

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 27, 2017

Findings Date: November 3, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: L-11374-17

Facility: Fresenius Kidney Care Boice-Willis

FID #: 170325

County: Edgecombe

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

Project: Develop a new 10-station dialysis facility by relocating 10 stations from BMA East Rocky Mount. Upon completion of this project, Project ID# L-11011-15 (Relocate 6 stations from BMA East Rocky Mount to develop a new 10-station dialysis facility in Tarboro) and Project ID# L-11093-15 (Add 6 dialysis stations to BMA East Rocky Mount), BMA East Rocky Mount will have 20 dialysis stations.

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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Kidney Care Boice-Willis (FKC Boice-Willis), proposes to develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. The proposed facility and the existing facility are in Edgecombe County, with the proposed facility to be located at 1794 East Raleigh Boulevard in Rocky Mount. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Boice-Willis will be certified for 10 dialysis stations and BMA East Rocky Mount will be certified for 20 dialysis stations upon completion of

Project ID# L-11011-15 (Relocate 6 stations from BMA East Rocky Mount to develop a new 10-station dialysis facility in Tarboro) and Project ID# L-11093-15 (Add 6 dialysis stations to BMA East Rocky Mount).

Need Determination

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

Policies

There is one policy in the 2017 SMFP that is applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2: Relocation of Dialysis Stations 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 a contiguous county 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 in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. Both facility locations are in Edgecombe 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 the applicable policy in the 2017 SMFP.

- (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 develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. Both locations are in Edgecombe County.

The following tables, summarized from Section A.9, page 4 of the application, illustrate the proposed FKC Boice-Willis stations, and the current projects under development which impact the number of dialysis stations at BMA East Rocky Mount, the facility from which the applicant plans to relocate 10 stations to develop the proposed new facility.

FKC BOICE-WILLIS		
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	L-11374-17
10	Total stations upon completion of above projects	
BMA EAST ROCKY MOUNT		
Stations	Description	Project ID #
30	Total existing certified stations as of the July 2017 SDR	
10	Stations to be deleted as part of this project	L-11374-17
6	Stations previously approved to be deleted - certified October 2, 2017	L-11011-15
6	Stations previously approved to be added - certified October 2, 2017	L-11093-15
20	Total stations upon completion of above projects	

As the tables above illustrate, upon project completion, FKC Boice-Willis will be certified for 10 dialysis stations and BMA East Rocky Mount will be certified for 20 stations following completion of this project, Project ID# L-11011-15 (Relocate 6 stations from BMA East Rocky Mount to develop a new 10-station dialysis facility in Tarboro) and Project ID# L-11093-15 (Add 6 dialysis stations to BMA East Rocky Mount for a total of 30 dialysis stations) are complete and were certified October 2, 2017.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” The proposed new facility, FKC Boice-Willis, will be located in Edgecombe County; thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

FKC Boice-Willis will be a new facility in Edgecombe 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.

FRESENIUS KIDNEY CARE BOICE-WILLIS 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	
			OY1	OY2
	In-Center Patients	In-Center Patients		
Edgecombe	32.2	32.3	100.0%	100.0%
Total*	32	32	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 South Rocky Mount.

In Section C.1, pages 18-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant states in Assumption #3 on page 19 that projected patient origin is based on the existing patients living in close proximity to the proposed facility who signed letters stating their willingness to transfer their care to the proposed facility. Exhibit C-1 contains copies of the 32 signed patient letters.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. Both the proposed and existing facilities are located are in Edgecombe County.

In Section C.2, page 20, the applicant states:

“... 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.”

The applicant has included 32 in-center patient letters of support (Exhibit C-1), which state that each patient would consider transferring their care to the new facility. The applicant states that each of these patients resides in close proximity to the proposed facility location, is currently receiving dialysis care at a Fresenius-affiliated dialysis facility in Edgecombe County, and has expressed a willingness to transfer to the proposed location because it is more convenient and closer to their homes. The applicant provides a table on page 19 of the application showing at which Fresenius-affiliated Edgecombe County facility the patients who are expected to transfer are currently dialyzing, and is summarized as follows.

FKC BOICE-WILLIS Patient Letters of Support	
Facility	Number of Patients Projected to Transfer
BMA East Rocky Mount	24
Rocky Mount Kidney Center	5
FMC South Rocky Mount	3
Total	32

On page 21 of the application, the applicant states that the need this population has for the proposed service is a function of the individual patient need for dialysis care, and the stated desire of the patients to have dialysis at the proposed facility.

