

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 9, 2017

Findings Date: November 9, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: J-11373-17

Facility: Fresenius Kidney Care Eno River

FID #: 170324

County: Durham

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

Project: Develop a new 10-station dialysis facility by relocating four dialysis stations from FMC Dialysis Services of West Pettigrew and six dialysis stations from Freedom Lake Dialysis Unit. Upon completion of this project, Freedom Lake Dialysis Unit will have 20 stations and FMC Dialysis Services of West Pettigrew will have 20 stations.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Kidney Care Eno River (FKC Eno River) proposes to relocate four dialysis stations from FMC Dialysis Services of West Pettigrew (FMC West Pettigrew) and six dialysis stations from Freedom Lake Dialysis Unit (Freedom Lake) to develop the proposed new 10-station dialysis facility in Durham. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon project completion, FMC Dialysis Services of West Pettigrew will be certified for 20 dialysis stations and Freedom Lake Dialysis Unit will be certified for 20 dialysis stations.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Durham County, therefore there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) applicable to this review.

Policies

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2017 SMFP states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 10-station dialysis facility, to be named FKC Eno River, in Durham by relocating four dialysis stations from FMC Dialysis Services of West Pettigrew and six dialysis stations from Freedom Lake Dialysis Unit. All three facilities are located in Durham County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate four dialysis stations from FMC Dialysis Services of West Pettigrew and six dialysis stations from Freedom Lake Dialysis Unit to develop the proposed new 10-station dialysis facility in Durham.

The following tables, summarized from pages 4-5 of the application, illustrate the proposed FKC Eno River dialysis stations, Freedom Lake Dialysis Unit and FMC Dialysis Services West Pettigrew dialysis inventory following completion of the proposed project.

Fresenius Kidney Care Eno River

Stations	Description	Project ID #
0	Total existing certified stations as of the July 2017 SDR	
+10	Stations to be added as part of this project	J-11373-17
10	Total stations upon completion of above projects	

Freedom Lake Dialysis Unit

Stations	Description	Project ID #
26	Total existing certified stations as of the July 2017 SDR	
-6	Stations to be deleted as part of this project	J-11373-17
20	Total stations upon completion of above projects	

FMC Dialysis Services West Pettigrew

Stations	Description	Project ID #
24	Total existing certified stations as of the July 2017 SDR	
-4	Stations to be deleted as part of this project	J-11373-17
20	Total stations upon completion of above projects	

As the tables above illustrate, upon project completion, FKC Eno River will be certified for 10 dialysis stations, Freedom Lake Dialysis Unit and FMC Dialysis Services West Pettigrew will each be certified for 20 dialysis stations. The July 2017 SDR projects a surplus of 15 dialysis stations in Durham County, however, the applicant projects to relocate dialysis stations within the county, therefore, the projected inventory of dialysis stations within Durham County will not change.

Patient Origin

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.

FKC Eno River will be a new facility in Durham County and therefore has no existing patient origin.

In Section C.1, page 18, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**FKC Eno River
 Projected Patient Origin by County**

County	Operating Year 1 1/1/19 –12/31/19	Operating Year 2 1/1/20-12/31/20	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Durham	33.3	34.6	100.0%	100.0%
Total*	33	34	100.0%	100.0%

*Rounded down to the whole patient

The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients. On page 18, the applicant states that patients who might be candidates for home dialysis will be referred to FMC West Pettigrew. (See Exhibit I.1) The applicant states that projected patient origin is based on the existing 35 Durham County patients living in close proximity to the proposed facility who signed letters stating their willingness to consider transferring their care to the proposed facility.

The applicant provides the assumptions and methodology used to project patient origin on pages 18-20. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C-2, page 21, the applicant describes the need for the proposed project as follows:

“The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise.”

