

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 21, 2018

Findings Date: May 21, 2018

Project Analyst: Tanya S. Rupp

Assistant Chief: Lisa Pittman

Project ID #: H-11472-18

Facility: Fresenius Medical Care Anson County

FID #: 061094

County: Anson

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

Project: Add one dialysis station for a total of 17 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care Anson County (FMC Anson County), proposes to add 1 dialysis station to the existing facility for a total of 17 certified dialysis stations upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the

January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is neither a surplus nor a deficit of dialysis stations in Anson County. An applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Anson County in Table B of the January 2018 SDR is 3.25 patients per station per week, or 81.25% of capacity (3.25 / 4 patients per station = 0.8125). This utilization rate was calculated based on 52 in-center dialysis patients and 16 certified dialysis stations (52 patients / 16 stations = 3.25 patients per station per week).

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

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		81.25%
Certified Stations		16
Pending Stations		0
Total Existing and Pending Stations		16
In-Center Patients as of 6/30/17 (SDR2)		52
In-Center Patients as of 12/31/16 (SDR1)		45
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.3111
(ii)	Divide the result of step (i) by 12	0.0259
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.1556
(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	60.0889
(v)	Divide the result of step (iv) by 3.2 patients per station	18.7778
	and subtract the number of certified and pending stations to determine the number of stations needed	3

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at this facility is three stations. 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

applicant is consistent with the facility need determination for dialysis stations at FMC Anson County.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 9, and Section O, page 58. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C, page 17, Section L, pages 50 - 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11, Section N, page 56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

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 stations to the existing facility for a total of 17 certified dialysis stations at FMC Anson County upon project completion.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the 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 states that, as of December 31, 2017, 100% of the dialysis patient population at FMC Anson County was from Anson County.

In Section C.1, page 15, the applicant that 100% of the dialysis patient population will also be from Anson County for the first two years of operation following project completion.

The applicant provides the assumptions and methodology for the patient origin projections on page 15. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add one dialysis station to the existing FMC Anson County, for a total of 17 certified dialysis upon project completion. In Section B.2, page 6, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP, utilizing data from the January 2018 SDR. In Section C.1, pages 15 - 16, the applicant provides the assumptions and methodology used to demonstrate the need for the project. The facility’s patients who reside in Anson County are projected to increase at a rate commensurate with the Five-Year Average Annual Change Rate (AACR) for Anson County, which is 4.3%. On page 15, the applicant states Operating Year One (OY 1) is Calendar Year (CY) 2019 (January 1, 2019 – December 31, 2019). The applicant projects that OY 1 is CY 2019 and OY 2 is CY 2020.

Projected Utilization

In Section C, page 16, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table:

FMC ANSON COUNTY	IN-CENTER PATIENTS
Begin with 55 Anson County ESRD patients dialyzing at the facility on December 31, 2017.	55
Project the population forward one year to December 31, 2018, using the Anson County Five Year AACR	$55 \times 1.043 = 57.4$
Project the population forward one year to December 31, 2019, using the Anson County Five Year AACR	$57.4 \times 1.043 = 59.8$
Project the population forward one year to December 31, 2020, using the Anson County Five Year AACR	$59.8 \times 1.043 = 62.4$

Thus, the applicant projects that FMC Anson County will serve a total of 59 in-center patients at the end of OY 1, which is a utilization rate of 86.7% or 3.47 patients per station per week (59 patients / 17 stations = 3.47; $3.47 / 4 = 0.867$ or 86.7%). The projected utilization of 3.47 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 for the in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

On pages 15 and 19 of the application, the applicant states FMC Anson County does not currently provide home hemodialysis (HH) or peritoneal dialysis (PD) training; furthermore, the applicant does not propose adding a home training program. On page 15, the applicant states that those patients who desire HH and PD training will be referred the FMC Charlotte facility. On page 39, the applicant states patients will be referred to FMC Charlotte for home training. In Exhibit I.1, the applicant provides a copy of the existing home training agreement between FMC Anson County and FMC Charlotte.

Access

In Section L.1(a), pages 50 - 51, the applicant states that each of BMA's 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.7, page 54, the applicant provides the historical payor mix from CY 2017 for FMC Anson County, as illustrated below.

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self Pay/ Indigent/ Charity	0.00%
Medicare	76.62%
Medicaid	2.15%
Commercial Insurance	8.68%
Medicare / Commercial	12.56%
Total	100.0%

Note numbers may not sum due to rounding

As illustrated in the table above, in CY 2017, 91.33% of all FMC Anson County patients were Medicare or Medicaid recipients. On page 51, the applicant projects the same payor mix in OY 2. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the dialysis 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

BMA does not propose the reduction or elimination of a service in the proposed application, but rather the addition of one dialysis station pursuant to the facility need methodology in the 2018 SMFP for FMC Anson County. 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

In Section E.1, page 23, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo – the applicant states the additional station is needed by the patients who dialyze at FMC Anson County, and to maintain the status quo would ignore the need and restrict access to dialysis for patients.
- Apply for More Stations – The applicant states application of the facility need methodology actually results in a need for three additional stations at FMC Anson County; however, the facility physical plant can only accommodate one additional

station without significant and costly building renovations. Therefore, the applicant states it is more cost-effective to add only one station at this time.

