

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 22, 2017

Findings Date: December 22, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11405-17

Facility: Freedom Lake Dialysis Unit

FID #: 955622

County: Durham

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

Project: Add six dialysis stations for a total of 26 dialysis stations upon completion of this project and Project I.D. # J-11373-17 (relocate six dialysis stations to FKC Eno River)

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 Freedom Lake Dialysis Unit (Freedom Lake Dialysis), whose parent company is Fresenius Medical Care Holdings, Inc. proposes to add 6 dialysis stations to the existing facility for a total of 26 certified dialysis stations at Freedom Lake Dialysis following completion of Project I.D. # J-11373-17 (relocate 6 stations to FKC Eno River) and this project.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 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 Freedom Lake Dialysis in the July 2017 SDR is 3.6154 patients per station per week, or 90.38% (3.6154 / 4 patients per station = 0.90385). This utilization rate was calculated based on 94 in-center dialysis patients and 26 certified dialysis stations (94 patients / 26 stations = 3.6154 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:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		90.38%
Certified Stations		26
Pending Stations		0
Total Existing and Pending Stations		26
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		94
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		90
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0889
(ii)	Divide the result of Step (i) by 12	0.0074
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0889
(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	102.3556
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.9861
	and subtract the number of certified and pending stations to determine the number of stations needed	5.9861

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

Policies

There is one policy in the 2017 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2017 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, and Section O, pages 54-58. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, page 9, Section C, page 16, Section L, pages 47-48, 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 N, 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant's use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant's use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 6 dialysis stations to the existing facility for a total of 26 certified dialysis stations at Freedom Lake Dialysis following completion of Project I.D. # J-11373-17 (relocate 6 stations to FKC Eno River) and this project.

Patient Origin

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On page 373, the 2017 SMFP defines the service area for dialysis stations as “the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by Freedom Lake Dialysis, as shown below:

Freedom Lake Dialysis Dialysis Patients as of 6/30/2017	
COUNTY	IC PATIENTS
Durham	86
Alamance	1
Granville	1
Orange	1
Person	2
Total	91

In Section C.1, page 13, the applicant provides the projected patient origin for Freedom Lake Dialysis for the first two years of operation following project completion, as follows:

	FREEDOM LAKE DIALYSIS			
	OPERATING YEAR 1 CY2019	OPERATING YEAR 2 CY2020	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	IN-CENTER	YEAR 1	YEAR 2
Durham	81.6	87.7	94.2%	94.6%
Alamance	1.0	1.0	1.2%	1.1%
Granville	1.0	1.0	1.2%	1.1%
Orange	1.0	1.0	1.2%	1.1%
Person	2.0	2.0	2.3%	2.2%
TOTAL	86.6	92.7	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 13-15. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add six dialysis stations to the existing Freedom Lake Dialysis facility for a total of 26 certified dialysis upon completion of Project I.D. # J-11373-17 and this project. In Section B.2, page 5, the applicant states the application is filed pursuant to the facility need

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methodology in the 2017 SMFP utilizing data from the July 2017 SDR. In Section C.1, pages 13-15, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s patients who reside in Durham County have increased at a rate greater than the Five-Year Average Annual Change Rate for Durham County, which is 4.0%. However, the applicant states that the utilization rate at Freedom Lake Dialysis has increased at a rate greater than the Five-Year Average Annual Change Rate for Durham County. The applicant states those patients have increased at a rate of 7.5% which the applicant used to project future utilization at Freedom Lake Dialysis. The applicant does not project growth of its patients residing in other counties; those existing patients were added to the projected Durham County patients at appropriate points in the methodology.

