

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 16, 2021

Findings Date: December 16, 2021

Project Analyst: Kim Meymandi

Co-Signer: Gloria C. Hale

Project ID #: J-12128-21

Facility: Fresenius Kidney Care East Johnston

FID #: 170323

County: Johnston

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

Project: Relocate no more than seven dialysis stations from BMA Johnston Dialysis Center for a total of no more than 17 dialysis stations upon project completion

REVIEW CRITERIA

G.S. 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.

NA

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “BMA”), proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to Fresenius Kidney Care East Johnston (FKC East Johnston) for a total of no more than 17 stations upon project completion.

Need Determination

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 137, the county need methodology shows there is no county need determination for additional dialysis stations in Johnston County. The applicant is proposing to relocate existing dialysis stations; therefore, the facility need methodology does

not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2021 SMFP apply to this proposal.

Policies

The applicant proposes to relocate dialysis stations within the same county. Therefore, there are no policies applicable to this proposal.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that Criterion (1) is not applicable to this review.

- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

FKC East Johnston does not currently serve home hemodialysis or peritoneal dialysis patients. The following table, summarized from data on page 15 of the application, shows the projected number of stations at FKC East Johnston upon project completion.

FKC East Johnston		
Stations	Description	Project ID #
10	Total existing certified stations in the SMFP in effect on the day the review will begin	
+7	Stations to be added as part of this project	J-12128-21
17	Total stations upon completion of proposed project and previously approved projects	

The following table shows the current and projected number of dialysis stations at BMA Johnston Dialysis Center upon completion of this project.

BMA Johnston Dialysis Center		
Stations	Description	Project ID #
33	Total existing certified stations as of December 31, 2019 in the 2021 SMFP in effect on the day the review will begin	
-7	Stations to be deleted as part of this project	J-12128-21
26	Total stations upon completion of proposed project and previously approved projects	

Source: 2021 SMFP

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Both FKC East Johnston and BMA Johnston Dialysis Center are located in Johnston County. Thus, the service area for this application is Johnston County. Facilities may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 23 and 24, the applicant provides the historical and projected in-center (IC) patient origin for FKC East Johnston during the last full operating year, January 1, 2020 – December 31, 2020 (CY 2020), and the projected patient origin for the second full operating year following project completion, January 1, 2024 – December 31, 2024 (CY 2024), as summarized in the following table:

FKC East Johnston Historical and Projected Patient Origin				
County	Historical 01/01/2020-12/31/2020 (CY 2020)		Second Full FY of Operation following Project Completion 01/01/2024-12/31/2024 (CY 2024)	
	Patients	% of Total	Patients	% of Total
Johnston	14	100.0%	52.3	100.0%
Total	14	100.0%	52.3	100.0%

Source: Section C, pages 23-24

In Section C.3, pages 24-26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

- Due to the impact of COVID-19, the applicant begins projections of the future patient population to be served with FKC East Johnston’s facility census as of August 1, 2021.
- The applicant projects that the relocated stations will be certified as of December 31, 2022. Therefore, Operating Year 1 (OY1) is Calendar Year (CY) 2023, January 1-December 31, 2023 and Operating Year 2 (OY2) is Calendar Year (CY) 2024, January 1-December 31, 2024.
- The applicant projects growth of the Johnston County patient census using the Five-Year Average Annual Change Rate (AACR) of 8.8%, as published in the 2021 SMFP.

- The applicant assumes the effects of COVID-19 will ease as more people are immunized, allowing full utilization of the FKC East Johnston facility and the projected transfer of 16 IC patients from Johnston Dialysis Center.

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin at FKC East Johnston based on its existing population.
- The patient origin of the patients expressing a willingness to transfer from Johnston Dialysis Center to FKC East Johnston is Johnston County and their letters state that FKC East Johnston is a more convenient location.
- The applicant increases the number of projected future patients based on the Five-Year Average Annual Change Rate (AACR) of Johnston County and the transfer of 16 IC patients from Johnston Dialysis Center, all of whom reside in Johnston County.

Analysis of Need

In Section C.4, pages 27-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- BMA operates five dialysis facilities in Johnston County and the overall census in these facilities has increased by 12 patients in the first seven months of 2021, which is a growth rate of 3.76% over seven months and an annualized growth rate of 6.45%.
- Patients have signed letters of support indicating their desire to transfer to FKC East Johnston for dialysis treatment upon project completion.
- The patient population requires frequent treatments. Patients typically receive three treatments per week and either dialyze on a Monday/Wednesday/Friday morning or afternoon or Tuesday/Thursday/Saturday morning or afternoon. If patients do not receive sufficient treatments, it will lead to the patients' demise.
- The applicant projects a utilization rate of 70.72%, or 2.83 patients per station as of the end of the first operating year of the project, which exceeds the minimum required by the performance standard.