Thus, after considering the above alternatives, the applicant states that its proposal to add one station to FMC Anson County is the most efficient or cost effective alternative. The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because the addition of one dialysis station will meet increased patient demand and *“The costs of adding one station involves a modest capital expenditure of \$3,750 on behalf of BMA.”*

Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Anson County shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station for a total of no more than 17 certified stations at Fresenius Medical Care of Anson County upon project completion which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Anson County shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station, which shall include any isolation or home hemodialysis training stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Anson County 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 17 certified dialysis stations at Fresenius Medical Care of Anson County upon project completion.

Capital and Working Capital Costs

In Section F, page 25, the applicant projects the total capital cost of the project as shown in the following table:

ITEM	COST
Reverse Osmosis Water Treatment Equipment	\$750
Other Equipment / Furniture	\$3,000
Total Capital Cost	\$3,750

In Section F, page 28, the applicant states that, since FMC Anson County is an existing facility, there are no start-up or operating expenses associated with the addition of one dialysis station.

Availability of Funds

In Section F, page 26, the applicant states it will fund the capital cost of the project with the accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company of BMA.

Exhibit F.1 contains a letter dated March 15, 2018, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the capital costs of the proposed project in the amount of \$3,750. Additionally the letter states,

“Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$3,750 as may be needed for this project.”

Exhibit F-2 contains the Subsidiaries Consolidated Financial Statements for FMC which indicates that it had \$357.9 million in cash and cash equivalents as of December 31, 2016, \$20.1 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	OPERATING YEAR 1 CY 2019	OPERATING YEAR 2 CY 2020
Total Treatments	8,595	9,040
Total Gross Revenues (Charges)	\$34,276,860	\$36,051,520
Total Net Revenue	\$ 3,160,406	\$ 3,324,033
Average Net Revenue / Treatment	\$ 367.70	\$ 367.70
Total Operating Expenses (Costs)	\$ 2,402,617	\$ 3,508,983
Average Operating Expense / Treatment	\$ 279.53	\$ 388.16
Net Income	\$ 757,789	\$ 815,050

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to add one dialysis stations to the existing facility for a total of 17 certified dialysis stations at FMC Anson County upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the 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.

According to the January 2018 SDR, there are currently two dialysis facilities in Anson County, as illustrated below.

Anson County Dialysis Facilities				
Existing and Approved Certified Stations and Utilization as of June 30, 2017				
Facility / Owner	# Certified Stations 06/30/17	# In-Center Patients	Percent Utilization	Patients per Station
FMC Anson County	16	52	3.25	81.25%
Dialysis Care of Anson County	15	28	1.86	46.67%
Totals	31	80	2.58	64.51%

As shown in the table above, BMA operates one dialysis facility that is currently utilized at over 80%. The other facility is operated by DaVita.

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 would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The Facility Need Methodology in the 2018 SMFP shows a need for the additional station at FMC Anson County.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, the applicant provides current and projected full time equivalent (FTE) staffing positions for the proposed services as illustrated in the following table:

POSITION	CURRENT FTE POSITIONS	PROJECTED FTE POSITIONS OY 2 (CY 2020)
Registered Nurse	3.00	3.00
Patient Care Technician	7.00	7.00
Dietician	0.67	0.67
Social Worker	0.67	0.67
Clinical Manager	1.00	1.00
Administration (FMC Dir. of Operations)	0.15	0.15
In-Service	0.15	0.15
Clerical	1.00	1.00
Chief Technician	0.15	0.15
Equipment Technician	1.00	1.00
Total	14.79	14.79

On page 35, the applicant states it does not propose to add any new FTE positions following the addition of one dialysis station at FMC Anson County.

The assumptions and methodology used to project staffing for the facility are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. 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. In Section I.3, page 40, the applicant identifies the current medical director, and in Exhibit I-5 the applicant provides a letter from the medical director indicating his commitment 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
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 39, the applicant includes a list of providers of the necessary ancillary and support services for the provision of dialysis services, as shown in the following table:

FMC ANSON COUNTY ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	BMA
Self-care training (in-center)	Refer to FMC Charlotte
Home training	
HH	--
PD	Refer to BMA Charlotte
Accessible follow-up program	--
Psychological counseling	CMC Union
Isolation – hepatitis	FMC Anson County
Nutritional counseling	FMC Anson County
Social Work services	FMC Anson County
Acute dialysis in an acute care setting	CMC Union
Emergency care	BMA Transport to hospital/fully trained staff
Blood bank services	CMC Anson County Hospital
Diagnostic and evaluation services	CMC Anson County Hospital
X-ray services	CMC Anson County Hospital
Laboratory services	Spectra Labs
Pediatric nephrology	The Charlotte-Mecklenburg Hospital Authority/ CMC Charlotte
Vascular surgery	Sanger Heart and Vascular, Metrolina Nephrology Associates Vascular Access Center, Surgical Specialists of Charlotte
Transplantation services	Carolinas Medical Center (Charlotte)
Vocational rehabilitation & counseling	Anson County Vocational Rehabilitation
Transportation	Anson County Transportation Services