Operating Year 1 (OY1) = Calendar Year (CY) 2019
 OY2 = CY2020

Projected Utilization

In Section C, page 15, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Durham County patients dialyzing at Freedom Lake Dialysis as of June 30, 2017.	86
The applicant projects Durham County patient population forward for six months using one half of its reported growth rate of 3.75 (7.5/2 = 3.75).	$86 \times 1.0375 = 89.2$
Project the Durham County patient population forward for one year to December 31, 2018.	$(89.2 \times 1.075) = 95.9$
The applicant subtracts the 20 patients projected to transfer their care to FKC Eno River.	$95.9 - 20 = 75.9$
Project the Durham County patient population forward one year to December 31, 2019.	$(75.9 \times 1.075) = 81.6$
OY1: Add 5 patients from outside Durham County. This is the projected census for OY 1.	$81.6 + 5 = 86.6$
Project the Durham County patient population forward one year to December 31, 2020.	$(81.6 \times 1.075) = 87.7$
OY2: Add 5 patients from outside Durham County. This is the projected census for OY 2.	$87.7 + 5 = 92.7$

On page 15, the applicant states it rounded the patient population down. Thus, the applicant projects that Freedom Lake Dialysis will serve a total of 86 in-center patients at the end of OY1 for a utilization rate of 82.7% or 3.3 patients per station per week ($86 \text{ patients} / 26 \text{ stations} = 3.3076 / 4 = 0.8269$ or 82.7%). The projected utilization of 3.3 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 for in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

On page 15 of the application, the applicant states Freedom Lake Dialysis 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 109 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) 2016 for Freedom Lake Dialysis, as illustrated below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.47%
Medicare	63.99%
Medicaid	7.30%
Commercial Insurance	7.98%
Medicare / Commercial	16.05%
Misc. (VA)	3.20%
Total	100.0%

As illustrated in the table above, in CY2016 87.34% of all Freedom Lake Dialysis patients were Medicare or Medicaid recipients. On page 48, the applicant projects that 86.37% of its patients in project year (PY) 2 will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

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- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

BMA does not propose the reduction or elimination of a service in the proposed application, but rather the addition of six dialysis stations pursuant to the facility need methodology in the 2017 SMFP, Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, page 22, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the number of people currently dialyzing at Freedom Lake Dialysis. BMA states that utilization at Freedom Lake Dialysis is growing faster

than the Five-Year Average Annual Change Rate for Durham County of 4.0 percent. BMA states the historical growth rate at Freedom Lake Dialysis has increased by 7.5 percent which the applicant uses to project future growth at Freedom Lake Dialysis. The applicant states that utilization at Freedom Lake Dialysis will be greater than 80% by the end of OY1 (See application, page 15). Therefore, this alternative was rejected.

- Apply for Fewer Stations - Application of the facility need methodology indicated a need for an additional six stations based on the continued growing need for dialysis services at Freedom Lake 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 Freedom Lake Dialysis. Therefore, this alternative was rejected.

Thus, after considering the above alternatives, the applicant states that its proposal to add six stations to Freedom Lake Dialysis is the most efficient or cost effective alternative.

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.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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 Freedom Lake Dialysis Unit shall materially comply with all representations made in the certificate of need application as conditioned.**
- 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 6 additional dialysis stations for a total of no more than 26 certified stations at Freedom Lake Dialysis Unit upon completion of this project and Project I.D. # J-11373-17**

(relocate 6 dialysis stations to FKC Eno River) which shall include any home hemodialysis training or isolation stations.

- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Freedom Lake Dialysis Unit shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Freedom Lake Dialysis Unit 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 6 dialysis stations to the existing facility for a total of 26 certified dialysis stations at Freedom Lake Dialysis following completion of Project I.D. # J-11373-17 (relocate 6 stations to FKC Eno River) and this project.

Capital and Working Capital Costs

In Section F, pages 23 and 27, the applicant projects no capital or working capital cost associated with the proposed project because Freedom Lake Dialysis is an existing facility.

Availability of Funds

Exhibit F.1 contains a letter dated September 15, 2017, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company of BMA, which states there is no capital expenditure for the proposed project and that he authorizes the addition of the six stations at Freedom Lake Dialysis.

