

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 29, 2021

Findings Date: December 29, 2021

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: G-12130-21

Facility: Fresenius Kidney Care Sandy Ridge

FID #: 210743

County: Guilford

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

Project: Develop a new 16-station dialysis facility by relocating no more than four stations from BMA of Greensboro, no more than eight stations from BMA of Southwest Greensboro and four stations from Fresenius Medical Care High Point

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.

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “BMA”), proposes to develop a new 16-station kidney disease treatment center (dialysis facility) in the city of Greensboro in Guilford County, by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from Fresenius Medical Care High Point (FKC High Point). The name of the proposed facility is Fresenius Kidney Care Sandy Ridge (FKC Sandy Ridge).

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 9D, page 134, the county need methodology shows there is no county need determination for additional dialysis stations in Guilford County. The applicant is proposing to relocate existing dialysis stations. 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 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 \$2 million but less than \$5 million. In Section B, pages 22-23, the applicant describes the project’s plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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 is consistent with Policy GEN-4 by including a 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, ... persons [with disabilities], 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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

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.*" Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to develop a new facility by relocating stations from three facilities in Guilford County. Therefore, there is no historical data to report for the proposed FKC Sandy Ridge. However, in Section C, pages 25-26, the applicant provides the historical patient origin during the last full fiscal year for BMA of Greensboro, FMC High Point and BMA of Southwest Greensboro.

BMA Greensboro Historical Patient Origin 01/01/2020-12/31/2020						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	# of Patients	% of Total Patients	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Guilford	160	99.4%	24	885.7% [85.7%]	28	80.0%
Forsyth	0	0	1	3.6%	1	2.9%
Rockingham	1	0.6%	3	10.7%	3	8.6%
Rowan	0	0	0	0	1	2.9%
Stanly	0	0	0	0	1	2.9%
Virginia	0	0	0	0	1	2.9%
Total	161	100.0%	28	100.0%	35	100.0%

Note: Project Analyst's calculation in brackets

BMA Southwest Greensboro Historical Patient Origin (In-Center) 01/01/2020-12/31/2020		
County	# of Patients	% of Total Patients
Guilford	103	94.5%
Durham	1	0.9%
Randolph	2	1.8%
South Carolina	1	0.9%
Other States	2	1.8%
Total	109	100.0%

FMC High Point Historical Patient Origin (In-Center) 01/01/2020-12/31/2020		
Payor Source	# of Patients	% of Total Patients
Guilford	37	82.2%
Davidson	1	2.2%
Forsyth	2	4.4%
Randolph	2	4.4%
Yadkin	1	2.2%
Other States	2	4.4%
Total	45	100.0%

In Section C, page 26, the applicant projects patient origin for the proposed FKC Sandy Ridge during the second full fiscal year of operation following completion of the project.

FKC Sandy Ridge Projected Patient Origin (In-Center) 01/01/2025-12/31/2025		
Patient Origin	# of Patients	% of Total Patients
Guilford	48.7	100.0%
Total	48.7	100.0%

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- To project patient origin, the applicant begins with the 45 in-center patients residing in Guilford County that demonstrated their intent to transfer their services to the new facility.
- The applicant projects growth of the Guilford County patient census using the Five-Year Average Annual Change Rate (AACR) of 4.0%, as published in the 2021 SMFP.
- The applicant projects that the relocation project will be certified as of December 31, 2023. Therefore, Operating Year 1 (OY1) is January 1-December 31, 2024 and Operating Year 2 (OY2) is January 1-December 31, 2025.

Analysis of Need

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, the applicant states:

“BMA believes the new facility will be closer to the residence location for a large number of patients and therefore more convenient for dialysis. Developing a new facility will enhance access to care for the patients of the area.”

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

- The proposed location of the facility will provide enhanced access to care to the Guilford County patients who reside in the area of the proposed facility.
- The applicant applies the 2021 SMFP Guilford County Five-Year AACR to project a facility census of 46.8 patients dialyzing on 16 stations as of the end of the first operating year. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Projected Utilization

In Section C, page 27 and Section Q, pages 91-93, the applicant provides projected utilization and the assumptions and methodology used to project utilization, which is summarized below.

