

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2021

Findings Date: December 17, 2021

Project Analyst: Mike McKillip

Co-Signer: Michaela Mitchell

Project ID #: J-12133-21

Facility: Fresenius Kidney Care Knightdale

FID #: 210745

County: Wake

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

Project: Develop a new 16-station dialysis facility by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA), proposes to develop a new 16-station dialysis facility, Fresenius Kidney Care Knightdale [**FKC Knightdale**], by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

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 9B, page 136, the county need methodology shows there is no county need determination for additional dialysis stations in Wake County. The applicant is proposing to develop a new facility; 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

There is one policy in the 2021 SMFP that is applicable to this review, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 29 of the 2021 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.6, pages 22-23, the applicant provides a written commitment to providing energy efficient

lighting, building materials, HVAC equipment and water conservation equipment in its construction design. Therefore, the application is consistent with Policy GEN-4.

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 the application is conforming to this criterion based on the following:

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

- (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 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

The following table, summarized from data on page 16 of the application, shows the projected number of stations at FKC Knightdale upon project completion.

FKC Knightdale		
Stations	Description	Project ID #
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
+16	Stations to be added as part of this project (develop new 16-station facility)	J-12133-21
16	Total stations upon completion of proposed project and previously approved projects	

The following tables, summarized from information on page 38 of the application, shows the current and projected number of dialysis stations at BMA of Raleigh Dialysis and Zebulon Kidney Center upon completion of this project.

BMA of Raleigh Dialysis		
Stations	Description	Project ID #
50	Total existing certified stations in the SMFP in effect on the day the review will begin	
-12	Stations to be deleted as part of this project	J-12133-21
38	Total stations upon completion of proposed project and previously approved projects	

Zebulon Kidney Center		
Stations	Description	Project ID #
30	Total existing certified stations in the SMFP in effect on the day the review will begin	
-4	Stations to be deleted as part of this project	J-12133-21
26	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2021 SMFP defines the service area for the county need methodology 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.” The proposed facility will be located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

This proposal is to develop FKC Knightdale, a new 16-station dialysis facility in Wake County; therefore, there is no historical patient origin data. In Section C.2, page 25, the applicant provides the historical (CY2020) patient origin for BMA of Raleigh Dialysis and Zebulon Kidney Center, as summarized in the following tables.

BMA of Raleigh Dialysis

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wake	162	95.3%	0.0	0.0%	0.0	0.0%
Durham	1	0.6%	0.0	0.0%	0.0	0.0%
Franklin	1	0.6%	0.0	0.0%	0.0	0.0%
Johnston	3	1.8%	0.0	0.0%	0.0	0.0%
Nash	2	1.2%	0.0	0.0%	0.0	0.0%
Wayne	1	0.6%	0.0	0.0%	0.0	0.0%
Total	170	100.0%	0.0	0.0%	0.0	0.0%

Zebulon Kidney Center

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wake	50	58.1%	0.0	0.0%	0.0	0.0%
Franklin	5	5.8%	0.0	0.0%	0.0	0.0%
Johnston	22	25.6%	0.0	0.0%	0.0	0.0%
Nash	9	10.5%	0.0	0.0%	0.0	0.0%
Total	86	100.0%	0.0	0.0%	0.0	0.0%

In Section C.3, page 26, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for FKC Knightdale for the second full operating year following project completion (CY2025), as summarized in the following table:

FKC Knightdale

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wake	48	100.0%	0.0	0.0%	0	0.0%
Total	48	100.0%	0.0	0.0%	0	0.0%

In Section C.3, page 26, the applicant provides the assumptions and methodology used to project FKC Knightdale’s patient origin. The applicant states the patient origin projections are based on the home addresses of the applicant’s in-center patients who have expressed an intention to transfer their care to the proposed facility in Knightdale. Copies of the letters are included in Exhibit C.3 of the application. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 27-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- The applicant identified the existing Wake County BMA facilities and the residence locations of in-center patients dialyzing at BMA facilities in Wake County that could be served more conveniently at the proposed FKC Knightdale facility (pages 28-29).
- The applicant obtained letters from 45 existing BMA patients expressing their willingness transfer their care to the proposed FKC Knightdale facility (page 26). See Exhibit C-3.

