessible follow-up program	Metrolina Kidney Center
Psychological counseling	CMC Unionl
Isolation – hepatitis	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Acute dialysis in an acute care setting	CMC Union
Emergency care	BMA transport to hospital
Blood bank services	CMC Anson County
Diagnostic and evaluation services	
X-ray services	
Laboratory services	Spectra
Pediatric nephrology	CMC Charlotte
Vascular surgery	Sanger Heart and Vascular; Metrolina Nephrology Associates Vascular Access Center; Surgical Specialists of Charlotte
Transplantation services	CMC Charlotte
Vocational rehabilitation & counseling	Anson County Vocational Rehabilitation Services
Transportation	Anson County Transportation Services

Source: Table in Section I, page 39

In Section I, page 43, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I-1, I-3 through I-4, the applicant

provides supporting documentation for other established relationships with local health care providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K, page 47, the applicant states that the project, renovating 3,241 square feet of existing space, involves “*relocating the nurse station and extending the dialysis cabinet at the center of the treatment area.*” A line drawing is provided in Exhibit K-1.

On page 47, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 45, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 45 - 46, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 55, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

**FMC Anson County
 Historical Payor Mix CY 2018**

Payment Source	% of Total
Self-pay/Indigent/Charity	0.58%
Medicare	79.89%
Medicaid	0.02%
Commercial Insurance	6.33%
Medicare/Commercial	13.17%
Total	100.00%

Note: numbers may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance **
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Anson	18%	48%	55%	25%	15%	13%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone, not Hispanic or Latino"

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

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

The IPRO SA Network 6 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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

Conclusion

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or 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 54, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 54, 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 52, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**FMC Anson County
Projected Payor Mix CY 2022**

Payment Source	% of Total
Self-pay/Indigent/Charity	0.38%
Medicare	77.32%
Medicaid	2.37%
Commercial Insurance	6.72%
Medicare/Commercial	13.20%
Total	100.00%

Note: numbers may not sum due to rounding

As shown in the table above, during the second year of operation, the applicant projects that 0.38% of total services will be provided to self-pay/indigent/charity patients, 90.52% to Medicare patients (includes Medicare and Medicare/Commercial), and 2.37% to Medicaid patients.

On page 52, 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.
- The applicant's proposed patient origin is based on historical patient origin of the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, 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 56, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add one dialysis station to the existing facility for a total of 18 dialysis stations upon project completion.

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

There are two dialysis providers in Anson County, and two existing facilities. DaVita operates the other dialysis facility and received a certificate of need on November 6, 2018 to relocate the entire facility to a new location in the same town, within Anson County. See the following table that shows the two dialysis facilities in Anson County, from Table B of the January 2019 SDR:

FACILITY	PROVIDER	LOCATION	# STATIONS	UTILIZATION
Fresenius Medical Care of Anson County	BMA	Wadesboro	16	87.50%
Dialysis Care of Anson County	DaVita	Wadesboro	15	41.67%

In Section N, page 57, 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 effect on the competitive climate in Anson County. The applicant does not project to serve dialysis patients currently served by another provider. The projected patient population for the FMC Anson County facility begins with patients currently served by BMA, and a growth of that patient population

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

BMA facilities have done an exceptional job of containing operation costs while continuing to provide outstanding care and treatment to patients.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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.

- (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 Exhibit A-4, 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 a total of 114 of this type of facility located in North Carolina.

In Section O, page 62, 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 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- FMC Anson County 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 15, the applicant projects that FMC Anson County will serve 71 in-center patients on 18 stations, or a rate of 3.94 patients per station per week, as of the end of the first operating year following project completion. 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 15 - 16, 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.