FKC Sandy Ridge	
Begin with the patient population who have signed letters of support to transfer their care to the facility upon completion of the project, December 31, 2023	45
Project the Guilford County patient population forward to December 31, 2024, using the Guilford County Five-Year AACR. This is the end of Operating Year 1.	$45 \times 1.04 = 46.8$
Project the Guilford County patient population forward to December 31, 2025, using the Guilford County Five-Year AACR. This is the end of Operating Year 2.	$46.8 \times 1.04 = 48.7$

The applicant projects to serve 46.8 in-center patients in OY1 and 48.7 in-center patients in OY2. Thus, the applicant projects that FKC Sandy Ridge will have a utilization rate of 73.91% or 2.96 patients per station per week ($46.8 \text{ patients} / 16 \text{ stations} = 2.93 / 4 = 0.7325$ or 73.25%) in OY1. The projected utilization of 2.93 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).

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

- The applicant begins projections of the future patient population to be served with the patient population who have signed letters of support to transfer their care to the facility upon completion of the project.
- The applicant projects growth using the 2021 SMFP Guilford County Five-Year AACR of 4.0%, as published in the 2021 SMFP.
- The utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section C, page 32, 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 health insurer.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	35.4%
Racial and ethnic minorities	73.8%
Women	40.2%
Persons with disabilities	19.3%
Persons 65 and older	38.4%
Medicare beneficiaries	36.8%
Medicaid recipients	35.4%

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 the patient population of BMA Greensboro, BMA of Southwest Greensboro, and FMC High Point.

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 develop a new 16-station dialysis facility by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

In Section D, pages 38-44, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced will be adequately met following completion of the project.

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

- The applicant projects that the three dialysis facilities losing stations will experience a growth in the patient population by the first operating year on the remaining stations.
- The applicant projects growth using the Guilford County Five-Year AACR of 4.0%, as published in the 2021 SMFP.
- The applicant’s projections are based on the assumption that the number of remaining stations at each facility will remain the same.

In Section D, pages 39-44, the applicant provides projected utilization for all three facilities, as illustrated in the following tables.

BMA of Greensboro			
	In-Center	Home Hemodialysis	Home Peritoneal
Begin with the Guilford County patient population as of December 31, 2020.	160	24	28
Project the Guilford County patient population forward for one year to December 31, 2021, using the Guilford County Five-Year AACR.	$160 \times 1.04 = 166.4$	$24 \times 1.04 = 25.0$	$28 \times 1.04 = 29.1$
Project the Guilford County patient population forward for one year to December 31, 2022.	$166.4 \times 1.04 = 173.1$	$25.0 \times 1.04 = 26.0$	$29.1 \times 1.04 = 30.3$
Project the Guilford County patient population forward for one year to December 31, 2023.	$173.1 \times 1.04 = 180.0$	$26.0 \times 1.04 = 27.0$	$30.3 \times 1.04 = 31.5$
Subtract 11 in-center patients projected to transfer their care to the new FKC Sandy Ridge.	$180 - 11 = 169.0$		
Add the one in-center patient from Rockingham County and the HH and PD patients from other counties. This is the projected ending census for the date the stations are projected to be located.	$169.0 + 1 = 170.0$	$27.0 + 4 = 31.0$	$31.5 + 7 = 38.5$
Project the Guilford County patient population forward for one year to December 31, 2024.	$170.0 \times 1.04 = 176.7$	$31.0 \times 1.04 = 32.2$	$38.5 \times 1.04 = 40.0$
Add the one in-center patient from Rockingham County and the HH and PD patients from other counties. This is the projected ending census for December 31, 2024.	$176.7 + 1 = 177.7$	$32.2 + 4 = 36.2$	$40.0 + 7 = 47.0$
Project the Guilford County patient population forward for one year to December 31, 2025.	$177.7 \times 1.04 = 184.8$	$36.2 \times 1.04 = 37.6$	$47.0 \times 1.04 = 48.9$
Add the one in-center patient from Rockingham County and the HH and PD patients from other counties. This is the projected ending census for December 31, 2025.	$184.8 + 1 = 185.8$	$37.6 + 4 = 41.6$	$48.9 + 7 = 55.9$