The information is reasonable and adequately supported because it is based on letters from 45 existing in-center BMA patients currently served at other Wake County facilities who have expressed an interest in transferring their care to the proposed FKC Knightdale facility, as documented in Exhibit C-3 of the application.

Projected Utilization

In-Center Projected Utilization

In Section C.3, pages 26-27, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- The applicant states that 45 existing BMA patients have signed letters expressing an interest in transferring their care to the proposed FKC Knightdale facility. The applicant’s projected beginning census on December 31, 2023 is composed of 45 patients from BMA facilities that are residents of Wake County who have signed those letter that are projected to transfer their care to the new facility upon certification.
- The applicant uses the 2021 SMFP Wake County Five-Year Annual Average Change Rate (AACR) of 3.3% for Wake County patient utilization growth.

The table below summarizes the beginning in-center patient census on December 31, 2023 and its growth through the ending patient census on December 31, 2025.

The applicant begins with 45 Wake County in-center patients as of December 31, 2023.	45
The applicant projects the Wake County in-center patients forward one year to December 31, 2024 using the Wake County Five-Year AACR. This is the projected ending census for Operating Year 1.	$45 \times 1.033 = 46.5$
The applicant projects the Wake County in-center patients forward one year to December 31, 2025 using the Wake County Five-Year AACR. This is the projected ending census for Operating Year 2.	$46.5 \times 1.033 = 48.0$

As the table above shows, the applicant projects 47 in-center patients by the end of the first operating year, OY1 (CY2024), for a utilization rate of 2.9 patients per station per week or 73% ($47 \text{ patients} / 16 \text{ stations} = 2.9 \text{ patients per station} / 4 = 0.73$). By the end of OY2 (CY2025), the applicant projects 48 in-center patients for a utilization rate of 75% ($48 / 16 = 3.0 / 4 = 0.75$). The projected utilization of 2.9 patients per station per week for CY2024 satisfies the 2.8 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on existing BMA patients who have expressed a desire to transfer their care to the proposed facility.
- The applicant projects the growth of the Wake County patient census using the Wake County Five-Year AACR of 3.3 percent, as reported in the 2021 SMFP.

Access to Medically Underserved Groups

In Section C.6, page 32, the applicant discusses access to the facilities' services, stating:

“Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. 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.

Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

On page 32, the applicant provides the estimated percentage for each medically underserved group it will serve during OY2, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	27.2%
Racial and ethnic minorities	85.8%
Women	37.5%
Persons with disabilities	13.8%
Persons 65 and older	45.3%
Medicare beneficiaries	68.5%
Medicaid recipients	27.2%

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:

- The Fresenius corporate policy commits to provide services to all patients referred for ESRD services.
- Fresenius' facilities have historically provided care to all in need of ESRD services, including underserved persons.

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 identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

In Section D.2, pages 38-42, 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.

BMA of Raleigh Dialysis

On page 40, the applicant provides a table which shows projected BMA of Raleigh Dialysis utilization assuming the relocation of 10 stations and 19 in-center patients to the proposed facility, FKC Knightdale, which is summarized below:

The applicant begins with total Wake County in-center patients at BMA Raleigh as of December 31, 2020.	162
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County Five-Year AACR.	$162 \times 1.033 = 167.3$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County Five-Year AACR.	$167.3 \times 1.033 = 172.9$
The applicant projects the Wake County in-center patients forward one year to December 31, 2023 using the Wake County Five-Year AACR.	$172.9 \times 1.033 = 178.6$
The applicant projects that 19 BMA Raleigh patients will transfer to the proposed new facility upon certification on December 31, 2023.	$178.6 - 19 = 159.6$
The applicant adds 7 patients from outside of Wake County to the facility's census, for a total in-center census as of January 1, 2024, following completion of the proposed project.	$159.6 + 7 = 166.6$