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	12,152	13,190
Total Gross Revenues (Charges)	\$48,462,176	\$52,601,720
Total Net Revenue	\$3,922,911	\$4,257,998
Total Operating Expenses (Costs)	\$3,402,473	\$3,577,110
Net Income	\$520,438	\$680,888

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

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 6 dialysis stations to the existing facility for a total of 26 certified dialysis stations at Freedom Lake Dialysis following completion of Project I.D. # J-11373-17 (relocate 6 stations to FKC Eno River) and this project.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are currently eight operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
Downtown Durham Dialysis* (DaVita)	10	0	0	0
Duke Hospital Dialysis	16	49	76.56%	3.0625
Durham Dialysis (DaVita)	29	100	86.21%	3.4483
Durham Regional Dialysis* (DaVita)	10	0	0	0
Durham West Dialysis (DaVita)	29	98	84.48%	3.3793
FMC Dialysis Services of Briggs Ave. (BMA)	29	90	77.59%	3.1034
FMC Dialysis Ser. W. Pettigrew (BMA)	24	64	66.67%	2.6667
Freedom Lake Dialysis Unit (BMA)	26	94	90.38%	3.6154
FMC South Durham (BMA)	18	53	73.61%	2.9444
Research Triangle Park Dialysis* (DaVita)	10	0	0	0
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500

Source: July 2017 SDR.

*New Facility

As shown in the table above, three facilities are under development, each of which is operated by DaVita. Of those operational facilities Southpoint (DaVita) operated with a utilization rate of 118.75%. Durham and Durham West Dialysis facilities, both operated by DaVita, operated with a

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utilization rate of 86.21% and 84.48%, respectively. Since the publication of the July 2017 SDR, BMA was approved in Project I.D. # J-11373-17 to develop a new ten 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. Freedom Lake Dialysis Unit (BMA) operated with a utilization over 90%. 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 77.59% and 66.67%, respectively. With regard to the underutilization of stations at FMC West Pettigrew, in Project I.D. # J-11373-17, the applicant proposed to relocate four dialysis stations to FKC Eno River. In Project I.D. # J-11373-17, page 35, BMA projected to serve 65 in-center patients dialyzing on 20 certified dialysis stations at FMC West Pettigrew by December 31, 2018 for a utilization 81.25% or 3.25 patients per station per week ($65 / 20 = 3.25$; $3.85 / 4 = 0.8125$ or 81.25%). Thus, even with the reduction of four dialysis stations, FMC West Pettigrew facility is still projected to be well utilized. Additionally, FMC South Durham Dialysis as of June 30, 2017 had 60 in-center patients dialyzing on 18 stations for a utilization of 83.33% or 3.3 patients per station per week. Duke Hospital Dialysis operated with a utilization rate of over 76%. Thus, all the facilities in Durham County are reasonably well utilized. On December 1, 20017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. With the acquisition of Duke Hospital Dialysis, DaVita, Inc., will own/operate seven of the existing and under development ESRD facilities in Durham.

According to Table D in the July 2017 SDR, there is a surplus of 15 dialysis station in Durham County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if its utilization rate, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. According to the July 2017 SDR, Freedom Lake Dialysis had a utilization rate of 90.38% or 3.6154 patients per station per week. This utilization rate was calculated based on 94 in-center dialysis patients and 26 certified dialysis stations ($94 \text{ patients} / 26 \text{ stations} = 3.6154 \text{ patients per station per week}$).

In Section C, pages 13-15, the applicant demonstrates that Freedom Lake Dialysis will serve a total of 86 in-center patients at the end of OY1 for a utilization rate of 82.7% or 3.3 patients per station per week ($86 \text{ patients} / 26 \text{ stations} = 3.3076 / 4 = 0.8269$ or 82.69%). The projected utilization of 3.3 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). The applicant adequately demonstrates the need to add six additional stations at Freedom Lake Dialysis based on the number of in-center patients it projects to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

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- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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, page 34, the applicant provides current and projected staffing in full time equivalents (FTEs) for Freedom Lake Dialysis. The applicant does not project a change in its FTE staff, as BMA is seeking to replace the six stations that were relocated from Freedom Lake Dialysis to FKC Eno River in Project I.D. # J-11373-17, as illustrated below.