Source: Section C, pages 39-40 and Section Q, page 96

BMA of Southwest Greensboro	
Begin with the Guilford County patient population as of December 31, 2020.	103
Project the Guilford County patient population forward for one year to December 31, 2021, using the Guilford County Five-Year AACR.	$103 \times 1.04 = 107.1$
Project the Guilford County patient population forward for one year to December 31, 2022.	$107.1 \times 1.04 = 111.4$
Project the Guilford County patient population forward for one year to December 31, 2023.	$114.4 \times 1.04 = 115.9$
Subtract 11 in-center patients projected to transfer their care to the new FKC Sandy Ridge.	$115.9 - 11 = 104.9$
Add the two patients from Randolph County. This is the projected ending census for the date the stations are projected to be relocated.	$104.9 + 2 = 106.9$
Project the Guilford County patient population forward for one year to December 31, 2024.	$104.9 \times 1.04 = 109.1$
Add the two patients from Randolph County. This is the projected ending census for 2024.	$109.1 + 2 = 111.1$
Project the Guilford County patient population forward for one year to December 31, 2025.	$109.1 \times 1.04 = 113.4$
Add the two patients from Randolph County. This is the projected ending census for 2025.	$113.4 + 2 = 115.4$

Source: Section C, page 42 and Section Q, page 100

Fresenius Medical Care High Point	
Begin with the Guilford County patient population as of December 31, 2020.	37
Project the Guilford County patient population forward for one year to December 31, 2021, using the Guilford County Five-Year AACR.	$37 \times 1.04 = 38.5$
Project the Guilford County patient population forward for one year to December 31, 2022.	$38.5 \times 1.04 = 40.0$
Project the Guilford County patient population forward for one year to December 31, 2023.	$40.0 \times 1.04 = 41.6$
Subtract 11 [5] in-center patients projected to transfer their care to the new FKC Sandy Ridge.	$41.6 - 5 = 36.6$
Add the five patients from Davidson, Forsyth and Randolph Counties. This is the projected ending census for the date the stations are projected to be relocated.	$36.6 + 5 = 41.6$
Project the Guilford County patient population forward for one year to December 31, 2024.	$36.6 \times 1.04 = 38.1$
Add the five patients from Davidson, Forsyth and Randolph Counties. This is the projected ending census for 2024.	$38.1 + 5 = 43.1$
Project the Guilford County patient population forward for one year to December 31, 2025.	$38.1 \times 1.04 = 39.6$
Add the five patients from Davidson, Forsyth and Randolph Counties. This is the projected ending census for 2025.	$39.6 + 5 = 44.6$

Source: Section C, page 44 and Section Q, page 104
Project Analyst's correction in brackets.

In Section D, pages 38-44, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with the facility census as of December 31, 2020.
- The applicant projects the growth of the facility census using the Guilford County Five-Year AACR of 4.0%, as published in the 2021 SMFP.
- The applicant subtracts 11 in-center patients from BMA of Greensboro, 11 from BMA Southwest and five from FMC High Point, who have all stated their intention to transfer care to the new FKC Sandy Ridge.
- The applicant adds one in-center patient from Rockingham County, 11 hemodialysis and home peritoneal dialysis patients from other counties and the State of Virginia to BMA of Greensboro and assumes that these patients will continue dialysis at the facility. The applicant does not project growth for this segment of the population.
- The applicant adds two in-center patients from Randolph County to BMA Southwest Greensboro and assumes that these patients will continue dialysis at the facility. The applicant does not project growth for this segment of the population.
- The applicant adds five in-center patients from Davidson, Forsyth, and Randolph Counties to FMC High Point and assumes that these patients will continue dialysis at the facility. The applicant does not project growth for this segment of the population.
- The applicant projects the following utilization rates as of December 31, 2023, the date the stations are projected to be relocated:

BMA of Greensboro-170.0 in-center patients / 50 stations = 3.40 / 4 = 0.85 or 85.00%
BMA Southwest Greensboro-106.9 in-center patients / 25 stations = 4.276 / 4 = 1.069 or 106.90%
Fresenius Medical Care High Point- 41.6 in-center patients / 10 stations = 4.16 / 4 = 1.04 or 104.00%

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

- The applicant begins projections of the future patient population to be served with the facility census as of December 31, 2020 and projects growth using the 2021 SMFP Guilford County Five-Year AACR.
- The applicant subtracts the patients that have stated their intention to transfer their care to the new FKC Sandy Ridge.
- The applicant added the patients residing in surrounding counties served by the facilities and assumes that this patient population will continue dialysis with the facility.
- BMA Southwest Greensboro and FMC High Point's projected utilization rates exceed four patients per station. The applicant has filed a Certificate of Need application on November 15, 2021 to replace the eight stations relocated from BMA Southwest Greensboro and is committed to applying to replace the four stations relocated from FMC High Point pursuant to the 2022 SMFP Facility Need Determination.