The information is reasonable and adequately supported based on the following:

- The applicant begins the projections with the existing FKC East Johnston patient census as of August 1, 2021.
- The applicant projects 16 patients will transfer their care from BMA Johnston Dialysis Center and provides letters of support from 16 patients expressing their willingness to consider a transfer to FKC East Johnston. See Exhibit C-3.
- The applicant uses the 2021 SMFP Johnston County Five-Year AACR to project a utilization rate of 70.75%, or 2.83 patients per station as of the end of the first operating year.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Projected Utilization

In Section C.3, pages 25-26 and Section Q, page 82, the applicant provides projected utilization, as illustrated in the following table.

FKC East Johnston	
The applicant begins with the Johnston County patient population as of August 1, 2021.	25
The applicant projects the Johnston County patient forward five months to December 31, 2021 using the Johnston County Five-Year AACR.	$25 \times [(0.088 / 12) \times 5] + 25 = 25.9$
The applicant projects the Johnston County patient population forward one year to December 31, 2022, using the Johnston County Five-Year AACR.	$25.9 \times 1.088 = 28.2$
The applicant adds 16 patients from Johnston Dialysis Center projected to transfer their care. This is the ending census for December 31, 2022.	$28.2 + 16 = 44.2$
The applicant projects the Johnston County population forward one year to December 31, 2023, using the Johnston County Five-Year AACR. This is the project ending census for Operating Year 1 .	$44.2 \times 1.088 = 48.1$
The applicant projects the Johnston County population forward one year to December 31, 2024, using the Johnston County Five-Year AACR. This is the project ending census for Operating Year 2 .	$48.1 \times 1.088 = 52.3$

At the end of OY1 (CY2023) FKC East Johnston is projected to serve 48.1 in-center patients on 17 stations; and at the end of OY2 (CY2024) the facility is projected to serve 52.3 in-center patients on 17 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 2.83 patients per station per week, or 70.75% utilization [$48.1 \text{ patients} / 17 \text{ stations} = 2.83 / 4 = 0.7075$].
- OY2: 3.08 patients per station per week, or 76.91% utilization [$52.3 \text{ patients} / 17 \text{ stations} = 3.08/4 = 0.7691$].

The projected utilization of 2.83 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant states that when FKC East Johnston was certified for operation in September 2020 it was identified as a facility dedicated to providing dialysis treatment for COVID-19 patients. As the COVID-19 pandemic has become more manageable, the

FKC East Johnston patient population has increased from 14 patients at opening in September 2020 to 25 patients as of August 1, 2021.

- The applicant assumes that with the COVID-19 pandemic becoming more manageable, the patient population at FKC East Johnston will continue to increase.
- The applicant projects that 16 in-center patients from Johnston Dialysis Center will transfer their care to FKC East Johnston and provides letters of support in Exhibit C-3.
- The applicant uses the Johnston County Five-Year AACR of 8.8%, as published in the 2021 SMFP to project patient growth.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant begins projections with the existing FKC East Johnston patient census as of August 1, 2021.
- The patient origin of all patients at FKC East Johnston is Johnston County.
- The applicant projects the patient census at FKC East Johnston will increase by the Johnston County Five Year AACR of 8.8 percent, as reported in the 2021 SMFP.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section C.6, page 30 the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

...

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.”

On page 30 of the application and in supplemental information requested by the Agency, the applicant provides the estimated percentage for each medically underserved group during the second operating year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	82.0%
Racial and ethnic minorities	52.0%
Women	40.0%
Persons with Disabilities	32.0%
The elderly	72.0%
Medicare beneficiaries	76.0%
Medicaid recipients	16.0%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- Fresenius Medical Care related facilities have a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.
- The applicant's estimated percentage for each underserved group is based upon FKC East Johnston's recent experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

The following table shows the projected number of stations at BMA Johnston Dialysis Center upon project completion.

BMA Johnston Dialysis Center		
County where the facility is located		Johnston
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	33
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	-7
3	Total number of dialysis station upon completion of this project and all other projects involving this facility	26

Source: Section D, page 35

In Section D, pages 35-36, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 35, the applicant states:

“BMA projects to relocate seven dialysis stations from BMA Johnston Dialysis Center. As this project is completed BMA also projects 16 in-center dialysis patients to transfer their care to the FKC East Johnston facility. BMA does not expect this relocation of stations will have any adverse effect on the patient population remaining at BMA Johnston Dialysis Center.”

