

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

### CORRECTED

Decision Date: June 6, 2018

Findings Date: June 6, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11474-18

Facility: FMC South Durham

FID #: 080098

County: Durham

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

Project: Add two dialysis stations for a total of 20 dialysis 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 South Durham Dialysis (FMC South Durham), whose parent company is Fresenius Medical Care Holdings, Inc. proposes to add 2 dialysis stations to the existing facility for a total of 20 certified dialysis stations at FMC South Durham upon project completion.

#### Need Determination

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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 a surplus of 21 dialysis station in Durham County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 South Durham in the January 2018 SDR is 3.3333 patients per station per week, or 83.33% ( $3.3333 / 4$  patients per station = 0.83332). This utilization rate was calculated based on 60 in-center dialysis patients and 18 certified dialysis stations ( $60$  patients /  $18$  stations = 3.3333 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:

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		83.33%
Certified Stations		18
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>18</b>
In-Center Patients as of 6/30/17 (SDR2)		60
In-Center Patients as of 12/31/16 (SDR1)		53
<b>Step</b>	<b>Description</b>	<b>Result</b>
(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	0.2642
(ii)	Divide the result of step (i) by 12	0.0220
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.1321
(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	67.9245
(v)	Divide the result of step (iv) by 3.2 patients per station	21.2264
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed 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 two new stations, therefore the application is consistent with the facility need determination for dialysis stations.

### **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, page 8, Section K.1(g), pages 42-43, Section N.1, page 52, Section O, pages 55-59, 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, page 9, Section C.3, page 15, Section L, pages 47-48, Section N.1, page 53, 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, pages 10-11, Section C.1, pages 13-15, Section F, pages 22-30, Section K, pages

41-43, Section N.1, page 53, 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 two dialysis stations to the existing facility for a total of 20 certified dialysis stations at FMC South Durham following project completion.

### **Patient Origin**

On page 365, the 2018 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 Durham County. Facilities may serve residents of counties not included in their service area.

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In Section C.1, page 13 and Section C.8, page 16, the applicant provides the projected and historical patient origin for FMC South Durham, as illustrated in the table below.

	FMC SOUTH DURHAM DIALYSIS					
	CURRENT AS OF 12/31/2017		OPERATING YEAR 1 CY2019	OPERATING YEAR 2 CY2020	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	% OF TOTAL	IN-CENTER	IN-CENTER	YEAR 1	YEAR 2
Durham	56.0	88.9%	63.0	65.5	90.0%	90.3%
Orange	1.0	1.6%	1.0	1.0	1.4%	1.4%
Wake	6.0	9.5%	6.0	6.0	8.5%	8.3%
<b>TOTAL</b>	63.0	100.0%	70.0	72.5	100.0%	100.0%

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 13-14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, pages 4-5, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January 2018 SDR. On page 15, the applicant states,

*“The patient population projected to utilize the FMC South Durham facility indeed has a need for the stations at this location. The need of the patient population for the proposed services is a function of the individual patient need for dialysis care and treatment.”*

On pages 13-14, the applicant states:

- The applicant begins the projections for the future patient population of FMC South Durham Dialysis by using the ending in-center patient census of 70 patients, as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Durham County which is 4.0% to project the Durham County patient population forward.
- The applicant does not project an increase in the patient population for Orange and Wake counties.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020  
Operating Year 2 (OY2) = Calendar Year (CY) 2021

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

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- the applicant begins its projections of the patient population to be served with the existing patient census of FMC South Durham on December 31, 2017;
- the applicant grows the Durham County patient population by the January 2018 SDR Durham County five-year AACR of 4.0% and holds utilization constant for patients from outside Durham County, and,
- the utilization rate of the in-center patients projected to be dialyzing at FMC South Durham by the end of the first year is above 3.2 patients per station per week.