POSITION	CURRENT # FTEs	PROJECTED # FTEs
Registered Nurse	4.00	4.00
Technician (PCT))	11.00	11.00
Clinical Manager	1.00	1.00
Administrator	0.15	0.15
Dietician	1.00	1.00
Social Worker	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	0.85	0.85
In-Service	0.15	0.15
Clerical	1.00	1.00
Total	20.30	20.30

In Section H, page 36, the applicant provides the projected direct care staff hours for Freedom Lake Dialysis in OY2. In Section I, page 38, the applicant identifies Dr. Amarnath Kathresal as the Medical Director of the facility. Exhibit I.5, of the application contains a signed letter from Dr. Kathresal of Durham Nephrology Associates, PA stating her willingness to continue to serve as the Medical Director. Exhibit I.6, contains a copy of Dr. Kathresal's curriculum

vitae (CV). In Section H, page 35, the applicant describes the methods used to recruit and fill vacant or new positions.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of Freedom Lake Dialysis.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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, page 37, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I.5 contains a letter from the medical director of the facility expressing her support and willingness to continue serving in that role. The applicant discusses coordination with the existing health care system on page 39. 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 information in Section I and Exhibits I-2, I-3 and I-4 is reasonable and adequately supports a finding of conformity with this criterion.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.

- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

NA

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

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

- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

NA

In Project I.D. # J-11373-17 the applicant proposed the relocation of six dialysis stations from Freedom Lake Dialysis to FKC Eno River. Project I.D. # J-11373-17 was approved on November 9, 2017 with a projected date of offering services by January 1, 2019. In the proposed application, the applicant proposes to add six stations to the existing facility in the same space that will be vacated once six stations are relocated to FKC Eno River. Thus, the applicant does not propose any new construction or renovation at Freedom Lake Dialysis. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 51, the applicant reports that 87.34% of the patients who received treatments at Freedom Lake Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated in the table below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.47%
Medicare	63.99%
Medicaid	7.30%
Commercial Insurance	7.98%
Medicare / Commercial	16.05%
Misc. (VA)	3.20%
Total	100.0%

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 ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². 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).

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant's historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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, pages 49-50, 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.6, page 50, the applicant states that there have been no patient civil rights complaints filed against any BMA North Carolina facilities in the past five years.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations. The applicant states it has not had any civil rights access complaints filed against it within the last five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section L.1, page 47, the applicant states:

“Fresenius related facilities in North Carolina have a long history of providing dialysis services to underserved populations in North Carolina. ... Each of the Fresenius related facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or other traditionally underserved persons.”

In Section L.1(b), page 48, the applicant projects that 86.37% of all in-center patients will have all or part of their services paid for by Medicare and or Medicaid in PY2 (2020).

Projected Payor Mix OY2

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.12%
Medicare	62.58%
Medicaid	7.24%
Commercial Insurance	9.28%
Medicare / Commercial	16.55%
Misc. (VA)	3.23%
Total	100.00%

On page 48, the applicant states that facility projections are based upon treatment volumes and not based upon patients. Projected payor mix is comparable with the facility's historical payor mix on page 51.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Freedom Lake Dialysis Unit has an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care

with the patient's regular nephrologist and a physician with staff privileges at the facility."

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 states that Freedom Lake Dialysis offered the facility as a site for clinical rotations for Durham Technical Community College's nursing students. Exhibit M.I contains a copy of a letter from Fresenius Kidney Care to the Dean of the Nursing Program of Durham Technical Community College documenting the offer.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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.