As shown in the table above, BMA of Raleigh Dialysis is projected to have a utilization rate of 4.4 patients per station per week or 110% ($167 \text{ patients} / 38 \text{ stations} = 4.4 / 4 = 1.1$) following completion of the proposed project on December 31, 2023. The applicant states that the population presently served at BMA of Raleigh Dialysis will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On page 41, the applicant states:

“BMA notes that 2021 SMFP, Table 9D: Dialysis Station Need Determination by Facility indicates that BMA Raleigh is eligible to apply for up to 20 additional stations in 2021. BMA has already applied for four stations (CON Project ID # J-12042-21). BMA now commits to applying to replace the 12 stations being relocated to FKC Knightdale. BMA Raleigh will apply for 12 stations on November 15, 2021, for the review planned to begin on December 1, 2021. ... This application to develop FKC Knightdale will not adversely affect the patients remaining at BMA Raleigh.”

Zebulon Kidney Center

On page 42, the applicant provides a table which shows projected Zebulon Kidney Center utilization assuming the relocation of four stations and three in-center patients to the proposed facility, FKC Knightdale, which is summarized below:

	Wake County Patients	Johnston County Patients
The applicant begins with total Wake County and Johnston in-center patients at Zebulon Kidney Center as of December 31, 2020.	50	22
The applicant projects the Wake and Johnston in-center patients forward one year to December 31, 2021 using the Wake and Johnston County Five-Year AACRs.	$50 \times 1.033 = 51.7$	$22 \times 1.088 = 23.9$
The applicant projects the Wake and Johnston County in-center patients forward one year to December 31, 2022 using the Wake and Johnston County Five-Year AACR.	$51.7 \times 1.033 = 53.4$	$23.9 \times 1.088 = 26.0$
The applicant projects the Wake and Johnston County in-center patients forward one year to December 31, 2023 using the Wake and Johnston County Five-Year AACR.	$53.4 \times 1.033 = 55.1$	$26.0 \times 1.088 = 28.3$
The applicant projects that 3 Wake County Zebulon Kidney Center patients will transfer to the proposed new facility upon certification on December 31, 2023.	$55.1 - 3 = 52.1$	28.3
The applicant adds 14 patients from Franklin and Nash counties to the facility's census, for a total in-center census as of January 1, 2024, following completion of the proposed project.	$52.1 + 28.3 + 14 = 94.4$	

As shown in the table above, Zebulon Kidney Center is projected to have a utilization rate of 3.6 patients per station per week or 90% ($94 \text{ patients} / 26 \text{ stations} = 3.6 / 4 = 0.9$) following completion of the proposed project on December 31, 2023. The applicant states that the population presently served at Zebulon Kidney Center will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On page 41, the applicant states:

“BMA notes that 2021 SMFP, Table 9D: Dialysis Station Need Determination by Facility indicates that BMA Zebulon is eligible to apply for up to four additional stations in 2021. BMA now commits to applying to replace the four stations being relocated to FKC Knightdale. BMA Raleigh will apply for four stations on November 15, 2021, for the review planned to begin on December 1, 2021.”

In Section D.3, page 43, the applicant states, *“This application to develop FKC Knightdale will not have any effect on the ability of any members of above identified [underserved] groups to have convenient access to dialysis care.”*

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 needs of the population currently using the services to be relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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

The applicant proposes to develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

In Section E.2, pages 46-47, 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 it would not bring dialysis services closer to the patient residences for patients in the Knightdale area.
- *Develop a facility with more or less than 16 dialysis stations* – The applicant states that developing a facility with more or less than 16 dialysis stations would be a less effective alternative because the applicant received letters from 45 existing in-center patients for whom the proposed facility would be more convenient, and 16 stations is the right number to meet the identified need.
- *Develop home therapies at the proposed facility* – The applicant states that developing home therapies at the proposed is not the most effective alternative because of the added expense that would be incurred, and the fact that those services are offered at several other area facilities.