Projected Utilization

In Section C.1, pages 18-20, the applicant provides the following assumptions used to project utilization:

- The applicant plotted the residence location of patients dialyzing at BMA facilities within Edgecombe County. The applicant includes 32 letters (Exhibit C-1) from patients who reside in close proximity to the proposed facility, who could be better served by the proposed location.
- The applicant projects, based on the patient letters, that 32 in-center dialysis patients will transfer their care to the new facility upon project certification. This is 100% of the patients who signed letters stating willingness to consider transferring their care to the proposed facility.
- The applicant states that the project will be completed on December 31, 2018. Operating Year 1 (OY1) is the period from January 1 through December 31, 2019. Operating Year 2 (OY2) is the period from January 1 through December 31, 2020.
- The applicant assumes that the Edgecombe County dialysis patients transferring to the new facility are part of the Edgecombe County ESRD patient population as a whole,

and that this population will increase at a rate commensurate with the Edgecombe County Five Year Average Annual Change Rate (AACR) of 0.5%, as published in the July 2017 Semiannual Dialysis Report (SDR).

- The applicant does not project any patients from outside Edgecombe County to transfer their care.

In Section C.1, page 20, the applicant provides the methodology used to project utilization, as summarized in the following table.

FKC BOICE-WILLIS	In-Center
Begin with 32 in-center Edgecombe County dialysis patients projected to transfer their care to the new facility upon certification of the project, December 31, 2018.	32
The applicant projects the patient population forward to December 31, 2019 (end of OY1), using the Edgecombe County Five Year AACR of 5%.	$(32 \times 1.005) = 32.2$
The applicant projects the patient population forward to December 31, 2020 (end of OY2), using the Edgecombe County Five Year AACR of 5%.	$(32.2 \times 1.005) = 32.3$

The applicant states on page 20, that it rounds down to the whole patient in this calculation. Therefore, the applicant projects that at the end of OY1, 32 patients will be dialyzing on 10 stations for a projected utilization rate of 3.2 patients per station per week (32 in-center patients / 10 stations = 3.2) which meets the minimum standard of 3.2 patients per station per week 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, page 67, the applicant states:

“It is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L.1(b), page 68, the applicant projects that 90.1% of its in-center patients will be covered by some combination of Medicare (82.7%) and Medicaid (7.4). The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed services based on reasonable

and supported utilization projections and assumptions, and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. Both facility locations are in Edgecombe 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, FKC Boice-Willis will be certified for 10 dialysis stations and BMA East Rocky Mount will be certified for 20 dialysis stations upon completion of Project ID# L-11011-15 (Relocate 6 stations from BMA East Rocky Mount to develop a new 10-station dialysis facility in Tarboro), and Project ID# L-11093-15 (Add 6 dialysis stations to BMA East Rocky Mount) ($30 - 6 = 24 + 6 = 30 - 10 = 20$). Project ID# L-11011-15 and Project ID# L-11093-15 are complete and were certified on October 2, 2017.

The following table shows the projected relocation of stations in the proposed FKC Boice-Willis project and identifies the number of patients projected to transfer from Fresenius-affiliated Edgecombe County facilities.

PROPOSED FKC BOICE-WILLIS PROJECT		
Facility	Number of Stations to be Relocated	Number of Patients Transferring
BMA East Rocky Mount	10	24
Rocky Mount Kidney Center	0	5
FMC South Rocky Mount	0	3
Total Relocated and Transferred	10	32

BMA East Rocky Mount

In the July 2017 Semiannual Dialysis Report (SDR), there were 125 patients dialyzing at BMA East Rocky Mount on 30 dialysis stations for a utilization rate of 104.17% ($125 / 30 = 4.1667 / 4 = 1.0417$). In Section D.1, page 33, the applicant states that as of June 30, 2017, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended June 30, 2017, there were 116 patients dialyzing at BMA East Rocky Mount on 30 dialysis stations. This indicates a utilization rate of 96.7% ($116 / 30 = 3.8667 / 4 = .9667$).

