

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 23, 2016

Findings Date: November 23, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: H-11226-16

Facility: Fresenius Medical Care of Anson County

FID #: 061094

County: Anson

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

Project: Add three dialysis stations for a total of 16 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Anson County (“FMC Anson County”) proposes to add three dialysis stations to the existing facility for a total of 16 certified in-center dialysis stations upon completion of the project.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for additional dialysis stations in Anson County. However, 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 the

July 2016 SDR is 3.38 patients per station per week. This utilization rate was calculated based on 44 in-center dialysis patients and 13 certified dialysis stations as of December 31, 2015 (44 patients / 13 stations = 3.38 patients per station per week). Application of the facility need methodology indicates three additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		84.6%
Certified Stations		13
Pending Stations		
Total Existing and Pending Stations		13
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		44
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		41
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 6/30/15	0.1463
(ii)	Divide the result of Step (i) by 12	0.0122
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1463
(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	50.4390
(v)	Divide the result of Step (iv) by 3.2 patients per station	15.7622
	and subtract the number of certified and pending stations to determine the number of stations needed	2.7622

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations, rounding up to the nearest whole number. 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 three new stations to the facility and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. 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.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 12, Section O, pages 61 - 64, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 13, Section L, pages 53 - 56, 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) and (d), pages 14 - 15, and Section N, pages 59 - 60. 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. The application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2016 SDR and with Policy GEN-3 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (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 three in-center dialysis stations to the existing facility for a total of 16 certified in-center dialysis stations upon completion of the project. In Section C.9, page 21, the applicant states FMC Anson County is not certified to provide home dialysis training. In Section C.1, page 18, the applicant states patients who are candidates for home dialysis are referred to FMC Charlotte.

Patient Origin

On page 369, the 2016 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 FMC Anson County is Anson County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 22, the applicant provides the current (as of June 30, 2016) in-center patient origin for FMC Anson County, as illustrated in the following table:

**FMC Anson County Patient Origin
 as of June 30, 2016**

COUNTY	IN-CENTER PATIENTS
Anson	47
Total	47

The applicant states on page 22 that the patient origin data is from its most recently completed ESRD Data Collection Forms. In Section C.1, page 18, the applicant states FMC Anson County serves only in-center dialysis patients. Patients in need of home training are referred to FMC Charlotte. The applicant provides the projected patient origin for FMC Anson County for the first two years of operation following completion of the project as follows:

FMC Anson County Projected Patient Origin, CY 2018 – CY 2019

COUNTY	OY 1 (CY 2018)	OY 2 (CY 2019)	COUNTY PATIENTS AS % OF TOTAL	
	IN-CENTER PTS	IN-CENTER PTS	OY 1	OY 2
Anson	52.9	55.5	98.2%	98.8%
Total	52.9	55.5	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin in Section C.1, pages 18 - 20. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.1, page 9, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP, utilizing data from the July 2016 SDR. The applicant provides a table on page 10 to illustrate that 3 stations are needed at FMC Anson County pursuant to the facility need methodology. The applicant proposes to add three dialysis stations to FMC Anson County for a total of 16 certified stations upon project completion.

In Section C.1, pages 18 – 19, the applicant provided the assumptions and methodology to support its need. The assumptions and methodology are summarized below:

- The applicant begins its patient census with 47 patients, as reported in the ESRD Data Collection Forms that will be used for the next SDR (January 2017). This is an increase

of three patients over the 44 patients reported in the July 2016 Semi-Annual Dialysis Report (SDR), which is the facility’s patient census as of December 31, 2015.

- The applicant states the project is scheduled for completion on December 31, 2017; therefore, the first project year is CY 2018 and the second project year is CY 2019.
- The applicant states on page 19 that “*the Facility Need Methodology calculates an annual increase of 14.63%.*” In addition, the applicant states the 2.8% Five Year Average Annual Change Rate (AACR) for Anson County as published in the July 2016 SDR is likewise not an accurate measure of projected growth for the facility, because the historical growth has been substantially more than that. Therefore, the applicant projects growth in the facility using a 4.83% rate, which it states is one-third of the “*most recent actual growth rate of the facility.*”

Projected Utilization

In Section C.1, page 19, the applicant begins with the Anson County patient census as of June 30, 2016 (reported on the ESRD Data Collection Form), and projects the following utilization for FMC Anson County following the addition of the three stations as proposed in this application:

Begin with Anson County patients dialyzing at FMC Anson County as of 6/30/16.	47
Using one-half of the 4.83% growth factor, BMA projects this population forward for 6 months to 12/31/16.	$[47 \times (0.483 / 12 \times 6) + 47 = 48.1$
Project patient census forward one year to 12/31/17, using the 4.83% growth rate determined by the applicant.	$48.1 \times 1.0483 = 50.5$
Project patient census forward one year to 12/31/18, using the 4.83% growth rate determined by the applicant.	$50.5 \times 1.0483 = 52.9$
Project patient census forward one year to 12/31/19, using the 4.83% growth rate determined by the applicant.	$52.9 \times 1.0483 = 55.5$

The applicant rounds down to the nearest whole number and projects to serve 52 in-center patients on 16 stations or 3.25 patients per station per week ($52 / 16 = 3.25$) by the end of Operating Year 1, and 55 in-center patients or 3.44 patients per station per week ($55 / 16 = 3.44$) by the end of Operating Year 2 for the proposed 16-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

With regard to the applicant’s use of a growth rate that is higher than the Anson County Five Year AACR published in the July 2016 SDR, the project analyst analyzed the last four SDR utilization reports for FMC Anson County, and determined the growth rate in the facility since the January 2015 SDR has been 29%, as shown in the following table:

	JAN. 2015 SDR	JULY 2015 SDR	JAN. 2016 SDR	JULY 2016 SDR
# Patients	34	40	41	44
% Growth				29%

The applicant is using a growth rate that is less than one-quarter of the historical growth rate in the facility reported in the last four SDRs [29 percent growth / 4 = 7.25]. The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, pages 20 - 21, the applicant states that BMA and its parent company, Fresenius Medical Care Holdings, Inc. currently operates over 100 facilities in 42 North Carolina Counties. Each one has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. In Section L.7, page 57, the applicant states that in CY 2015, 90.1% of the in-center patients were recipients of Medicare or Medicaid. In Section L.1, page 54, the applicant projects that 88.33% of the projected in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section C.3, page 20, the applicant states that it is corporate policy of Fresenius Medical Holdings, Inc. to provide dialysis services to all low income persons at Fresenius related facilities.

The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project, and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (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

- (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 26, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it ignores the current needs of the current patients dialyzing at FMC Anson County. The applicant states failure to expand the facility would not assure

continued access to dialysis care for existing patients at convenient times and in a convenient location.

- Apply for Fewer Stations – The applicant states it rejected this alternative because the facility is expected to be utilized at 100% without adding stations by the end of CY 2018. The applicant states adding stations now ensures adequate dialysis capacity for more patients at times that are convenient for those patients.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County shall add no more than three dialysis stations for a total of 16 stations, which shall include any home hemodialysis or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County shall install plumbing and electrical wiring through the walls for no more than three dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC 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, Bio-Medical Applications of North Carolina Inc., proposes to add three stations to FMC Anson County for a facility total of 16 in-center dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 28, the applicant projects \$13,600 in capital costs to add the three proposed stations. In Sections F.10 - F.12, page 31, the applicant projects no start-up expenses or initial operating expenses, since the facility is currently operational.

Availability of Funds

In Section F.2, page 29, the applicant states it will finance the capital costs of the project with the accumulated reserves of Bio-Medical Applications of North Carolina, Inc.

Exhibit F-1 contains a letter dated September 15, 2016, from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA and also as the guarantor of the funds on behalf of FMC Anson County, which confirms availability and commitment of sufficient cash reserves for the capital costs of \$13,600 for the project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents, \$19,332,534 in total assets and \$10,144,288 in net assets (total assets less total liabilities) as of December 31, 2015. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In Section R, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (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.

	CY 2018	CY 2019
Total Net Revenue	\$2,424,588	\$2,435,174
Total Operating Expenses	\$2,165,009	\$2,215,116
Net Income	\$ 259,579	\$ 220,058

Source: application page 75; totals may not foot due to rounding

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, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and operating needs of the project. Furthermore, the applicant adequately demonstrates

that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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 three in-center dialysis stations to the existing facility for a total of 16 certified in-center dialysis stations upon completion of the project.

On page 369, the 2016 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 FMC Anson County is Anson County. Facilities may serve residents of counties not included in their service area.