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- (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 6 dialysis stations to the existing facility for a total of 26 certified dialysis stations at Freedom Lake Dialysis following completion of Project I.D. # J-11373-17 (relocate 6 stations to FKC Eno River) and this project.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are currently eight operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

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DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
Downtown Durham Dialysis* (DaVita)	10	0	0	0
Duke Hospital Dialysis	16	49	76.56%	3.0625
Durham Dialysis (DaVita)	29	100	86.21%	3.4483
Durham Regional Dialysis* (DaVita)	10	0	0	0
Durham West Dialysis (DaVita)	29	98	84.48%	3.3793
FMC Dialysis Services of Briggs Ave. (BMA)	29	90	77.59%	3.1034
FMC Dialysis Ser. W. Pettigrew (BMA)	24	64	66.67%	2.6667
Freedom Lake Dialysis Unit (BMA)	26	94	90.38%	3.6154
FMC South Durham (BMA)	18	53	73.61%	2.9444
Research Triangle Park Dialysis* (DaVita)	10	0	0	0
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500

Source: July 2017 SDR.

*New Facility

As shown in the table above, three facilities are under development, each of which is operated by DaVita. Of those operational facilities Southpoint (DaVita) operated with a utilization rate of 118.75%. Durham and Durham West Dialysis facilities, both operated by DaVita, operated with a utilization rate of 86.21% and 84.48%, respectively. Since the publication of the July 2017 SDR, BMA was approved in Project I.D. # J-11373-17 to develop a new ten 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. Freedom Lake Dialysis Unit (BMA) operated with a utilization over 90%. 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 77.59% and 66.67%, respectively. With regard to the underutilization of stations at FMC West Pettigrew, in Project I.D. # J-11373-17, the applicant proposed to relocate four dialysis stations to FKC Eno River. In Project I.D. # J-11373-17, page 35, BMA projected to serve 65 in-center patients dialyzing on 20 certified dialysis stations by December 31, 2018 for a utilization 81.25% or 3.25 patients per station per week ($65 / 20 = 3.25$; $3.85 / 4 = 0.8125$ or 81.25%). Thus, with the reduction of four dialysis stations, FMC West Pettigrew facility is projected to be well utilized. Additionally, FMC South Durham Dialysis as of June 30, 2017 had 60 in-center patients dialyzing on 18 stations for a utilization of 83.33% or 3.3 patients per station per week. Duke Hospital Dialysis

operated with a utilization rate of over 76%. Thus, all the facilities in Durham County are reasonably well utilized. On December 1, 20017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. With the acquisition of Duke Hospital Dialysis, DaVita, Inc., will own/operate seven of the existing and under development ESRD facilities in Durham.

In Section N.1, page 53, the applicant discusses how any enhanced competition in the service area will promote 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 Durham County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the Freedom Lake Dialysis Unit facility begins with patients currently served by BMA, and a growth of that patient population at a rate of 7.5% annual, based on recent facility history.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 86% of the patients at Freedom Lake Dialysis will have their services covered by Medicare or Medicaid.

See also Sections C, F, G, H, L and P where the applicant discusses cost-effectiveness, quality and access.

The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality, and access to the proposed services in Section N, page 53. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative.
- The applicant adequately demonstrates that Freedom Lake Dialysis Unit will continue to provide quality dialysis services.
- The applicant demonstrates that Freedom Lake Dialysis Unit will continue to provide adequate access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 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 16, the applicant states, Fresenius operates 109 facilities in 48 North Carolina counties In Section O, pages 57-58 and referenced Exhibits, the applicant identifies the two kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. Those two facilities had immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. Both facilities are back in compliance with the Medicare conditions of participation. 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Freedom Lake Dialysis Unit 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 13-15, the applicant demonstrates that Freedom Lake Dialysis will serve a total of 86 in-center patients at the end of OY1 for a utilization rate of 82.7% or 3.3 patients per station per week ($86 \text{ patients} / 26 \text{ stations} = 3.3077 / 4 = 0.8269$ or 82.7%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-15, 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.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

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- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.