Projected Utilization

In Section C, page 14, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table,

Begin with Durham County patients dialyzing at FMC South Durham Dialysis as of December 31, 2017.	56
Project the Durham County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Durham County of 4.0%	$56 \times 1.040 = 58.2$
Project the Durham County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Durham County of 4.0%.	$58.2 \times 1.040 = 60.6$
Add in the six patients from Wake County and the one patient from Orange County. This is the starting census for the project.	$60.6 + 7 = 67.6$
Project the Durham County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Durham County of 4.0%.	$60.6 \times 1.040 = 63.0$
<b>OY1:</b> Add 7 patients from outside Durham County. This is the projected census for OY 1.	$63.0 + 7 = 67.0^*$ [ $63.0 + 7 = 70.0$ ]
Project the Durham County patient population forward one year to December 31, 2021 using the Five-Year Average Annual Change Rate for Durham County of 4.0%.	$63.0 \times 1.040 = 65.5$
<b>OY2:</b> Add 7 patients from outside Durham County. This is the projected census for OY 2.	$65.5 + 7 = 72.5$

\*On page 14 the applicant states that  $63 + 7 = 67$ , which the project analyst assumes to be a typographical error.

The applicant provides the assumptions for the projected in-center utilization on pages 13-14, as summarized below:

- Beginning census, December 31, 2017, is as listed in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in February 2018.
- OY1 is the period from January 1 through December 31, 2020.

- OY2 is the period from January 1 through December 31, 2021.
- The 56 in-center patients from Durham County and the seven patients from Wake and Orange County will continue to dialyze at FMC South Durham.
- The Durham County patient census will grow at the Durham County AACR of 4.0%, as reported in the January 2018 SDR, and the Wake and Orange County census will be held constant.

In Section C.2, page 14, the applicant states:

*“Within this application, BMA has projected a patient population of 70 in-center patients, to be dialyzing at the FMC South Durham facility at the end of the first year. Utilization by 70 patients on 20 dialysis stations is calculated to be 3.50 patients per station, or 87.5% utilization.”*

Thus, the applicant projects that FMC South Durham will serve a total of 70 in-center patients at the end of OY1 for a utilization rate of 87.5% or 3.5 patients per station per week (70 patients / 20 stations = 3.5 / 4 = 0.875 or 87.5%). The projected utilization of 3.5 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant begins its utilization projection with the existing patients of FMC South Durham,
- the applicant grows the Durham County patient population by the January 2018 SDR Durham County AACR and holds the patient population from outside Durham County constant, and
- the resulting utilization rate at FMC South Durham by the end of the first year is above the minimum standard of 3.2 patients per station per week.

#### Home Hemodialysis and Peritoneal Dialysis

The applicant does not currently provide home hemodialysis (HH) or peritoneal dialysis (PD) training nor does the applicant propose adding a home training program in the proposed application. On page 37, the applicant states that those patients who desire HH and PD training will be referred to FMC West Pettigrew.

#### Access

In Section L-1(a), pages 47-48, 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 51, the applicant provides the historical payor mix calendar year (CY) 2017 for FMC South Durham Dialysis, as illustrated below.

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Self Pay/ Indigent/ Charity	0.83%
Medicare	71.19%
Medicaid	5.86%
Commercial Insurance	6.43%
Medicare / Commercial	14.74%
Misc. (VA)	0.95%
<b>Total</b>	<b>100.0%</b>

As illustrated in the table above, in CY2017 91.8% of all FMC South Durham patients were Medicare or Medicaid recipients. On page 48, the applicant projects the same number of Medicare and Medicaid recipients in OY2 as served in CY2017.

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.



- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

BMA does not propose the reduction, elimination or relocation of a facility or service in the proposed application. 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

BMA proposes to add 2 dialysis stations to the existing facility for a total of 20 certified dialysis stations at FMC South Durham upon project completion.

In Section E.1, pages 20-21, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because, *“Failure to develop additional capacity at the facility will result in higher utilization rates at the facility and could potentially restrict patient admissions.”* The applicant states that utilization at FMC South Durham Dialysis will be greater than 80% by the end of OY1 (See application, page 14). Therefore, this alternative was rejected.
- Apply for fewer stations - Application of the facility need methodology indicated a need for an additional three stations based on the continued growing need for dialysis services at FMC South Durham Dialysis. Applying for fewer stations would result in a higher utilization for the existing stations and would not be in the best interest of patients dialyzing at the facility. Therefore, this alternative was rejected.
- Apply for more stations - Application of the facility need methodology indicated a need for an additional three stations. The facility’s physical plant cannot accommodate more than 20 stations without significant construction and expense. Therefore, BMA did not consider this to be a cost effective alternative.