In addition, the applicant states that 72 of the 116 in-center patients live in Edgecombe County, with 40 patients from Nash County, three patients from Halifax and one patient from Wilson County. Twenty-four Edgecombe residents have indicated a desire to transfer from BMA East Rocky Mount to FKC Boice-Willis.

The applicant assumes that the number of in-center patients at BMA East Rocky Mount who live in Edgecombe County will increase at 0.5% per year based on the Five Year Average Annual Change Rate (AACR) for Edgecombe County, as reported in Table B of the July 2017 SDR. In Section D.1, page 33, the applicant calculates the in-center patient census for BMA East Rocky Mount starting June 30, 2017 through OY1 (CY2019) and OY2 (CY2020), summarized as follows:

BMA EAST ROCKY MOUNT	In-Center Patients
Begin with the ESRD patient population of Edgecombe County, as of June 30, 2017.	72
Project this population forward 3 months to September 30, 2017, using the Five Year AACR for Edgecombe County.	$[(72 \times (.005 / 12 \times 3)) + 72 = 72.2$
Subtract 3 Edgecombe County patients projected to transfer their care to FMC Tarboro.	$72.2 - 3 = 69.2$
Project this population forward 3 months to December 31, 2017, using the Five Year AACR for Edgecombe County.	$[69.2 \times (.005 / 12 \times 3)] + 69.2 = 69.3$
Project this population forward 12 months to December 31, 2018.	$69.3 \times 1.005 = 69.8$
Subtract 32 Edgecombe County patients projected to transfer their care to FKC Boice-Willis.	$69.8 - 24 = 45.8$
Add 44 patients from Nash, Halifax and Wilson counties.	$45.8 + 44 = 89.8$

Thus, on December 31, 2018, BMA East Rocky Mount is projected to have 20 (30 - 6 + 6 - 10 = 20) certified dialysis stations with a patient population of 90 (rounded up). Utilization is calculated to be 4.5 patients per station (90 / 20 = 4.5) or 112.5% utilization (4.5 / 4 = 1.125).

Therefore, the applicant states that no BMA East Rocky Mount patients will be adversely impacted by this application to relocate 10 stations to FKC Boice-Willis. In Section D.1, page 36, the applicant states that relocating 10 stations from BMA East Rocky Mount to FKC Boice-Willis will not create any undue hardship or restrict admissions to BMA East Rocky Mount. The applicant states that it plans to apply for additional stations for BMA East Rocky Mount when necessary.

Further, in Section L.1(b), page 68, the applicant states that the projected payor mix at the proposed facility is based on the payor mix of its existing Edgecombe County facilities. The applicant states that the proposed relocation of stations and transfer of patients will not will not adversely affect 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.

The applicant adequately demonstrates that the needs of the populations presently served at BMA East Rocky Mount will continue to be met following the proposed relocation of dialysis stations and transfer of patients to FKC Boice-Willis, 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.1, page 37, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant states that it dismissed this alternative because there are a significant number of patients dialyzing in Fresenius-affiliated facilities and residing in close proximity to the proposed FKC Boice-Willis facility, who can be more conveniently served by the development of the proposed facility. Therefore, the applicant determined the status quo would not be the most effective alternative.
2. Develop Facility in Another Area in Edgecombe County – the applicant states that based on its evaluation of existing patients served by Fresenius related facilities, coupled with projections of future patient populations, there is indication of the need for an additional facility in the north and eastern areas of Rocky Mount and Edgecombe County near the location of the proposed facility. Thus, the applicant determined any other location would be less effective.
3. Develop a Larger Facility with More Stations – after evaluation of the patient letters and the patient population served, the applicant states that it determined that FKC Boice-Willis should not apply for more than 10 stations. The applicant projects that 32 patients will transfer to the facility upon certification, sufficient to meet Performance Standard 10A NCAC 14C .2203. Thus, the applicant determined a larger facility would not be the more effective alternative.
4. Apply to Offer Home Therapies – the applicant states that it could have proposed to provide home therapies at this location, however Fresenius has home therapy programs in Edgecombe County at the Rocky Mount Kidney Center and FMC South Rocky Mount. The applicant states that the home patient penetration rate does not currently warrant developing additional home treatment capacity. Therefore, by utilizing existing home therapies programs, Fresenius is able to reduce development costs for the proposed facility. Therefore, the applicant rejected this alternative as more costly.