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.

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 develop a new 16-station kidney disease treatment center to be known as Fresenius Kidney Care Knightdale by relocating no more than 12 in-center and home hemodialysis stations from BMA of Raleigh Dialysis and 4 in-center and home hemodialysis stations from Zebulon Kidney Center.**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify 12 stations at BMA of Raleigh Dialysis for a total of no more than 38 in-center and home hemodialysis stations upon completion of the project.**
- 4. Upon completion of this project, the certificate holder shall take the necessary steps to decertify 4 stations at Zebulon Kidney Center for a total of no more than 26 in-center and home hemodialysis stations upon completion of the project**
- 5. 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.**

6. **The certificate holder shall install plumbing and electrical wiring through the walls for no more than 16 in-center and home hemodialysis stations.**
 7. **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 develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Construction Costs	\$2,031,764
Architect/Engineering Fees	\$182,859
Nonmedical Equipment	\$353,399
Furniture	\$118,837
Other: Generator	\$89,397
Contingency	\$221,462
Total Capital Costs	\$2,997,718

The applicant provides the assumptions used to project the capital cost in Section Q.

In Section F, page 50, the applicant states it projects \$167,681 in start-up costs and \$934,185 initial operating expenses, for total working capital required of \$1,101,866.

Availability of Funds

In Section F, pages 48 and 50, the applicant states that the capital and working capital cost, respectively, will be funded by BMA, as shown in the tables below.

Sources of Capital Financing

Type	BMA
Loans	
Accumulated reserves or OE *	\$2,997,718
Bonds	
Other (Specify)	
Total Financing	\$2,997,718

* OE = Owner's Equity

Sources of Working Capital Financing

Type	BMA
Loans	
Accumulated reserves or OE *	\$1,101,866
Bonds	
Other (Specify)	
Total Financing	\$1,101,866

* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated September 15, 2021, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, parent company for BMA, documenting its commitment to fund the capital and working capital costs of the project. The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

FKC Knightdale Revenue and Expenses		
	CY2024	CY2025
Treatments	5,852	6,993
Gross Patient Revenue	\$36,814,817	\$43,994,827
Net Patient Revenue	\$1,938,524	\$231,659
Average Net Revenue per Treatment	\$331	\$331
Total Operating Expenses	\$1,868,370	\$1,991,472
Average Operating Expense per Treatment	\$319	\$285
Net Income	\$70,154	\$325,123

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

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.” All of the facilities referred to in this application are located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate 14 dialysis centers and have been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2019. DaVita, Inc. operates two dialysis centers in Wake County; Wake Forest Dialysis Center and Oak City Dialysis. However, Oak City Dialysis did not become operational until June 2019. Also, DaVita has been approved to develop an additional facility, Downtown Raleigh Dialysis, but the facility was not operational as of December 31, 2019. The following table shows the existing and approved dialysis facilities in Wake County, from Table 9A, pages 130-131 of the 2021 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/19	In-Center Patients 12/31/19	Utilization Percent 12/31/19
BMA of Fuquay-Varina Kidney Center (BMA)	28	85	75.89%
BMA of Raleigh Dialysis (BMA)	50	193	96.50%
Cary Kidney Center (BMA)	24	79	82.29%
Downtown Raleigh Dialysis (DaVita)	0	0	0.00%
FMC Eastern Wake (BMA)	17	39	57.35%
FMC Morrisville (BMA)	10	32	80.00%
FMC New Hope Dialysis (BMA)	36	119	82.64%
FMC Northern Wake (BMA)	14	48	85.71%
Wake Dialysis Clinic (BMA)	47	204	108.51%
FKC Holly Springs (BMA)	0	0	0.00%
FMC Apex (BMA)	20	61	76.25%
FMC Central Raleigh (BMA)	19	46	60.53%
FMC Millbrook (BMA)	17	62	91.18%
FMC Rock Quarry (BMA)	0	0	0.00%
FMC White Oak (BMA)	15	53	88.33%
Oak City Dialysis (DaVita)	10	20	50.00%
Southwest Wake County Dialysis (BMA)	30	110	91.67%
Wake Forest Dialysis Center (DaVita)	21	80	95.24%
Zebulon Kidney Center (BMA)	30	99	82.50%