On page 36, the applicant provides a table which shows projected BMA Johnston Dialysis Center utilization assuming the relocation of seven stations to the FKC East Johnston facility, which is summarized below:

BMA Johnston Dialysis Center	
The applicant begins with the Johnston County patient population at Johnston Dialysis Center as of December 31, 2020.	116
The applicant projects the Johnston County patient population forward to December 31, 2021, using the Johnston County Five-Year AACR.	$116 \times 1.088 = 126.2$
The applicant projects the Johnston County patient population forward to December 31, 2022, using the Johnston County Five-Year AACR.	$126.2 \times 1.088 = 137.3$
The applicant adds the Wilson County patients.	$137.3 + 2 = 139.3$
The applicant subtracts the 16 Johnston County patients projected to transfer their care. This is the projected census for the date the stations have been relocated.	$139.3 - 16 = 123.3$

The applicant projects to serve 123.3 in-center patients on 26 stations as of the date the stations are projected to be relocated. Thus, the applicant projects that Johnston Dialysis Center will have a utilization rate of 118.56% or 4.74 patients per station per week ($123.3 \text{ patients} / 26 \text{ stations} = 4.74 / 4 = 1.1856$ or 118.56%).

On page 36, the applicant states:

“BMA recognizes that utilization rates exceeding 100% necessarily mean a third, or evening dialysis shift. If it were necessary, BMA would create a third dialysis shift for Johnston dialysis center. However, it will not become necessary.”

The 2021 SMFP, Table 9D shows that Johnston Dialysis Center qualifies to apply for up to 20 additional stations in 2021. In 2021 the facility submitted one application (Project ID# J-12163-21) to add seven dialysis stations at Johnston Dialysis Center and the review begins

December 1, 2021. Assuming approval of the application to add seven dialysis stations back to Johnston Dialysis Center, the applicant states the utilization rate for December 31, 2022 is calculated to be 3.74 patients per station per week ($123.3 \text{ patients} / 33 \text{ stations} = 3.74 / 4 = .9341$ or 93.4%).

In Section D, pages 35-36, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects that the relocated stations will be certified as of December 31, 2022.
- The applicant begins projections of the future patient population served by the Johnston Dialysis Center facility with the Johnston County patient population as of December 31, 2020.
- The applicant projects growth of the Johnston County patient census using the Johnston County AACR of 8.8%, as published in Table 9B of the 2021 SMFP.
- The applicant projects that the facility will continue to serve the two patients residing in Wilson County which is contiguous to Johnston County. The applicant assumes these patients will continue dialysis with the facility and does not project any growth for this segment of the patient population. The applicant states that these patients will be added to projections of future patient populations at the appropriate time.
- The applicant assumes the application they have submitted to add seven stations back to Johnston Dialysis Center will be approved and will provide a utilization rate of 3.74 patients per station per week as of December 31, 2022.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant begins projections of the future patient population served by the Johnston Dialysis Center facility as of December 31, 2020.
- The applicant projects growth using the 2021 SMFP County Five-Year AACR for Johnston County.
- The applicant projects that the facility will continue to serve the two patients residing in Wilson County and does not project any growth for this segment of the patient population.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section D, page 37, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.”

The applicant provides the estimated percentage for each medically underserved group during the second operating year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	56.1%
Racial and ethnic minorities	57.0%
Women	47.4%
Persons with Disabilities	44.7%
The elderly	61.4%
Medicare beneficiaries	84.2%
Medicaid recipients	56.1%

Source: Table on page 37 of the application.

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project for the following reasons:

- Fresenius Medical Care related facilities have a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.
- The applicant's estimated percentage for each underserved group is based upon Johnston Dialysis Center's recent experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (4) Where 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

The applicant proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

In Section E.2, page 39, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because this alternative fails to recognize the growing patient population and there are a significant number of patients supporting the relocation. Therefore, the applicant determined this is not the most effective alternative.
- *Relocate more than seven stations* - The applicant states that relocating more than seven stations would require a physical plant expansion and thus significant capital expenditure to develop additional space. Therefore, the applicant determined this is not the least costly nor most effective alternative.
- *Relocate fewer than seven stations* - The applicant states that relocating fewer than seven stations is less effective because there is high demand for dialysis at FKC East Johnston and could result in delays of treatment due to a lack of capacity. Therefore, the applicant determined this is not the most effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.
- The applicant can address high utilization rates and avoid possible patient admission interruptions while avoiding the capital expense of a physical plant expansion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall relocate no more than seven in-center stations from BMA Johnston Dialysis Center to Fresenius Kidney Care East Johnston for a total of no more than 17 in-center stations upon project completion.**
 - 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify seven in-center stations at BMA Johnston Dialysis Center for a total of no more than 26 in-center stations at BMA Johnston Dialysis Center.**
 - 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every Fourth month. The first progress report shall be due on June 1, 2022. The second progress report shall be due on October 1, 2022 and so forth.**
 - 5. The certificate holder 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 relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$26,250
Total	\$26,250

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides the specific costs related to each station.
- The applicant has knowledge and experience in calculating costs related to the relocation of ESRD stations.