The July 2016 SDR shows that there are currently two dialysis facilities in Anson County, one of which is operated by the applicant and one is operated by DaVita (Dialysis Care of Anson County). The following table shows the utilization of both facilities as reported in the July 2016 SDR:

DIALYSIS FACILITY	PROVIDER	# CERTIFIED STATIONS IN JULY 2016 SDR	# IN-CENTER PATIENTS	PATIENTS PER STATION	% UTILIZATION
FMC Anson County	BMA	13	44	3.38	84.62%
Dialysis Care of Anson County	DaVita	15	31	2.06	51.67%

*Source: July 2016 Semi-Annual Dialysis Report, *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates*

As shown in the table above, FMC Anson County is operating at over 84% utilization. The applicant proposes to add three stations to the existing facility pursuant to the facility need methodology. In Section C.1, pages 18 - 19, the applicant provides reasonable projections for the in-center patient population it proposes to serve. The applicant’s growth projections are based on one-third of the most recent utilization at the facility. Indeed, the growth rate used by the applicant is less than one-fourth of the historical growth of the facility as reported in the last four SDRs. The applicant adequately demonstrates the need to add three stations to FMC Anson County based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that projected utilization of FMC Anson County is based on growth of in-center patients at the facility. Therefore, it is not duplicating services; rather, it is adding stations to an existing facility based on the demonstrated need at that facility. Furthermore, the applicant provides reasonable projections for the patient population it proposes to serve in Section C, pages 18 - 20 of the application.

The applicant adequately demonstrates the need to add three stations to FMC Anson County based on the number of in-center patients it proposes to serve. The discussion of analysis of need found in Criterion (3) is incorporated herein by reference. The discussion of competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Anson County. Therefore, the application is conforming to this criterion.

- (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 38, the applicant provides the proposed staffing for the facility following the addition of three dialysis stations, as shown in the following table:

POSITION	# EXISTING FTE POSITIONS	# FTE POSITIONS TO BE ADDED	# TOTAL FTE POSITIONS
Registered Nurse	2.00	--	2.00
Patient Care Technician	5.25	1.00	6.25
Clinical Manager	1.00	--	1.00
Administrator	0.20	--	0.20
Dietician	0.50	--	0.50
Social Worker	0.50	--	0.50
Chief Technician	0.15	--	0.15
Equipment Technician	0.67	--	0.67
In-Service	0.20	--	0.20
Clerical	1.00	--	1.00
Total	11.47	1.00	12.47

As shown in the table above, the applicant proposes to add 1.00 FTE position to the existing facility for a total of 12.47 FTE positions following project completion. In Sections H.3 and H.4, page 39, the applicant describes its experience and processes for recruiting, training and retaining staff. In Section I.3, page 43, the applicant identifies Andrew O'Connor, M.D. as the existing and continuing Medical Director for the facility. Exhibit I-5 contains a letter from Dr. O'Connor, expressing his interest in continuing to serve as the Medical Director for the proposed facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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.1, page 42, the applicant includes a list of providers of the necessary ancillary and support services for the patients who dialyze at the facility. In Exhibit I-1, I-2, I-3 and I-4, the applicant provides home training, lab, hospital affiliation and transplant agreements, respectively. In Section L-4, page 46, the applicant discusses FMC Anson County's relationship with local healthcare and social services providers. The applicant adequately demonstrates that the necessary ancillary and support services will continue to be available and that the proposed services will be continue to be coordinated with the existing health care system. Therefore, 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

- (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

- (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

- (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.1, page 53, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 105 facilities in 42 North Carolina Counties, including affiliations with RRI facilities. The applicant states there are additional facilities under development. The applicant further states its policy is 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 which would classify a patient as underserved.

In Section L.7, page 57, the applicant provides the historical payor mix for FMC Anson County for CY 2015, as shown in the following table:

**FMC Anson County Payor Mix
CY 2015**

PAYOR TYPE	% OF PATIENTS
Private Pay	0.08%
Commercial Insurance	9.82%
Medicare	70.49%
Medicaid	8.74%
Misc. (includes VA)	0.00%
Other Medicare Commercial	10.87%
Total	100.00%

Totals may not foot due to rounding

As illustrated in the table above, 90.10% of FMC Anson County's patients were Medicare or Medicaid recipients in CY 2015.