Source: 2021 SMFP, Table 9A.

In Section G, pages 50-51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. On page 57, 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 Wake 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 for the following reasons:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Wake County.
- The applicant adequately demonstrates that the proposed relocation of the 16 stations for the development of a new facility is needed in addition to the operational facilities in Wake 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 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 develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

POSITION	PROJECTED FTE POSITIONS CY2024	PROJECTED FTE POSITIONS CY2025
Administrator	1.00	1.00
Registered Nurse	2.00	2.00
Technicians (PCT)	4.00	4.00
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.25	0.25
Administrative/Business Office	0.50	0.50
FMC Director of Operations	0.15	0.15
FMC Chief Technician	0.15	0.15
FMC In-service	0.15	0.15
Total	9.20	9.20

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 58-59, 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.

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.

- (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 develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

Ancillary and Support Services

In the table in Section I, page 60, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 60-65, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at multiple facilities in Wake County.
- The applicant discusses how it will provide each necessary ancillary and support service at FKC Knightdale.

Coordination

In Section I, page 65, 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 discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.

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. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

In Section K.2, page 68, the applicant states that the project will involve renovation of 9,960 square feet of space to be leased in an existing building. The proposed floor plan is provided in Exhibit K-2.

In Section K.3, page 68, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal because the applicant states the building has already been developed and the existing space can be cost-effectively renovated by the applicant's experienced facility and construction services team.

In Section K.3, page 69, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the applicant states developing the new facility is considered the “*necessary part of doing business*” and those costs will be borne by the applicant, and not by the patients who will be served.

In Section K.3, page 69, the applicant identifies applicable energy saving features that will be incorporated into the construction plans.

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

The applicant proposes to develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center. FKC Knightdale will be a new facility and therefore has no history. In Section L.1, page 73, the applicant provides the historical payor mix for CY2020 for BMA Raleigh and BMA Zebulon, as shown in the table below.

Payor Source	BMA of Raleigh Dialysis	Zebulon Kidney Center
Self Pay	3.5%	2.8%
Insurance	10.1%	4.7%
Medicare	73.5%	71.5%
Medicaid	9.8%	16.0%
Other (VA)	3.1%	5.0%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section L.1(a), pages 74-75, the applicant provides comparison of the demographical information on BMA of Raleigh Dialysis and Zebulon Kidney Center patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total BMA Raleigh Patients Served during the Last Full OY	Percentage of Total BMA Zebulon Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	38.0%	36.5%	51.4%
Male	62.0%	63.5%	48.6%
Unknown	0.0%	0.0%	0.0%
64 and Younger	60.8%	41.9%	88.0%
65 and Older	39.2%	58.1%	12.0%
American Indian	0.0%	0.0%	0.8%
Asian	3.2%	1.4%	7.7%
Black or African-American	74.7%	63.5%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.1%
White or Caucasian	4.4%	35.1%	59.6%
Other Race	17.7%	0.0%	10.8%
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.

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 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 75, the applicant states that the facility is not obligated to provide uncompensated care or community service.

The facility is not an operational facility; therefore, there have been no civil rights access complaints filed against the facility within the last five years.