In Section F, page 42, the applicant states there will be no working capital cost because FKC East Johnston is an operational facility.

Availability of Funds

In Section F, page 40, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Fresenius Medical Care Holdings, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$26,250	\$26,250
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$26,250	\$26,250

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F-2 contains a letter dated September 15, 2021, from Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project.
- The applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects

that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

FKC East Johnston Projected Revenue and Operating Expenses

	1ST FULL FISCAL YEAR CY 2023	2ND FULL FISCAL YEAR CY 2024
Total Treatments	6,829	7,430
Total Gross Revenue (charges)	\$42,961,355	\$46,741,954
Total Net Revenue	\$1,965,497	\$2,138,461
Average Net Revenue per Treatment	\$288	\$288
Total Operating Expenses (costs)	\$1,954,726	\$2,040,385
Average Operating Expense per Treatment	\$286	\$275
Net Income / Profit	\$10,771	\$98,075

*Source: application Form F.2, Section Q

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Contractual adjustments are calculated by payor class and modality for each year.
- Salary expenses are projected to increase at a rate of 2.0% annually.
- The employer pays 36% of the staff expense for benefits and payroll taxes.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

- (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 no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Both FKC East Johnston and BMA Johnston Dialysis Center are located in Johnston County. Thus, the service area for these facilities is Johnston County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the proposed 2022 SMFP and the information provided by the applicant in Section G page 47, there are six existing or approved dialysis facilities in Johnston County, five of which are owned and operated by BMA. Information on these dialysis facilities is summarized below:

Johnston County Dialysis Facilities

Dialysis Facility	Owner	Certified Stations as of 12/31/2020	# of IC Patients as of 12/31/2020	Percent Utilization as of 12/31/2020	Patients Per Station Per Week as of 12/31/2020	Number of Additional Approved Stations
Johnston Dialysis Center	BMA	33	118	89.39%	3.5758	0
FMC Stallings Station*	BMA	24	89	92.71%	3.7083	0
FMC Stallings Station**	BMA	0	0	0	0	20
FMC Four Oaks	BMA	20	60	75.00%	3.000	0
FKC East Johnston	BMA	10	14	35.00%	1.400	0
FKC West Johnston^	BMA	0	0	0.00%	0.000	12
Clayton Dialysis^	Total Renal Care	0	0	0.00%	0.000	10
Total		89	206	57.87%		

Source: Proposed 2022 SMFP, Table 9A, page 128 & application Section G page 47

*Current Location

**After relocation

^Decisions currently under appeal at the NC Court of Appeals

In Section G, page 48, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Johnston County. The applicant states:

“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations within Johnston County. These stations have been previously approved and do not duplicate services.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Johnston County.
- The applicant adequately demonstrates that the proposed relocation of the seven stations is needed in addition to the existing or approved dialysis stations in Johnston County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

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

C

The applicant proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for FKC East Johnston, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
		OY1 (1/1/2023 to 12/31/2023)	OY2 (1/1/2024 to 12/31/2024)
Administrator	1.00	1.00	1.00
Registered Nurses (RN)	1.00	2.00	2.00
Licensed Practical Nurses (LPN)	1.00	1.00	1.00
Technicians (PCT)	2.00	5.00	5.00
Dietician	0.30	0.50	0.50
Social Worker	0.30	0.50	0.50
Maintenance	0.25	0.25	0.25
Admin/Business Office	0.50	0.67	0.67
Director of Operations	0.15	0.15	0.15
Chief Technician	0.10	0.10	0.10
FMC In-Service	0.10	0.10	0.10
TOTAL	6.70	11.27	11.27

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 49-50, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at FKC East Johnston.
- The increased costs are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

Ancillary and Support Services

In Section I, pages 51-56, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is and will continue to be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for dialysis patients located in or near Johnston County and how these will be made available.
- The applicant describes how the necessary ancillary and support services will be coordinated with the existing healthcare system.

Coordination

In Section I, page 56, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients.
- The applicant has established relationships with community health care and ancillary service providers where dialysis patients can receive appropriate referrals for necessary services related to their condition.
- The applicant provides a letter from the Medical Director in Exhibit H-4., committing to the continuation of the established relationships.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 63, the applicant states that FKC East Johnston was certified on 9/2/2020 and provided 2,104 dialysis treatments before the year end. The historical payor mixes for FKC East Johnston and Johnston Dialysis Center for the period 9/2/2020 through 12/31/2020 are provided by the applicant and shown in the table below.