Thus, after considering the above alternatives, the applicant concludes that its proposal to develop a new 10-station dialysis center in Rocky Mount by relocating stations from BMA East Rocky Mount is the most effective alternative.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application 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 need. Consequently, 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 Boice-Willis shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
 - 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 Boice-Willis by relocating 10 dialysis stations from BMA East Rocky Mount.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Boice-Willis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 10 dialysis stations at BMA East Rocky Mount for a total of no more than 20 dialysis stations at BMA East Rocky Mount upon completion of this project.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Boice-Willis 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 develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. Both locations are in Edgecombe County.

Capital and Working Capital Costs

In Section F.1, page 40, the applicant projects \$1,679,472 in capital costs, including \$1,090,893 for the construction contract, \$225,000 for water treatment equipment, \$205,945 for other equipment and furniture (dialysis machines are leased) and \$157,634 in other costs. In Section F.10, page 43, the applicant states that there are \$122,268 in start-up expenses and \$931,878 in initial operating expenses for the new facility; for total estimated working capital of \$1,054,146.

Availability of Funds

In Section F.2, page 41, the applicant states it will finance the capital costs and working capital costs with accumulated reserves. Exhibit F-1 contains a letter dated July 17, 2017 from the Senior Vice President and Treasurer, authorizing and committing \$1,679,472 in capital costs for the project and any additional funds necessary for start-up costs.

Exhibit F-2 contains the Consolidated Financial Statements for Fresenius Medical Care Holdings, Inc. for the year ending December 31, 2016 and December 31, 2015. These statements indicate that as of December 31, 2016, it had \$357,899,000 in cash and cash equivalents, \$20,135,661 in total assets and \$10,533,279 in net assets (total assets of \$20,135,661 less total liabilities of \$9,602,364). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

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

FKC BOICE-WILLIS		
	Operating Year 1	Operating Year 2
Total Treatments*	4742	4860
Total Gross Revenues (Charges)	\$18,910,664	\$18,910,664
Total Net Revenue**	\$1,462,122	\$1,462,122
Total Operating Expenses (Costs)	\$1,397,817	\$1,419,311
Net Income	\$64,305	\$42,811

*Adjusted for missed treatments. **In Form B, the commercial contractual adjustment is off by \$25,000 (\$1,371,054 x 0.73467418 = \$1,007,278, not \$1,032,287)

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 the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. 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 develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. The proposed and existing facility are located in Edgecombe 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, FKC Boice-Willis will be certified for 10 dialysis stations and BMA East Rocky Mount will be certified for 20 dialysis stations; following completion of this project. The following projects were certified on October 2, 2017: Project ID# L-11011-15 (Relocate 6 stations from BMA East Rocky Mount to develop a new 10-station dialysis facility in Tarboro) and Project ID# L-11093-15 (Add 6 dialysis stations to BMA East Rocky Mount for a total of 30 dialysis stations).

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The proposed new facility, FKC Boice-Willis, will be located in Edgecombe County; thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR (as of December 31, 2016), there are two operational dialysis facilities in Edgecombe County and one approved dialysis facility, as follows:

EDGECOMBE COUNTY DIALYSIS FACILITIES			
Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA East Rocky Mount	30	104.17%	4.1667
Dialysis Care of Edgecombe County	35	70.71%	2.8286
FMC Tarboro*	0	00.00%	0.0000
FMS ENA Home, LLC**	NA	NA	NA

Source: June 2017 SDR, Table A. *Approved 10-station dialysis facility. **Freestanding Peritoneal Dialysis Facility.

Fresenius related entities own and operate the two existing and one approved dialysis facilities in Edgecombe County. BMA East Rocky Mount, from which 10 stations are being relocated to FKC Boice-Willis has operated above 100%; while Dialysis Care of Edgecombe County is operating slightly above 70% utilization and 2.83 patients per station.