- Relocation stations from another facility in Durham County - The applicant rejected this idea because all the facilities in Durham are “*well utilized*”. The applicant provides a discussion as to why the dialysis stations at FMC West Pettigrew are underutilized and why it would not be appropriate to relocate stations from this facility. (See application pages 20-21)

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 facility is operating above 80% capacity,
- the applicant need methodology indicates a need for additional stations at the facility,
- maintain the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions,
- applying for fewer stations than two would result in higher utilization that 3.33 patients per station, and
- relocation of stations from other BMA facilities in Durham County would result in higher utilization levels at those facilities.

### **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 South Durham Dialysis shall materially comply with all representations made in the certificate of need application as conditioned.**
- 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 2 additional dialysis stations for a total of no more than 20 certified stations at Fresenius Medical Care South Durham Dialysis 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 South Durham Dialysis shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care South Durham Dialysis 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 2 dialysis stations to the existing facility for a total of 20 certified dialysis stations at FMC South Durham Dialysis following project completion.

**Capital and Working Capital Costs**

In Section F, pages 23, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$95,816
Miscellaneous Costs	\$28,845
<b>Total</b>	<b>\$124,661</b>

In Section R, the applicant provides the assumptions used to project the capital cost.

In Section F, page 26, the applicant projects that there will be no start-up or initial operating costs associated with the proposed project as FMC South Durham is an existing facility.

**Availability of Funds**

In Section F, page 24, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	Bio-Medical Applications of North Carolina	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$124,4661	\$124,661
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing **</b>	\$124,661	\$124,661

\* OE = Owner's Equity

Exhibit F.1 contains a letter dated March 15, 2018, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company of BMA, which states,

*“The project calls for a capital expenditure of \$124,661 on behalf of BMA ... Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$124,661 as may be need for this project.”*

Exhibit F.2 contains the Subsidiaries Consolidated Financial Statements for FMCH 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, should there be a need.

**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 CY2019	Operating Year 2 CY2020
Total Treatments	10,077	10,522
Total Gross Revenues (Charges)	\$40,187,076	\$41,961,736
Total Net Revenue	\$3,207,572	\$3,349,219
Average Net Revenue per Treatment	\$318.31	\$318.31
Total Operating Expenses (Costs)	\$2,812,242	\$2,905,646
Average Operating Expense per Treatment	\$279.08	\$276.15
Net Income	\$395,330	\$443,573

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 2 dialysis stations to the existing facility for a total of 20 certified dialysis stations at FMC South Durham upon project completion.

On page 365, the 2018 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 Durham County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently nine operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

<b>DURHAM COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of DECEMBER 31, 2017</b>				
<b>Dialysis Facility/Owner</b>	<b>Certified Stations 6/30/17</b>	<b># In-center Patients 6/30/2017</b>	<b>Percent Utilization 6/30/2017</b>	<b>Patients per Station</b>
Downtown Durham Dialysis* (DaVita)	10	0	0	0
Duke Hospital Dialysis (DaVita)	16	45	70.31%	2.8125
Durham Dialysis (DaVita)	28	101	90.18%	3.6071
Durham Regional Dialysis* (DaVita)	10	0	0	0
Durham West Dialysis (DaVita)	30	91	75.83%	3.0333
FMC Dialysis Services of Briggs Ave. (BMA)	29	91	78.45%	3.1379
FMC Dialysis Ser. W. Pettigrew (BMA)	24	67	69.79%	2.7917
Freedom Lake Dialysis Unit (BMA)	26	91	87.50%	3.5000
FMC South Durham (BMA)	18	60	83.33%	3.3333
FKC Eno River* (BMA)	10	0	0	0
Research Triangle Dialysis (DaVita)	10	10	25.00%	1.0000
Southpoint Dialysis (DaVita)	16	79	123.44%	4.9375
<b>Total</b>	<b>227</b>	<b>635</b>	<b>69.93%</b>	<b>2.7973</b>

Source: January 2018 SDR.