In Section C, pages 18-20, the applicant states the need for the proposed new FKC Eno River Dialysis facility is based on the following factors:

- The applicant plotted the residence of patients currently being served in BMA facilities in Durham and noted a significant number of patients that reside in northern Durham (city) and in Durham County, north of the city and concluded that these patients could be better served by the proposed facility which would provide a more convenient location. (page 18).
- The number of patients served in BMA facilities has increased by 41 patients over the past three years from January 2015 to January 2018 (as reported in the June 30, 2017

SDR). The applicant reports this is an annualized growth of 5.10% which is 25% higher than the Durham County average annual change rate of 4.0%. (page 19) The applicant provides the following table on page 19, regarding BMA’s Durham County facilities census as reported in the following SDRs.

SDR	Census
January 2015	268
July 2015	269
January 2016	283
July 2016	278
January 2017	283
July 2017	301
January 2018	309

The applicant concludes on page 19 that the continued growth in the census served by BMA facilities warrants the development of a new facility.

- The applicant provides 35 letters of support from patients currently dialyzing at BMA facilities in Durham who have expressed a willingness to consider transferring to the proposed Eno River facility because the facility would be closer to their residence in northern Durham. (page 19) The applicant provides a table on page 20, that illustrates the BMA patients currently receiving dialysis services by ZIP Code and the facility were they currently receive services, as summarized below:

BMA Facility	FKC Eno Rivers Letters of Support		
	ZIP Code of Residence		
	27704	27712	Totals
Freedom Lake Dialysis	15	5	20
FMC West Pettigrew	2	2	4
FMC South Durham	1	1	2
FMC Briggs Avenue	7	2	9
Totals	25	10	35

- The applicant assumes that 32 of the 35 patients who provided letters of support will transfer their care to the proposed FKC Eno River facility based upon a reduction in travel time to receive services. (page 20)
- The applicant assumes the Durham County dialysis patients transferring to the proposed facility will grow at a rate commensurate with the Durham County Five Year Average Annual Change Rate as published in the July 2017 SDR of 4.0%. (page 20)

Projected In-center Utilization

The applicant projects that Operating Year One (OY1) and Operating Years Two (OY2) for the proposed project will be Calendar Year (CY) 2019 and CY2020, respectively. In Section

C.1, page 20, the applicant provides its methodology for projecting in-center (IC) utilization as follows:

FKC Eno River IN-CENTER	
In-center Methodology:	
BMA begins with 32 Durham County IC dialysis patients upon project certification December 31, 2018.	32
BMA projects this census forward one year using the Durham County Five Year Average Annual Change Rate of 4.0% to December 31, 2019. This is the end of OY1.	$32 \times 1.04 = 33.28$
BMA projects this Durham County patient population forward to December 31, 2020. This is the ending census for Operating Year 2.	$33.28 \times 1.04 = 34.61$

The applicant rounds down to the nearest whole number. Therefore, the applicant projects to serve 33 in-center patients or 3.3 patients per station per week ($33/10 = 3.3$) by the end of OY1 with a utilization rate of 82.5% ($3.3/4 = 0.825$ or 82.5%) and 34 in-center patients or 3.35 patients per station per week ($34/10 = 3.4$) with a utilization rate of 85% ($3.34/4 = 0.85$ or 85%) by the end of OY2 for the proposed facility. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed facility.

Access

In Section L.1(a), pages 66-67, 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. In Section L, page 67, the applicant projects that 86.2% of its in-center patients will be covered by some combination of Medicare or Medicaid at the proposed FKC Eno River facility. Additionally, in Section L-7, page 70, the applicant provides the historical payor mix for Freedom Lake and FMC West Pettigrew. In FY 2016, the applicant reports that 86.2% of its total patients at Freedom Lake and 91.2 % of FMC West Pettigrew had some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

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

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

C

The applicant proposes to develop a new 10-station facility by relocating four dialysis stations from FMC West Pettigrew and six dialysis stations from Freedom Lake. All three facilities are located in Durham County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FMC Dialysis Services of West Pettigrew will be certified for 20 dialysis ($24 - 4 = 20$) and Freedom Lake Dialysis Unit will also be certified for 20 dialysis stations ($26 - 6 = 20$).