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 76, 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 Knightdale
 Projected Payor Mix CY2025**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.6	3.51%	0.0	0.0%	0.0	0.0%
Insurance*	4.7	10.06%	0.0	0.0%	0.0	0.0%
Medicare*	34.2	73.52%	0.0	0.0%	0.0	0.0%
Medicaid*	4.6	9.79%	0.0	0.0%	0.0	0.0%
Other (VA)	1.4	3.11%	0.0	0.0%	0.0	0.0%
Total	46.5	100.00%	0.0	0.0%	0.0	0.0%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second full calendar year of operation, the applicant projects that 3.51% of the in-center dialysis patients will be self pay patients, 73.52% will be Medicare patients and 9.79% will be Medicaid patients.

On page 76, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on the historical payor mix for BMA of Raleigh Dialysis, from which 12 of the 16 dialysis stations will be relocated.

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, pages 77-78, 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

The applicant proposes to develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

In Section M, page 79, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately

demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides documentation of its willingness to provide applicable health professional training programs in the area with access to the facility.

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 develop a new 16-station dialysis facility, FKC Knightdale, by relocating no more than 12 stations from BMA of Raleigh Dialysis and no more than four stations from Zebulon Kidney Center.

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.” All of the facilities referred to in this application are located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate 14 dialysis centers and have been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2019. DaVita, Inc. operates two dialysis centers in Wake County; Wake Forest Dialysis Center and Oak City Dialysis. However, Oak City Dialysis did not become operational until June 2019. Also, DaVita has been approved to develop an additional facility, Downtown Raleigh Dialysis, but the facility was not operational as of December 31, 2019. The following table shows the existing and approved dialysis facilities in Wake County, from Table 9A, pages 130-131 of the 2021 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/19	In-Center Patients 12/31/19	Utilization Percent 12/31/19
BMA of Fuquay-Varina Kidney Center (BMA)	28	85	75.89%
BMA of Raleigh Dialysis (BMA)	50	193	96.50%
Cary Kidney Center (BMA)	24	79	82.29%
Downtown Raleigh Dialysis (DaVita)	0	0	0.00%
FMC Eastern Wake (BMA)	17	39	57.35%
FMC Morrisville (BMA)	10	32	80.00%
FMC New Hope Dialysis (BMA)	36	119	82.64%
FMC Northern Wake (BMA)	14	48	85.71%
Wake Dialysis Clinic (BMA)	47	204	108.51%
FKC Holly Springs (BMA)	0	0	0.00%
FMC Apex (BMA)	20	61	76.25%
FMC Central Raleigh (BMA)	19	46	60.53%
FMC Millbrook (BMA)	17	62	91.18%
FMC Rock Quarry (BMA)	0	0	0.00%
FMC White Oak (BMA)	15	53	88.33%
Oak City Dialysis (DaVita)	10	20	50.00%
Southwest Wake County Dialysis (BMA)	30	110	91.67%
Wake Forest Dialysis Center (DaVita)	21	80	95.24%
Zebulon Kidney Center (BMA)	30	99	82.50%

Source: 2021 SMFP, Table 9A.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Wake County. The applicant does not project to serve dialysis patients currently being served by another provider.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 81, the applicant states:

“Approval of this application will allow the facility to continue serving 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 B, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 81, the applicant states:

“Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:

‘We deliver superior care that improves that quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 81, the applicant states:

“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.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

See also Sections B, C and L 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 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 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 based on the reasons stated above.

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

C

In Section Q Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 86, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility was found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*." After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are 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 dialysis 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. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-C- In Section C.3, pages 26-27, the applicant projects 47 in-center patients will be served by the proposed facility by the end of the first operating year, CY2024, for a utilization rate of 2.9 patients per station per week or 73% (47 patients / 16 stations = 2.9 patients per station / 4 = 0.73). The projected utilization of 2.9 patients per station per week exceeds the 2.8 in-center patients per station threshold required by 10A NCAC 14C .2203(a).

- (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.

-NA- The applicant is proposing to establish a new ESRD facility.

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

-C- In Section C.3, pages 26-27, the applicant provides the assumptions and methodology used to project utilization of the facility.