Access to Medically Underserved Groups

In Section D, page 45, the applicant states:

“This application to develop FKC Sandy Ridge will not have any effect on the ability of any members of the above identified groups to have convenient access to dialysis care.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis will be adequately met following completion of the project. The applicant does not project a change to the percentage of each medically underserved group currently being served by the facilities upon relocation of stations and projects the percentage of each medically underserved group at FKC Sandy Ridge based on a weighted average of the patient population currently served at BMA of Greensboro, BMA of Southwest Greensboro and FMC High Point.

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 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 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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

In Section E, pages 48-49, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Not Develop FKC Sandy Ridge-The applicant states that developing this new dialysis facility is an effort to bring dialysis care and treatment closer to the patient's residence and ultimately shortening their commute to and from dialysis. Therefore, not developing this facility was not an effective alternative.

Develop FKC Sandy Ridge with More Than 16 In-Center Stations-The applicant states that this alternative would result in drawing patients from further distances. The applicant's intent is to make dialysis treatment more convenient; therefore, this alternative was dismissed.

Develop FKC Sandy Ridge with Fewer Than 16 In-Center Stations-The applicant chose a 16-station facility based on the number of patients projected to be served. Fewer stations would not meet the need of the patients in the area.

Include Home Therapies at the New Location-The applicant states that BMA did not include home therapies at the new location in an effort to contain cost. A home therapy program would require additional space. The applicant dismissed this alternative because it would require additional capital to develop the required space.

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

- The proposed project will bring dialysis care and treatment closer to the patient's resident location, thus, enhancing access to dialysis services.
- FKC Sandy Ridge will meet the need of the patients projected to be served by the facility. In Exhibit C-3, the applicant provides 45 patient letters of support for the project indicating their willingness to consider transferring their care.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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 kidney disease treatment center by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from Fresenius Medical Care High Point for a total of no more than 16 stations at FKC Sandy Ridge upon project completion.**
 - 3. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 16 in-center dialysis stations.**
 - 4. Upon completion of this project, the certificate holder or parent shall take the necessary steps to decertify four stations BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from Fresenius Medical Care High Point for a total of no more than 50 stations at BMA of Greensboro, 25 stations at BMA of Southwest Greensboro and 10 stations at Fresenius Medical Care High Point.**
 - 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 September 1, 2022. The second progress report shall be due on January 2, 2023 and so forth.**
 - 6. 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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

Capital and Working Capital Costs

In Section Q, page 106, the applicant projects the total capital cost of the project, as shown in the table below.

FKC Sandy Ridge Capital Costs	
Constructions/Renovation Contract (s)	\$1,649,537
Architect / Engineering Fees	\$148,458
Non-Medical Equipment	\$293,399
Furniture	\$103,142
Other: Generator	\$89,964
Other Contingency	\$179,800
Total	\$2,464,300

In Section Q, page 106, 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.

In Section F, page 53, the applicant projects that the start-up costs will be \$180,866 and initial operating expenses will be \$956,359 for a total working capital of \$1,137,226. On pages 52-53, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Initial operating expenses were projected based on the assumption that it will be six months before revenue exceeds expenses.
- Start-up costs were projected based on the need to hire and train staff, and to have four weeks of clinical supplies and medication upon opening of the facility.

Availability of Funds

In Section F, page 50, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$2,464,300	\$2,464,300
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,464,300	\$2,464,300

* OE = Owner's Equity

In Section F, page 54, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$1,137,226
Lines of credit	\$0
Bonds	\$0
Total	\$1,137,226

Exhibit F-2 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., stating its commitment to fund the project through its cash reserves. The letter states that Fresenius Medical Care Holdings' 2020 consolidated balance sheets reflect more than \$446 million in cash and total assets exceeding \$45 billion.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the second full fiscal year following completion of the project, as shown in the table below.