The following table shows the proposed relocation of stations and transfer of Durham County dialysis patients projected in the proposed project.

Facility	Number of Stations to be Relocated	Number of Patients Transferring
Freedom Lake Dialysis	6	20
FMC West Pettigrew	4	4
FMC South Durham	0	2
FMC Briggs Avenue	0	9
Total	10	35

Freedom Lake Dialysis Unit

In Section D-1, pages 32-33, the applicant provides the assumptions used to project Freedom Lake Dialysis Unit utilization as of December 31, 2018. The applicant discusses how it will continue to meet the needs of dialysis patients at Freedom Lake after the relocation of six stations to the FKC Eno River facility. The July 2017 SDR reported as December 31, 2016, 94 patients dialyzing at Freedom Lake on 26 dialysis stations, for a utilization rate of 90.38% ($94 / 26 = 3.615 / 4 = 0.9038$). On page 33, the applicant states that as of June 30, 2017 there were 91 patients dialyzing at Freedom Lake and that 86 of those patients were residents of Durham County. The applicant provides a table on page 33, which illustrates the county of residence for the in-center patients at Freedom Lake as of June 30, 2017, as shown below.

Freedom Lake Dialysis Unit	Number of Patients by County
Durham	86
Alamance	1
Granville	1
Orange	1
Person	2
Total	91

The applicant assumes that the number of in-center patients at Freedom Lake who live in Durham County will increase at 4.0% per year based on the Five Year AACR for Durham County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the five in-center patients from outside Durham County. In Section D.1, page 33, the applicant calculates the in-center patient census for Freedom Lake starting June 30, 2017 through December 31, 2018 (projected certification date of FKC Eno River facility), summarized as follows:

Freedom Lake Dialysis Unit	
BMA begins with the Durham County patient census as of June 30, 2017.	86
BMA projects this census forward for six months using the Durham County Five Year Average Change Rate to December 31, 2017.	$[86 \times (.040 / 12 \times 6)] + 86 = 87.72$
BMA projects this census forward for one year to December 31, 2018.	$87.7 \times 1.04 = 91.21$
Subtract 20 Durham County residents projected to transfer their care to FKC Eno River.	$91.21 - 20 = 71.21$
Add the 5 patients from outside Durham County – this is the projected census for December 31, 2018	$71.21 + 5 = 76.21$

On page 33, the applicant states that BMA rounds the patient population of 76.22 up to 77 in-center patients for a utilization of 96.25% or 3.85 patients per station, per week. This is based on 77 in-center patients dialyzing on 20 certified dialysis stations ($77 / 20 = 3.85$; $3.85 / 4 = 0.9625$ or 96.25%). However, throughout the application and historically, the patient census is typically rounded down not up, thus the project analyst calculated the utilization based on 76 in-center patients dialyzing on 20 certified stations for a utilization of 95% or 3.8 patients per stations per week ($76 / 20 = 3.8$; $3.8 / 4 = 0.95$ or 95%).

FMC Dialysis Services West Pettigrew

In Section D-1, pages 34-35, the applicant provides the assumptions used to project FMC West Pettigrew utilization as of December 31, 2018. The applicant discusses how it will continue to meet the needs of dialysis patients at FMC West Pettigrew after the relocation of four stations to the FKC Eno River facility. The July 2017 SDR reported as December 31, 2016, 64 patients dialyzing at FMC West Pettigrew on 24 dialysis stations, for a utilization rate of 66.67% ($64 /$

24 = 2.666 / 4 = 0.6666). On page 34, the applicant states that as of June 30, 2017 there were 67 patients dialyzing at FMC West Pettigrew and that 63 of those patients were residents of Durham County. The applicant provides a table on page 34, which the applicant refers to as “the in-center patient population at Freedom Lake Dialysis,” in the narrative and the table below. The project analyst assumed this to be a typographical error as the information above the narrative provided data for FMC West Pettigrew. The applicant provides a table which illustrates the county of residence for the in-center patients at FMC Dialysis Services West Pettigrew (not Freedom Lake Dialysis Unit), as of June 30, 2017, as shown below.