Exhibit I.5 contains a letter from the medical director of the facility expressing his support and willingness to continue serving in that role. The applicant discusses coordination with the existing health care system on page 40 Exhibits I.2 through I.4, respectively, contain copies of agreements for Spectra Laboratories services, The Charlotte-Mecklenburg Hospital Authority transfer agreement, and Duke University Medical Center for transplant services.

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

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.

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

NA

The proposed application is for the addition of one dialysis station at FMC Anson County. The applicant does not propose any new construction or renovation at FMC Anson County. Therefore, Criterion (12) is not applicable to this review.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 54 of the application, the applicant provides the historical payor mix for FMC Anson County during CY 2017, as shown in the following table:

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self Pay/ Indigent/ Charity	0.00%
Medicare	76.62%
Medicaid	2.15%
Commercial Insurance	8.68%
Medicare / Commercial	12.56%
Total	100.0%

The IPRO ESRD Network of the South Atlantic (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, and is representative of North Carolina patient profiles.

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

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 following reasons:

- The facility is an existing facility with a documented historical payor mix.
 - BMA proposes to serve the same in-center patient population as it has historically served.
 - The applicant adequately demonstrates the extent to which medically underserved populations currently use BMA's existing services.
- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 53, the applicant states:

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

"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status."

In Section L.6, page 53, the applicant states that there have been no patient civil rights complaints filed within in the past five years.

The Agency reviewed the:

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

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1(b), page 51, the applicant projects that 91.33% of all patients who will receive treatments at FMC Anson County in OY 2 (CY 2020) will have some or all of their services paid for by Medicare or Medicaid. The table below, from page 51 of the application, shows the projected OY 2 payor mix for the facility for all patients:

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self Pay/ Indigent/ Charity	0.00%
Medicare	76.62%
Medicaid	2.15%
Commercial Insurance	8.68%
Medicare / Commercial	12.56%
Total	100.0%

Note numbers may not sum due to rounding

In Section L, page 51, the applicant states projected payor mix is based on the facility's historical payor mix and no change is anticipated. Therefore, the projected payor mix is reasonable and adequately supported.

The Agency reviewed the:

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

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

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

C

In Section L.4, page 53, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Anson County, stating that any nephrologist may apply for privileges to admit patients and receive referrals from other nephrologists, other physicians, or hospital emergency rooms.

The Agency reviewed the:

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

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

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

C

In Section M.1, page 55, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

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

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

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

C

The applicant, FMC Anson County, proposes to add one dialysis stations to the existing facility for a total of 17 certified dialysis stations at FMC Anson County upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the 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.

According to the January 2018 SDR, there are currently two dialysis facilities in Anson County, as illustrated below.

Anson County Dialysis Facilities Existing and Approved Certified Stations and Utilization as of June 30, 2017				
Facility / Owner	# Certified Stations 06/30/17	# In-Center Patients	Percent Utilization	Patients per Station
FMC Anson County	16	52	3.25	81.25%
Dialysis Care of Anson County	15	28	1.86	46.67%
Totals	31	80	2.58	64.51%

As shown in the table above, BMA operates one dialysis facility that is currently utilized at over 80%. The other facility is operated by DaVita.

In Section N, page 56, the applicant states it does not expect the proposed services to have any effect on competition in the service area. The applicant explains and discusses how any enhanced competition in the service area, if it existed, would promote the cost-effectiveness, quality and access to the proposed services. On page 56, the applicant states:

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ... In this application, BMA projects that greater than 91% of the In-center patients will be relying upon government payors (Medicare /Medicaid). The facility must capitalize upon every opportunity for efficiency.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

In Section B.4, page 9 and Section O, the applicant discusses the methods it uses to insure and maintain quality. In Section A.11, page 5, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. On page 61, the applicant states there are more than 100 Fresenius related dialysis facilities in 48 North Carolina counties.

In Section O.3, page 61, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, BMA East Rocky Mount. On page 62, the applicant states that all of the problems have been corrected. After reviewing and considering the quality of care provided at all BMA facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- FMC Anson County is an existing facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C, pages 15 - 16, the applicant demonstrates that FMC Anson County will serve a total of 59 in-center patients at the end of OY 1 for a utilization rate of 86.7% or 3.47 patients per station per week (59 patients / 17 stations = 3.47; $3.47 / 4 = 0.867$ or 86.7%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.1, pages 15 - 16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.