FKC Sandy Ridge	1st FFY OY1	2nd FFY OY2
Total Treatments	5,852	7,065
Total Gross Revenues (Charges)	\$36,814,817	\$44,445,462
Total Net Revenue	\$1,908,196	\$2,303,710
Average Net Revenue per Treatment	\$326	\$326
Total Operating Expenses (Costs)	\$1,912,719	\$2,068,023
Average Operating Expense per Treatment	\$327	\$326
Net Income	(\$4,523)	\$235,687

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 109. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant's provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- 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 and working 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 and working 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 develop a new 16-station dialysis facility by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

Guilford County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2019	# of In-Center Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station
BMA of Greensboro	44	156	88.64%	3.55
BMA of South Greensboro	44	171	97.16%	3.89
BMA of Southwest Greensboro	33	108	81.82%	3.27
Central Greensboro Dialysis	0	0	0.00%	0
FMC of East Greensboro	43	130	75.58%	3.02
FKC Garber-Olin	28	66	58.93%	2.35
FMC High Point	14	37	66.07%	2.64
High Point Kidney of Wake Forest University	48	159	82.81%	3.31
Northwest Greensboro Kidney Center	37	97	65.54%	2.62
Triad Dialysis Center of Wake Forest University	27	104	96.30%	3.85
Total	318	1,028		

Source: 2021 SMFP, Table 9A, pages 123-124

In Section G, page 59, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford 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 Guilford County. The stations have been previously approved and do not duplicate services.”

The applicant adequately demonstrates that the proposal would 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 an increase in dialysis stations in Guilford County.
- The applicant adequately demonstrates that the proposed dialysis services are needed in addition to the existing or approved dialysis services.

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.

- (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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

In Section Q, page 116, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff
	2 nd Full Fiscal Year OY2
Administrator (FMC Clinic Manager)	1.00
Registered Nurses (RNs)	2.00
Technicians (PCT)	4.00
Dietician	0.50
Social Worker	0.50
Maintenance	0.25
Administration/Business Office	0.50
Other (FMC Director of Operations)	0.15
Other (FMC Chief Technician)	0.15
Other (FMC In-Service)	0.15
Total	9.20

The assumptions and methodology used to project staffing are provided in Section Q, page 117. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 60-61, 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 facility offers competitive salaries and personnel benefits to attract qualified staff.
- BMA has implemented several initiatives to attract staff in a Covid-19 competitive market.
- New employees are required to complete a 10-week training program that includes clinical training, corporate policy and procedures, and safety precautions.

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 all 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.

The applicant proposes to develop a new 16-station dialysis facility by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

Ancillary and Support Services

In Section I, page 62, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 62-67, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available. Ancillary and support services will be provided by the facility staff and the corporate structure of Fresenius Medical Care; such as administration and management, clinical and technical services, human resources and information systems.

Coordination

In Section I, page 67, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an existing provider with established relationships with physicians, local hospitals, and other health professionals within the community.
- The applicant states that it has agreements in place for lab services, a hospital affiliation and transplant.

In Section I, page 67, the applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- BMA's working relationships with the physicians of North Carolina Nephrology who will provide referrals to the facility and will also have admitting and rounding privileges.
- A nephrologist with Carolina Kidney Associates, PA, in Greensboro will serve as the medical director for FKC Sandy Ridge.

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 all the reasons described above.

- (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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

In Section K, page 70, the applicant states that the project involves renovating 7,890 square feet of existing space. Line drawings are provided in Exhibit K-2.

On pages 72-73, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed dialysis facility based on the applicant's representations and supporting documentation.

On pages 70-71, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The proposed project involves renovating an existing space as opposed to building new space which can result in a higher capital cost.
- The applicant relies on the extensive experience of the Fresenius Medical Care Real Estate and Construction Services to develop the project at a reasonable cost while designing the facility with energy efficiency features.

On page 71, 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. The proposed project will ensure convenient access to care for patients in the area and the cost to develop the project will not be passed on to the patient.

On pages 71-73, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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 all the reasons described above.

- (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

The applicant proposes to develop a new facility by relocating stations from three facilities in Guilford County. There is no historical data to report for the proposed FKC Sandy Ridge. However, in Section L, page 75, the applicant provides the historical payor mix during the last full fiscal year for BMA of Greensboro, BMA of Southwest Greensboro and FMC High Point.

BMA of Greensboro Historical Payor Mix 01/01/2020-12/31/2020						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
Payor Source	# of Patients	% of Total Patients	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	0.8	0.5%	0.2	0.7%	0.00	0.0%
Insurance*	15.8	9.8%	4.6	16.3%	9.3	26.7%
Medicare*	127.8	79.4%	22.7	81.2%	20.9	59.6%
Medicaid*	11.7	7.3%	0.0	0.0%	0.6	1.6%
Other: Misc. Incl. VA	5.0	3.1%	0.5	1.9%	4.2	12.1%
Total	161.0	100.0%	28.0	100.0%	35.0	100.0%

*Including any managed care plans.