FMC Dialysis Services West Pettigrew	Number of Patients by County
Durham	63
Orange	2
Person	1
Other States	1
Total	67

The applicant assumes that the number of in-center patients at FMC West Pettigrew who live in Durham County will increase at 4.0% per year based on the Five Year AACR for Durham County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the five in-center patients from outside Durham County. In Section D.1, page 35, the applicant calculates the in-center patient census for FMC West Pettigrew starting June 30, 2017 through December 31, 2018 (projected certification date of FKC Eno River facility), summarized as follows:

FMC Dialysis Services West Pettigrew	
BMA begins with the Durham County patient census as of June 30, 2017.	63
BMA projects this census forward for six months using the Durham County Five Year Average Change Rate to December 31, 2017.	*[63 x (.040 / 12 x 6)] + 63 = 64.26
BMA projects this census forward for one year to December 31, 2018.	64.26 x 1.04 = 66.83
Subtract 4 Durham County residents projected to transfer their care to FKC Eno River.	66.83 - 4 = 62.83
Add the 3 patients from outside Durham County (does not included the one patient from another state) – this is the projected census for December 31, 2018	62.83 + 3 = 65.83

*Reflects analyst calculations based on the data provided. The information on page 35 reflects the following: December 31, 2017 64.1 x 1.04 = 65.8 – 4 = 61.8 + 3 = 64.8. Thus, there is a difference of one patient based on the analyst’s calculations.

On page 35, the applicant states that BMA rounds the patient population of 64.8 up to 65 in-center patients. As the actual projected number of in-center patients is 65.83, calculating the utilization on 65 in-center patients is accurate. Therefore, a utilization of 81.25% or 3.25 patients per station, per week is projected for the FMC West Pettigrew facility. This is based

on 65 in-center patients dialyzing on 20 certified dialysis stations ($65 / 20 = 3.25$; $3.85 / 4 = 0.8125$ or 81.25%).

The applicant states on page 35, that no patients will be adversely affected by the proposed relocation of six dialysis stations from Freedom Lake and four stations from FMC West Pettigrew

In Section L.1(b), page 67, the applicant states that the projected payor mix at the proposed new facility is based on the historical payor mix of Freedom Lake. Thus, the applicant states that the proposed relocation of stations and transfer of patients will not have an adverse impact 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

Conclusion

The applicant demonstrates that the needs of the population presently served at Freedom Lake and FMC West Pettigrew will continue to be adequately met following the proposed relocation of six dialysis stations from Freedom Lake and four dialysis stations from FMC West Pettigrew to FKC Eno River and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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, page 36, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the number of people currently dialyzing at a BMA facility in Durham who live in closer proximity to the proposed FKC Eno River facility. Therefore, this alternative was rejected.
- Develop a facility in another area of Durham County - After an evaluation of the current patient population served at BMA facilities in Durham and an analysis of projected population growth, the applicant concluded that the proposed area in northern Durham would be best served by a new facility. Therefore, development of a facility in another area of Durham was not considered to be an effective alternative.
- Development of a larger facility - After evaluation of the current patient population and the projected population growth, the applicant concluded that a larger facility was not needed and therefore would not be an effective alternative.

- Inclusion of home hemodialysis and peritoneal dialysis services - The applicant concluded that the current home patient population is well served by the centralized home therapies program. The applicant will save money by not adding home hemodialysis services to the proposed facility. Therefore, this alternative was rejected.