\*New Facility

As shown in the table above, three facilities are under development, two of which will be operated by DaVita and one of which will be operated by BMA. Of those BMA operational facilities, Freedom Lake Dialysis Unit operated with the highest utilization rate of 87.50%. BMA was approved in Project I.D. # J-11373-17 to develop a new 10 station facility in Durham to be known as Fresenius Kidney Care Eno River (FKC Eno River) by relocating four dialysis stations from FMC Dialysis Services of West Pettigrew and six dialysis stations from Freedom Lake Dialysis Unit. The other two dialysis facilities in Durham County operated by BMA (FMC Dialysis Services of Briggs Ave. and FMC West Pettigrew), operated with a utilization rate of 78.45% and 69.79%, respectively. With regard to the underutilization of stations at FMC West Pettigrew, on pages 20-21, the applicant states the following,

*“FMC West Pettigrew has one patient requiring isolation. When a patient requires isolation, that station can not [sic] be used of for other patients ... A single isolation patient has the effect of four patients utilizing an in-center dialysis station. The isolation station can only be used by patients who require isolation. Thus, in a practical sense FMC West Pettigrew has only 23 dialysis stations.*

... However, another station is set aside for home hemodialysis training and support. Thus, the effective utilization was a function of 67 patients dialyzing on 22 stations. This is a utilization of 76.14. [67 patients / 22 stations = 3.045; 3.045 / 4 = 0.76136 or 76.14%].

[T]he census increased by two patients in the six months ended December 31, 2017. Thus, the July 2018 SDR will report a utilization rate of 71.88% Consider again that two stations are set aside for isolation and home hemodialysis training and support, and the effective utilization rate at FMC West Pettigrew is a function of 69 patients dialyzing on 22 stations, or 78.41% [69 patients / 22 stations = 3.136; 3.136 / 4 = 0.78409 or 78.41%].

Overall, the operational facilities in Durham County owned/operated by BMA operated with a utilization above 79.64%, as illustrated below.

<b>BMA Operational Facilities Durham County</b>				
	<b>Certified Stations 6/30/17</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients per Station</b>
FMC Dialysis Services of Briggs Ave.	29	91	78.45%	3.1379
FMC Dialysis Ser. W. Pettigrew	24	67	69.79%	2.7917
Freedom Lake Dialysis Unit	26	91	87.50%	3.5000
FMC South Durham	18	60	83.33%	3.3333
<b>Totals</b>	<b>97</b>	<b>309</b>	<b>79.64%</b>	<b>3.1856</b>

In Section G, page 31, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham. The applicant states, “Further, the census at BMA facilities in Durham is increasing. It is more appropriate to add stations as opposed to shifting the location of stations.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of two dialysis stations at FMC South Durham 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, page 33, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES OY2
Registered Nurse	3.00	3.50
Technician (PCT))	7.00	8.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.17	0.17
In-Service	0.15	0.15
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	0.50	0.50
<b>Total</b>	<b>13.97</b>	<b>15.47</b>

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 63, which is found in Section R. In Section H, pages 33-34, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of FMC South Durham. In Exhibit H, the applicant provides supporting documentation.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application



- 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 37, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>FMC South Durham Dialysis Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	FMC South Durham (on site)
Self-care training (in-center)	FMC West Pettigrew (BMA)
Home training HH PD Accessible follow-up program	FMC West Pettigrew (BMA)
Psychological counseling	Duke University Med. Center
Isolation – hepatitis	FMC South Durham (on site)
Nutritional counseling	FMC South Durham (on site)
Social Work services	FMC South Durham (on site)
Acute dialysis in an acute care setting	Duke Regional Hospital
Emergency care	BMA/911/Hospital
Blood bank services	Duke Regional Hospital
Diagnostic and evaluation services	Duke Regional Hospital
X-ray services	Duke Regional Hospital
Laboratory services	Spectra
Pediatric nephrology	Duke University Med. Center
Vascular surgery	Dr. Dillavou or Dr. Cox
Transplantation services	Duke University Med. Center
Vocational rehabilitation & counseling	Durham County Vocational Rehab.
Transportation	Durham C. Public Transportation

The applicant provides supporting documentation in Exhibit I.1-5. Exhibits I-2 through I-4, respectively, contain copies of agreements for Spectra laboratories services, Duke Regional Hospital 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.

C

In Section K, page 43, the applicant indicates that the project involves no new construction. FMC South Durham currently consist of 2,883 square feet of which includes 129 square feet for the isolation station. Line drawings are provided in Exhibit K.1.

In Section F, page 23, the applicant projects construction cost to total \$95,816 for the two station addition to FMC South Durham. On page 21, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 41, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.2.

### **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

(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 51, the applicant provides the historical payor mix for FMC South Durham from January 1 to December 31, 2017 for CY 2017, as shown in the table below.