BMA Southwest Greensboro Historical Payor Mix 01/01/2020-12/31/2020		
Payor Source	# of IC Patients	% of Total Patients
Self-Pay	1.8	1.6%
Insurance*	8.4	7.7%
Medicare*	83.7	76.8%
Medicaid*	10.0	9.2%
Other: Misc. Incl. VA	5.1	4.7%
Total	109.0	100.0%

*Including any managed care plans.

FMC High Point Historical Payor Mix 01/01/2020-12/31/2020		
Payor Source	# of IC Patients	% of Total Patients
Self-Pay	0.3	0.7%
Insurance*	6.6	14.6%
Medicare*	35.2	78.2%
Medicaid*	1.1	2.5%
Other: Misc. Incl. VA	1.8	4.1%
Total	45.0	100.0%

*Including any managed care plans.

In Section L, page 76, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY before submission of the application^			Percentage of the Population of the Service Area*
	BMA of Greensboro	BMA Southwest Greensboro	FMC High Point	
Female	40.2%	44.3%	33.3%	52.7%
Male	59.8%	55.7%	66.7%	47.3%
64 and Younger	61.6%	63.5%	59.5%	84.5%
65 and Older	38.4%	36.5%	40.5%	15.5%
American Indian	0.3%	0.9%	0.0%	0.8%
Asian	2.9%	4.3%	2.4%	5.3%
Black or African-American	70.6%	62.6%	61.9%	35.4%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.0%	0.1%
White or Caucasian	26.2%	32.2%	33.3%	49.4%
Other Race	0.0%	0.0%	0.0%	9.0%
Declined / Unavailable	0.0%	0.0%	2.4%	

^All patients (in-center, home hemodialysis, and peritoneal)

*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

In Section L, page 78, the applicant states that the facility is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 78, 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, page 78, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FKC Sandy Ridge Projected Payor Mix CY 2025		
Payor Source	# of IC Patients	% of Total Patients
Self-Pay	0.4	0.90%
Insurance*	4.7	9.73%
Medicare*	38.1	78.31%
Medicaid*	3.5	7.26%
Other: Misc. Incl. VA	1.8	3.80%
Total	48.7 [48.5]	100.00%

*Including any managed care plans
Project Analyst's calculation in brackets.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.90% of total services will be provided to self-pay patients, 78.31% to Medicare patients and 7.26% to Medicaid patients.

On page 79, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Payor mix is based on recent facility performance at BMA of Greensboro, BMA of Southwest Greensboro and FMC High Point.
- Payor mix is calculated based upon treatment volumes as opposed to percent of patients to account for patients that change payor source during the fiscal year.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 80, 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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

In Section M, page 81, 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-1. 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:

- All health related education and training will have the opportunity to receive instruction and observe the operation of the facility while patients are receiving treatments.
- Exhibit M-1 contains a letter addressed to Guilford Technical Community College encouraging the school to include FKC Sandy Ridge in their clinical rotations for nursing students.

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 all the reasons described above.

- (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 by relocating no more than four stations from BMA of Greensboro, eight stations from BMA of Southwest Greensboro and four stations from FMC High Point.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

Guilford County Dialysis Facilities

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Triad Dialysis Center of Wake Forest University	27	104	96.30%	3.85
Total	318	1,028		

Source: 2021 SMFP, Table 9A, pages 123-124

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 82, the applicant states:

“The SMFP reports there are nine operational dialysis facilities with in-center dialysis stations within Guilford County; there is also one planned facility. Seven of these facilities are operated by Fresenius Medical Care. 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 Sandy Ridge.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, 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 C, F, K, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 83, the applicant states:

“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 83, 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.”

See also Sections 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.
- 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 118-121, the applicant identifies the kidney treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 126 of this type of facility located in North Carolina.

In Section O, page 88, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. In Section O, pages 85-87, the applicant describes how Fresenius Medical Care incorporates quality improvement programs in all of its facilities to ensure and maintain quality of care. After reviewing and considering information provided by the applicant, 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

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.*

- C- In Section C, page 27 and Section Q, page 93, the applicant projects that FKC Sandy Ridge will serve 47 in-center patients on 16 stations, or a utilization rate of 2.93 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (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 not proposing to increase the number of dialysis stations in an existing dialysis facility or 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.

- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*

- NA- The applicant is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

- NA- The applicant is not proposing to increase the number home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

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

- C- In Section C, pages 26-28, and Section Q, pages 92-93, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.