Thus, after considering the above alternatives, the applicant states that its proposal to develop a new 10-station facility in Durham by relocating six dialysis stations from Freedom Lake Dialysis Unit and four dialysis stations from FMC Dialysis Services West Pettigrew 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. In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Eno River shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD 2, Bio-Medical Applications of North Carolina, Inc. shall develop a new kidney disease treatment center to be known as Fresenius Kidney Care Eno River by relocating six dialysis stations from Freedom Lake Dialysis Unit and four dialysis stations from FMC Dialysis Services West Pettigrew.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Eno River shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify six dialysis stations at Freedom Lake Dialysis Unit for a total of no more than twenty dialysis stations at Freedom Lake Dialysis Unit and to decertify four dialysis stations from FMC Dialysis Services West Pettigrew for a total of twenty dialysis stations at FMC Dialysis Services West Pettigrew.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Eno River 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.

The applicant proposes to develop a new 10-station facility by relocate four dialysis stations from FMC West Pettigrew and six dialysis stations from Freedom Lake. All three facilities are located in Durham County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Capital and Working Capital Costs

In Section F-1, page 39, the applicant projects \$1,798,137 in capital costs to develop the proposed project as summarized below:

Projected Capital Costs

		Total Capital Costs
Construction Project Costs		
Construction Contract	\$1,169,400	
Sub-Total Construction Costs		\$1,169,400
Miscellaneous Project Costs		
Water Treatment Equipment	\$225,000	
Equipment/Furniture	\$204,343	
Architect & Engineering Fees	\$105,246	
Other: Contingency	\$63,732	
Sub-Total Miscellaneous Costs		\$598,321
Total Capital Cost		\$1,767,721

In Sections F.10 - F.12, pages 42-43, the applicant estimates start-up expenses of \$129,723 and initial operating expenses of \$1,051,653 for a total working capital of \$1,181,376.

Availability of Funds

In Section F.2, page 40, the applicant states it will finance the capital costs with accumulated reserves/owner's equity of Fresenius Medical Care Holdings, Inc. (FMC). In Section F.13, page 44, the applicant states the working costs will be financed by the accumulated reserves of FMC.

Exhibit F-1 contains a letter dated July 17, 2017, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the capital costs of the proposed project in the amount of \$1,767,721. Additionally the letter states,

“Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$1,767,721 as may be needed for this project. I am also authorized, and authorize an additional funds as may be necessary for the start-up costs in the new location.”

The letter contained in Exhibit F-1, does not specifically list the total working capital of the project as \$1,181,376, however, it is clear from the intent of the letter that the working capital needs of the project will be financed by FMC.

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

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that operating expenses will exceed revenues in OY1. However, the applicant projects that revenues will exceed operating expenses in OY2 of the project, as shown in the table below.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	4,742	4,860
Total Gross Revenues (Charges)	\$18,911,096	\$19,501,320
Total Net Revenue	\$1,568,798	\$1,617,761
Total Operating Expenses (Costs)	\$1,577,480	\$1,615,736
Net Income	(\$8,682)	\$2,025

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 and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate four dialysis stations from FMC West Pettigrew and six dialysis stations from Freedom Lake to develop the proposed new 10-station dialysis facility in Durham.

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 11 dialysis facilities 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*	10	0	0	0
Duke Hospital Dialysis	16	49	76.56%	3.0625
Durham Dialysis	29	100	86.21%	3.4483
Durham Regional Dialysis*	10	0	0	0
Durham West Dialysis	29	98	84.48%	3.3793
FMC Dialysis Services of Briggs Ave.	29	90	77.59%	3.1034
FMC Dialysis Ser. W. Pettigrew	24	64	66.67%	2.6667
Freedom Lake Dialysis Unit	26	94	90.38%	3.6154
FMC South Durham	18	53	73.61%	2.9444
Research Triangle Park Dialysis*	10	0	0	0
Southpoint Dialysis	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 West Durham Dialysis facilities, both operated by DaVita, operated with a utilization rate of 86.21% and 84.48%, respectively. 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. Duke Hospital Dialysis operated with a utilization rate of over 76%, thus all the facilities in Durham County are reasonably well utilized.