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Self Pay/ Indigent/ Charity	0.83%
Medicare	71.19%
Medicaid	5.86%
Commercial Insurance	6.43%
Medicare / Commercial	14.74%
Misc. (VA)	0.95%
<b>Total</b>	<b>100.0%</b>

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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Durham	12%	52%	58%	17%	7%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

\*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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>1</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because 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.

### **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

<sup>1</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)

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, page 49, 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 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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section L, page 50, 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
- 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, page 48, 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.

**Projected Payor Mix OY2**

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Self Pay/ Indigent/ Charity	0.83%
Medicare	71.19%
Medicaid	5.86%
Commercial Insurance	6.43%
Medicare / Commercial	14.74%
Misc. (VA)	0.95%
<b>Total</b>	<b>100.00%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.83% of total services will be provided to self-pay/indigent/charity patients, 85.93% to Medicare patients (includes Medicare and Medicare/Commercial) and 5.86% to Medicaid patients.

On page 48, the applicant states the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project is based on the facility experience throughout 2017. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at FMC South Durham.

### **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.

- (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 50, the applicant adequately describes the range of means by which patients will have access to the proposed services

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, page 52, 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
- 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 proposes to add 2 dialysis stations to the existing facility for a total of 20 certified dialysis stations at FMC South Durham following project completion.

On page 365, the 2018 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 Durham County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently nine operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

<b>DURHAM COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of DECEMBER 31, 2017</b>				
<b>Dialysis Facility/Owner</b>	<b>Certified Stations 6/30/17</b>	<b># In-center Patients 6/30/2017</b>	<b>Percent Utilization 6/30/2017</b>	<b>Patients per Station</b>
Downtown Durham Dialysis* (DaVita)	10	0	0	0
Duke Hospital Dialysis (DaVita)	16	45	70.31%	2.8125
Durham Dialysis (DaVita)	28	101	90.18%	3.6071
Durham Regional Dialysis* (DaVita)	10	0	0	0
Durham West Dialysis (DaVita)	30	91	75.83%	3.0333
FMC Dialysis Services of Briggs Ave. (BMA)	29	91	78.45%	3.1379
FMC Dialysis Ser. W. Pettigrew (BMA)	24	67	69.79%	2.7917
Freedom Lake Dialysis Unit (BMA)	26	91	87.50%	3.5000
FMC South Durham (BMA)	18	60	83.33%	3.3333
FKC Eno River* (BMA)	10	0	0	0
Research Triangle Dialysis (DaVita)	10	10	25.00%	1.0000
Southpoint Dialysis (DaVita)	16	79	123.44%	4.9375
<b>Total</b>	<b>227</b>	<b>635</b>	<b>69.93%</b>	<b>2.7973</b>

Source: January 2018 SDR.

\*New Facility

In Section N.1, page 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 53, the applicant states:

*“BMA does not expect this proposal to have effect on the competitive climate in Durham County. ... BMA seeks the opportunity to continue providing dialysis care and treatment to patients of the area. ... This facility also has added value stemming from the strength of our relationship with the physicians of Durham Nephrology Associates.”*

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 A.11, page 4, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. On page 15, the applicant states, Fresenius operates 112 facilities in 48 North Carolina counties. In Section O, page 58, the applicant states, *“As of February 28, 2018, Fresenius related facilities were providing dialysis care and treatment for more than 9,800 dialysis patients receiving care in a North Carolina dialysis facility.”*

Of the more than 100 applicant-related Fresenius facilities in North Carolina, the applicant identifies East Rocky Mount as the only BMA facility cited for an immediate jeopardy citation within the most recent 18-month period. The applicant summarizes the deficiencies cited and the resolution in Section O.3 and provides documentation in Exhibit O-3(a) and (b). On page 59, the applicant states that East Rocky Mount was back in full compliance with all CMS Guidelines upon the submittal of the application. After reviewing and considering the information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past.

The Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 South Durham 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 13-14, the applicant demonstrates that FMC South Durham Dialysis will serve a total of 70 in-center patients at the end of OY1 for a utilization rate of 87.5% or 3.5 patients per station per week ( $70 \text{ patients} / 10 \text{ stations} = 3.5 / 4 = 0.875$  or 87.5%). 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 13-14, 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.