According to Table D in the July 2017 SDR, there is a surplus of eight dialysis stations in Edgecombe County. The methodology as discussed on page 376 of the 2017 SMFP requires a deficit of 10 stations to identify a county need for an additional facility. However, the applicant is not proposing to increase the number of dialysis stations in Edgecombe County, rather it is proposing to relocate 10 existing Edgecombe County stations to develop a new facility, pursuant to Policy ESRD-2, which 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 the applicant states that it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 21, the applicant demonstrates that FKC Boice-Willis will serve a total of 32 in-center patients on 10 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80.% ($32 / 10 = 3.2$; $3.2 / 4 = 0.8$). The applicant provides documentation in Exhibit C-1 from 32 in-center patients dialyzing at Fresenius-affiliated Edgecombe County facilities stating their willingness to consider transferring to FKC Boice-Willis 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 Edgecombe County Fresenius-affiliated dialysis stations to develop a new Fresenius dialysis facility in Edgecombe County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the need of the population presently served at BMA East Rocky Mount, 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 Edgecombe 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, pages 51-54, the applicant provides the projected staffing for FKC Boice-Willis in OY2 by full-time equivalent (FTE) positions, as shown below in the table:

FKC BOICE-WILLIS Projected FTEs OY2 (2020)	
Position	Total FTE Positions
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

Notes: The Medical Director is an independent contractor, not an employee.

In Exhibit I.5, the applicant provides a letter from Nakshatra Saxena, MD, dated June 15, 2017, indicating support for the project and a willingness to serve as Medical Director of the facility. In Section H.3, page 57, the applicant states it does not anticipate any difficulties in filling staff positions as it will use aggressive recruiting and advertising efforts, coupled with a range of benefits and competitive salaries to attract qualified staff. 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 55, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation, and X-ray will be referred to UNC Nash Healthcare. Exhibit I-3 includes a letter of support from UNC Nash Healthcare President and CEO confirming its willingness to provide those services to FKC Boice-Willis patients. Exhibit I-4 contains a letter from UNC Hospitals agreeing to enter in to an agreement with FKC Boice-Willis to provide its patients with transplant services. Exhibit I-1 contains an agreement for home training services at FMC South Rocky Mount. Exhibit I-2 contains an agreement for lab services between FMC and Spectra. The applicant discusses coordination

with the existing health care system in Sections I.3 and I.4, pages 56-58, stating that Fresenius has relationships with the medical community in the area, including area physicians and hospitals. 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 healthcare 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 62, the applicant states that the proposed facility will have 2,874 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts a facility with nine main floor dialysis stations and one isolation dialysis station, for a total of 10 stations. On page 40, the applicant provides the proposed costs, including \$1,090,893 for construction, \$588,579 in

miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,679,472. In Section K.1, pages 60-62, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.
- HVAC system operating efficiency “will equal current industry standards for high seasonal efficiency.” In addition, the system will be controlled via 7 day/24 hour set back time clock and maintained and serviced quarterly.
- Energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches and external insulation wrap for hot water heaters will be used for energy and water conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 40-48, 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 Boice-Willis is not an existing facility, thus, it has no historical payor mix. However, in Section L.7, page 71, the applicant provides the CY2016 payor mix for BMA East Rocky Mount. This is the facility from which the 10 dialysis stations will

come to develop the proposed facility. The BMA East Rocky Mount historical payor mix is illustrated as follows:

BMA EAST ROCKY MOUNT	
Payor Source	Percentage of In-Center Patients
Private Pay/Indigent/ Charity	0.54%
Medicare	71.34%
Medicaid	7.43%
Commercial Insurance	7.25%
Medicare/Commercial	11.36%
Miscellaneous, including VA	2.08%
Total	100.00%

Total 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
Edgecombe	18%	54%	64%	28%	13%	12%
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 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), pages 69-70, 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 70, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

The application is conforming to this criterion.

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

C

In Section L.1(b), page 68, the applicant provides the projected payor mix for the proposed services at FKC Boice-Willis as shown below in the table:

FKC BOICE-WILLIS Projected Payor Mix PY2 (1/1/2020 – 12/31/2020)	
Payor Source	Percentage of In-Center Patients
Private Pay/Indigent/ Charity	0.54%
Medicare	71.34%
Medicaid	7.43%
Commercial Insurance	7.25%
Medicare/Commercial	11.36%
Miscellaneous, including VA	2.08%
Total	100.00%

As shown in the table above, the applicant projects that over 90% of in-center patients will have some or all of their services paid for by Medicare (82.7%) and Medicaid (7.43%). In Section L.1(b), page 68, the applicant states that the projected payor mix is calculated based upon the payor mix of BMA facilities in Edgecombe County. The projected payor mix is comparable to the 2016 payor mix for BMA East Rocky Mount as shown in Criterion (13)(a). The applicant adequately demonstrates that medically underserved populations would have 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 70, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FKC Boice-Willis will have 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.”