According to Table D in the July 2017 SDR, there is a surplus of 15 dialysis station in Durham County. However, the applicant is not increasing the number of dialysis stations in Durham County, rather it is relocating 10 existing Durham County stations to develop a new facility that the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 20, the applicant demonstrates that FKC Eno River will serve a total of 33 in-center patients or 3.3 patients per station per week ($33/10 = 3.3$) by the end of OY1 with a utilization rate of 82.5% ($3.3/4 = 0.825$ or 82.4%) and 34 in-center patients or 3.35 patients per station per week ($34/10 = 3.4$) with a utilization rate of 85% ($3.34/4 = 0.85$ or 85%) by the end of OY2 .

The applicant provides documentation in Exhibit C-1 from 35 Durham County in-center patients dialyzing at Fresenius-affiliated facilities stating their willingness to consider transferring to FKC Eno River because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate existing Durham County Fresenius-affiliated dialysis stations to develop a new Fresenius dialysis facility in Durham County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the need of the populations presently served at FMC West Pettigrew and Freedom Lake, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Durham County. Consequently, the application is conforming to this criterion

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

C

In Section H.1, page 50, the applicant provides the projected staffing for FKC Eno River in OY2 by full-time equivalent (FTE) staff, as shown below:

FKC Eno River Proposed FTE Positions OY2	
Position	Total
Registered Nurse	1.50
Patient Care Technician	4.00
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.40
Social Worker	0.40
Chief Tech	0.15
Equipment Tech	0.60
In-Service	0.15
Clerical	0.75
Total FTEs	9.10

Note: The Medical Director is a contracted position.

In Section H.3, page 51, the applicant describes its experience and process for recruiting and retaining staff. In Section I.3, page 55, the applicant identifies the medical director for the proposed facility as Amar Kathresal, M.D. Exhibit I.5 contains a copy of a letter dated June 15, 2017 from Dr. Kathresal expressing support for the proposed project and a willingness to serve as the Medical Director. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 54, the applicant includes a list of providers of the necessary ancillary and support services for the proposed project. Exhibits I.1-4 contains documentation for home dialysis training, laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the proposed medical director of the facility describing Nephrology services that will be offered by Durham Nephrology. The applicant discusses coordination with the existing health care system on page 56. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

In Section K.2, page 61, the applicant states that the proposed facility will have 2,942 square feet of treatment area, which includes an isolation room. The applicant provides the proposed facility's line drawings in Exhibit K.1. The drawing depicts a 7,776 square foot facility, with nine main floor dialysis stations and one isolation dialysis station, for a total of 10 dialysis stations. In Section F.1, page 38, the applicant states that it relies upon the Fresenius Facility Design and Maintenance Department to develop anticipated project development costs. On page 39, the applicant provides the proposed costs, including \$1,169,400 for construction, \$598,321 in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,767,721. In Section K.1, pages 59-60, the applicant describes its plans for energy-efficiency, including water conservation.

Costs and charges are described by the applicant in Section F, pages 38-39, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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

FKC Eno River is not an existing facility, therefore, it has no historical payor mix. However, in Section L.7, page 70, the applicant provides the historical payor mix for Freedom Lake and FMC West Pettigrew for CY2016. These are the two facilities from which the applicant proposes to relocate the ten existing dialysis stations to develop the proposed new FKC Eno River facility. Their payor mix is illustrated below:

	Percentage of In-Center Patients	
	Freedom Lake Dialysis	FMC West Pettigrew
Self Pay/Idigent/Charity	1.65%	0.18%
Medicare	62.48%	74.69%
Medicaid	7.18%	4.17%
Commercial Insurance	8.97%	8.57%
Medicare/Commercial	16.53%	12.36%
Miscellaneous Including VA)	3.18%	0.04%
Total	100.0%	100.0%

Note: The applicant states on page 70 that totals may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
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.