The applicant does not propose to provide home training at the proposed facility.

In addition, the applicant describes its admission and financial policies in Section L.3, page 55, and provides a copy of its admission policy in Exhibit L-1, which states that patients will be admitted *“without regard to race, creed or religion, color, age, sex, disability, national origin, and or sexual orientation.”*

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 applicants' 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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Anson	16%	48%	55%	25%	15%	19%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*Excludes "White alone" who are "not Hispanic or Latino"

***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates"

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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

The applicant adequately demonstrates that it currently provides adequate access to medically underserved populations. 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

In Section L.3(e), page 55, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section L.6, page 56, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the past five years. Therefore, 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 54, the applicant projects that 88.32% of the in-center patients who will receive treatments at FMC Anson County will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected payor mix for the facility for in-center patients in PY 2 (CY 2019):

PAYOR TYPE	IN-CENTER PATIENTS
Medicare	66.90%
Medicaid	9.70%
Commercial Insurance	11.68%
Medicare/Commercial Insurance	11.72%
Total	100.00%

Totals may not foot due to rounding

In Section L, page 54, the applicant provides the assumptions used to project payor mix. The applicant's projected payor mix in Section L is consistent with the facility's projected (CY 2019) payor mix as reported by the applicant in Section R, page 78. The applicant demonstrates that medically underserved groups will continue to have adequate access to the dialysis services offered at FMC Anson County. Therefore, 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 56, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Anson County, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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 58, the applicant states that it has communicated with the student nursing program at South Piedmont Community College to offer the facility as a clinical training site for nursing students. In Exhibit M-1, the applicant provides a September 15, 2016 letter to South Piedmont Community College that invites the college to include the facility in its clinical nursing rotation. The information provided is reasonable and adequately supports a determination that 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 three in-center dialysis stations to the existing facility for a total of 16 certified in-center dialysis stations upon completion of the project.

On page 369, the 2016 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 FMC Anson County is Anson County. Facilities may serve residents of counties not included in their service area.

The July 2016 SDR shows that there are currently two dialysis facilities in Anson County, one of which is operated by the applicant and one is operated by DaVita (Dialysis Care of Anson County). The following table shows the utilization of both facilities as reported in the July 2016 SDR:

DIALYSIS FACILITY	PROVIDER	# CERTIFIED STATIONS IN JULY 2016 SDR	# IN-CENTER PATIENTS	PATIENTS PER STATION	% UTILIZATION
FMC Anson County	BMA	13	44	3.38	84.62%
Dialysis Care of Anson County	DaVita	15	31	2.06	51.67%

*Source: July 2016 Semi-Annual Dialysis Report, *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates*

As shown in the table above, FMC Anson County is operating at over 84% utilization (3.38 patients per station per week). This is based on the assumption that dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station per week.

The applicant adequately demonstrates that projected utilization of FMC Anson County is based on growth of in-center patients at the facility. Therefore, it is not duplicating services; rather, it is adding stations to an existing facility based on the demonstrated need at that facility. Furthermore, the applicant provides reasonable projections for the patient population it proposes

to serve in Section C, pages 18 - 20 of the application. Growth projections for the patient population are based on a reasonably calculated growth rate that is less than one-fourth of the facility's recent documented growth.

In Section N.1, page 59, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA 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 being served by another provider. The projected population for FMC Anson County begins with patients currently served by BMA, and a growth of that patient population consistent recent growth of the facility census [sic]; BMA uses a conservative rate of 4.83%, which is one-third of the actual performance.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 90% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.

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

See also Sections B, C, E, F, G, H and L in which the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add three dialysis stations to the existing facility and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.

- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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 and operated by the applicant or an affiliated company. In Section O.3, pages 64 - 67, the applicant identifies three of its North Carolina facilities, BMA Lumberton, BMA East Charlotte and RAI West College-Warsaw Dialysis that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. On pages 66 - 67, the applicant states all three facilities are currently back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- The applicant does not propose to establish a new End Stage Renal Disease 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- The applicant proposes to increase the number of in-center stations at FMC Anson County pursuant to the facility need methodology. In Section P.1, page 68 and Section C.1, pages 18 - 19, the applicant projects the facility will dialyze 52 in-center patients on 16 stations in the first operating year, which is 3.25 patients per station per week.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 18 - 19.