The applicant adequately demonstrates that FKC Boice-Willis will provide a range of means by which a person can access its 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 72, the applicant states that students from health-related education programs will be welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the Dean of Health and Related Sciences at Nash Community College, dated July 12, 2017, inviting the school to include FKC Boice-Willis in its clinical rotations for its student nurses. 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 develop a new 10-station dialysis facility in Rocky Mount by relocating 10 stations from BMA East Rocky Mount. The proposed and existing facility are located in Edgecombe 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, FKC Boice-Willis will be certified for 10 dialysis stations and BMA East Rocky Mount will be certified for 20 dialysis stations following completion of this project and completion of Project ID# L-11011-15 (Relocate 6 stations from BMA East Rocky Mount to develop a new 10-station dialysis facility in Tarboro), and Project ID# L-11093-15 (Add 6 dialysis stations to BMA East Rocky Mount for a total of 30 dialysis stations). Project ID# L-11011-15 and Project ID# L-11093-15 were certified on October 2, 2017.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The proposed new facility, FKC Boice-Willis, will be located in Edgecombe County; thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR (as of December 31, 2016), there are two operational dialysis facilities in Edgecombe County and one approved dialysis facility, as follows:

EDGECOMBE COUNTY DIALYSIS FACILITIES			
Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA East Rocky Mount	30	104.17%	4.1667
Dialysis Care of Edgecombe County	35	70.71%	2.8286
FMC Tarboro*	0	00.00%	0.0000
FMS ENA Home, LLC**	NA	NA	NA

Source: June 2017 SDR, Table A. *Approved 10-station dialysis facility. **Freestanding Peritoneal Dialysis Facility.

Fresenius related entities own and operate the two existing and one approved in-center dialysis facilities in Edgecombe County. BMA East Rocky Mount, from which 10 stations are being relocated to FKC Boice-Willis has operated above 100%; while Dialysis Care of Edgecombe County is operating slightly above 70% utilization and 2.83 patients per station. BMA also owns a free-standing peritoneal dialysis facility in the county.

According to Table D in the July 2017 SDR, there is a surplus of eight dialysis stations in Edgecombe County. The methodology as discussed on page 376 of the 2017 SMFP requires a deficit of 10 stations to identify a county need for an additional facility. However, the applicant is not proposing to increase the number of dialysis stations in Edgecombe County, rather it is proposing to relocate 10 existing Edgecombe County stations to develop a new facility, pursuant to Policy ESRD-2. The applicant states that the proposed facility is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather the applicant states that it is proposing to create a new facility to better serve existing patients using existing stations.

In Section N.1, page 73, 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 does not expect this proposal to have effect on the competitive climate in Edgecombe County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC Boice-Willis facility begins with patients currently served by BMA at other BMA locations, and a growth of that patient population consistent with the Edgecombe County five year average annual change rate of 0.5% 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 90% of the patients at FKC Boice-Willis will have their services covered by Medicare and Medicaid. Moreover, the applicant states, on page 73, that its proposal will,

“... enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In 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. In Exhibit A-4, the applicant lists 112 existing kidney disease treatment centers in North Carolina which its parent company owns and operates or is affiliated. In Section O, pages 77-78, the applicant provides information on quality of care provided at its facilities, including citations received during the 18 months immediately preceding the submittal of the application, and their resolution. BMA East Rocky Mount (from which 10 stations will be relocated to FKC Boice-Willis) and RAI West College-Warsaw had immediate jeopardy citations. The applicant summarizes the deficiencies cited, the resolutions, and provides documentation in Exhibits O-3 and O-4, including correspondence from Acute and Home Care Licensure and Certification and the Centers for Medicare and Medicaid Services. On page 78 and in clarifying information received from the applicant on October 11, 2017, the applicant states that both facilities were back in full compliance with all CMS guidelines. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at BMA East Rocky Mount, RAI West College-Warsaw and all the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section C.1, pages 18-21, the applicant documents the need for the project and demonstrates that it will serve a total of 32 in-center patients on 10 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80% (32 patients / 10 stations = 3.2; $3.2 / 4 = 0.80$). 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 applicant is seeking to develop a new 10-station dialysis facility.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 18-21. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.