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

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).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(e), page 69, the applicant states:

“Fresenius related facilities in North Carolina 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 69, the applicant states there have been no civil rights access complaints filed within the last five years against any BMA North Carolina facility. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 67, the applicant projects that 86.2% of the patients who will receive in-center treatments at FKC Eno River will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 (CY2020) payor sources for the facility for in-center patients

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

FKC Eno River	
PROJECTED PAYOR SOURCE (OY2) (CY2020)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self Pay/Indigent/Charity	1.65%
Medicare	62.48%
Medicaid	7.18%
Commercial Insurance	8.97%
Medicare/Commercial	16.53%
Miscellaneous (Includes VA)	3.18%
Total	100.00%

In Section L1, page 67, the applicant states the projected payor mix is calculated based on the payor mix of BMA facilities in Durham County as of April 30, 2017. The projected payor mix mirrors the payor mix of Freedom Lake. The applicant demonstrates that medically underserved groups will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 69, the applicant describes the range of means by which a person will have access to the dialysis services at the proposed FKC Eno River facility, including referrals from nephrologists and hospital emergency departments. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 71, the applicant states that health related education programs will be welcomed at the facility. Exhibit M.1 includes a letter from the applicant to the Dean and Department Head of Health Technologies at Durham Technical Community College, dated July 17, 2017, inviting the school to include FKC Eno River in its clinical rotations for its nursing students. The information provided in Section M.1 and Exhibit M.1 is reasonable and supports a finding of conformity 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 relocate four dialysis stations from FMC West Pettigrew and six dialysis stations from Freedom Lake Dialysis to develop the proposed new 10-station dialysis facility in Durham.

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 11 dialysis facilities 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*	10	0	0	0
Duke Hospital Dialysis	16	49	76.56%	3.0625
Durham Dialysis	29	100	86.21%	3.4483
Durham Regional Dialysis*	10	0	0	0
Durham West Dialysis	29	98	84.48%	3.3793
FMC Dialysis Services of Briggs Ave.	29	90	77.59%	3.1034
FMC Dialysis Ser. W. Pettigrew	24	64	66.67%	2.6667
Freedom Lake Dialysis Unit	26	94	90.38%	3.6154
FMC South Durham	18	53	73.61%	2.9444
Research Triangle Park Dialysis*	10	0	0	0
Southpoint Dialysis	16	76	118.75%	4.7500

Source: July 2017 SDR.

*New Facility

As shown in the table above, three facilities are under development, each is operated by DaVita. Of those operational facilities Southpoint (DaVita) operated with a utilization rate of 118.75%. Durham and West Durham Dialysis facilities, both operated by DaVita, operated with a utilization rate of 86.21% and 84.48%, respectively. 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. Duke Hospital Dialysis operated with a utilization rate of over 76%, thus all the facilities in Durham County are reasonably well utilized.

According to Table D in the July 2017 SDR, there is a surplus of 15 dialysis station in Durham County. However, the applicant is not increasing the number of dialysis stations in Durham County, rather it is relocating 10 existing Durham County stations to develop a new facility that the applicant states is closer to patients living in the area where the new facility will be located.

In Section N-1, page 72, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Durham County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC Eno River facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Durham County five year average annual change rate of 4.0% as published within the July 2017 SDR.”

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 FKC Eno River will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 72, that its proposal will *“enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

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

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue providing quality services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.

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

Therefore, the application is conforming to this criterion.

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

C

In Section A.11, page 5, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. On page 66, the applicant states, Fresenius operates 109 facilities in 48 North Carolina counties. In Section O, pages 77-78 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 application is conforming to this criterion.

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

C

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

- .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.*
- C- In Section C.1, pages 18-20, the applicant states the need for the proposed project. The applicant projects to serve 33 in-center patients or 3.3 patients per station per week ($33/10 = 3.3$) by the end of OY1 with a utilization rate of 82.5% ($3.3/4 = 0.825$ or 82.4%) and 34 in-center patients or 3.35 patients per station per week ($34/10 = 3.4$) with a utilization rate of 85% ($3.34/4 = 0.85$ or 85%) by the end of OY2 for the proposed facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- .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.*
- NA- The application is for the development of a new 10-station facility.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicant provides its assumptions, including the methodology by which patient utilization is projected in Section C-1, pages 18-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.