9/2/2020 to 12/31/2020

Payor Source	FKC East Johnston		Johnston Dialysis Center	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.0	0.00%	7.1	6.03%
Insurance*	0.2	1.68%	9.1	7.73%
Medicare*	12.5	89.50%	81.4	68.95%
Medicaid*	1.2	8.82%	15.7	13.27%
Other (including VA)	0.0	0.00%	4.7	4.02%
Total	14.00	100.00%	118.00	100.00%

Source: Tables on page 64 of the application.

*Including any managed care plans.

In Section L, pages 65-66, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY		Percentage of the Population in the Service Area *
	FKC East Johnston	BMA Johnston Dialysis Center	
Female	40.0%	47.4%	51.0%
Male	60.0%	52.6%	49.0%
Unknown	0.0%	0.0%	0.0%
64 and Younger	28.0%	38.6%	86.4%
65 and Older	72.0%	61.4%	13.6%
American Indian	0.0%	0.0%	0.9%
Asian	0.0%	0.0%	0.9%
Black or African-American	44.0%	57.0%	17.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.1%
White or Caucasian	40.0%	43.0%	66.8%
Other Race	16.0%	0.0%	14.3%
Declined / Unavailable	0.0%	0.0%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L,

page 66, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 66, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.3, page 67, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**FKC East Johnston
Projected Payor Mix CY2024**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	3.4	6.0%
Insurance*	4.4	7.7%
Medicare*	39.2	68.9%
Medicaid*	7.6	13.3%
Miscellaneous (incl. VA)	2.3	4.0%
Total	56.9	100.0%

Totals may not sum due to rounding
*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 6.0% of in-center dialysis services will be provided to self-pay patients, 68.9% to Medicare patients, and 13.3% to Medicaid patients.

On page 67, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of BMA Johnston Dialysis Center.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.5, page 69, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 70, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant offers the facility as a clinical learning site for students from Johnston Community College.
- The applicant provides a copy of the letter sent to Johnston Community College offering training opportunities in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to relocate no more than seven dialysis stations from BMA Johnston Dialysis Center to FKC East Johnston for a total of no more than 17 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* Both FKC East Johnston and BMA Johnston Dialysis Center are located in Johnston County. Thus, the service area for this facility is Johnston County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the proposed 2022 SMFP and the information provided by the applicant in Section G page 47, there are six existing or approved dialysis facilities in Johnston County, five of which are owned and operated by BMA. Information on these dialysis facilities is summarized below:

**Johnston County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2020**

Dialysis Facility	Owner	Certified Stations as of 12/31/2020	# of IC Patients as of 12/31/2020	Percent Utilization as of 12/31/2020	Patients Per Station Per Week as of 12/31/2020	Number of Additional Approved Stations
Johnston Dialysis Center	BMA	33	118	89.39%	3.5758	0
FMC Stallings Station*	BMA	24	89	92.71%	3.7083	0
FMC Stallings Station**	BMA	0	0	0	0	20
FMC Four Oaks	BMA	20	60	75.00%	3.000	0
FKC East Johnston	BMA	10	14	35.00%	1.400	0
FKC West Johnston^	BMA	0	0	0.00%	0.000	12
Clayton Dialysis^	Total Renal Care	0	0	0.00%	0.000	10
Total		89	206	57.87%		

Source: Proposed 2022 SMFP, Table 9A, page 128 & application Section G page 47

*Current Location

**After relocation

^Decisions currently under appeal at the NC Court of Appeals

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 71, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider.

...

With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at FKC East Johnston.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 72, the applicant states:

“Approval of this application will allow the facility to serve patients of the area in a convenient setting. As a result, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 72, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities...Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 72, the applicant states:

“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina.

....

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

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, pages 99-103, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.2, page 77, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 126 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.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

- (b) *An applicant proposing to increase the number of dialysis stations in:*
- (1) *an existing dialysis facility; or*
 - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*
- shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section C, pages 25-26 and Section Q, page 82, the applicant projects that FKC East Johnston will serve 48.1 in-center patients on 17 stations, or a utilization rate of 2.83 patients per station per week or 70.72% ($48.1 / 17 = 2.8294 = 0.7072$ or 70.72%), as of the end of the first operating year (CY2023) following project completion. This exceeds the minimum performance standard requirement of 2.8 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.3, pages 24-26, and Section Q, pages 81-82, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.