

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2021

Findings Date: June 25, 2021

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-12043-21

Facility: Rockingham Kidney Center

FID #: 001548

County: Rockingham

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

Project: Add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations upon project completion and add home training and support for home hemodialysis and peritoneal dialysis

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at Rockingham Kidney Center (RKC) upon project completion and add home training and support for home hemodialysis (HH) and peritoneal dialysis (PD).

## **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 135, the county need methodology shows there is not a county need determination for additional dialysis stations in Rockingham County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 129, the utilization rate reported for the facility is 82.89% or 3.39 patients per station per week, based on 63 in-center dialysis patients and 19 certified dialysis stations ( $63 \text{ patients} / 19 \text{ stations} = 3.32$ ;  $3.32 / 4 = 0.8289$ ).

As shown in Table 9D, page 139, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to six additional stations; thus, the applicant is eligible to apply to add up to six stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than six new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to six stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

## **Policies**

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 SMFP, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

## **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, page 75; Section O, page 77-80; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 32; Section L, pages 67-70; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with policy GEN-3.

### 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 the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources

- (2) Repealed effective January 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

**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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.*” RKC is located in Rockingham County. Thus, the service area for this application is Rockingham County. Facilities may serve residents of counties not included in their service area.

The applicant provides the following historical in-center (IC) patient origin for RKC, as summarized below.

County	Historical (1/1/2020-12/31/2020)	
	Patients	% of Total
Rockingham	51	76.12%
Caswell	8	11.94%
Guilford	4	5.97%
Stokes	2	2.99%
Virginia	2	2.99%
<b>Total</b>	<b>67</b>	<b>100.00%</b>

Source: Section C.2, page 25

The following table illustrates the projected in-center patient origin at RKC in the second full fiscal year (FY) of operations, CY2023. The facility does not presently serve home training patients but proposes to add home training and support for home hemodialysis and peritoneal dialysis.

County	Second Full FY of Operation following Project Completion 1/1/23-12/31/23*					
	IC Patients		HH Patients		PD Patients	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Rockingham	53.3	76.92%	4.1	100.00%	2.0	100.00%
Caswell	8.0	11.54%	0.0	0.00%	0.0	0.00%
Guilford	4.0	5.77%	0.0	0.00%	0.0	0.00%
Stokes	2.0	2.89%	0.0	0.00%	0.0	0.00%
Virginia	2.0	2.89%	0.0	0.00%	0.0	0.00%
<b>Total</b>	<b>70.2 [69.3]</b>	<b>100.00%</b>	<b>4.1</b>	<b>100.00%</b>	<b>2.0</b>	<b>100.00%</b>

Source: Section C.3, page 26

\*The applicant labels the table as the second full fiscal year of operation and dates it as CY2023; however, that is the end of the first full fiscal year of operation. CY2024 in-center utilization is 69.3 patients (as shown in brackets above)

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization. On page 26, the applicant states:

*“BMA is proposing to add six dialysis stations to Rockingham Kidney Center for a total of 26 [25] stations upon project completion. The facility will continue to offer in-center dialysis. The facility will also begin to offer home dialysis training and support for both peritoneal dialysis and home hemodialysis, subject to approval of this application.”*

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

- The applicant begins with the December 31, 2020 patients
- The Average Annual Change Rate (AACR) published in the 2021 SMFP is a reliable measure for predicting patient growth by county: Rockingham County – 3.9%
- The applicant subtracts three patients in both CY2023 and CY2024 who are expected to transition their in-center care to home training care (two to HH and one to PD)
- The applicant adds the 16 in-center patients residing outside of Rockingham County

**Analysis of Need**

In Section C, pages 29-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 30, the applicant states:

*“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 70.2 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 70.2%, or 2.81 patients per station and exceeds the minimum required by the performance standard.”*

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

- The 2021 SMFP shows a facility need determination for up to six stations at RKC (page 129)
- The applicant applies the Rockingham County AACR as provided in the 2021 SMFP to project growth in Rockingham County patient utilization and does not project a growth for patients from outside Rockingham County

### Projected Utilization

In Section Q Form C, page 83, the applicant provides the projected utilization, as summarized in the following table.

**Form C Utilization as Provided by Applicant in Section Q**

Form C Utilization	Last Full FY CY2020	Interim FY CY2021	Interim FY CY2022	1st Full FY CY2023	2nd Full FY CY2024
<b>In-Center Patients</b>					
# of Patients at the Beginning of the Year	63	67	69	71	70
# of Patients at the End of the Year	67	69	71	70	69
Average # of IC Patients during the Year	65	68	70	71	70
# of Treatments / Patient / Year	148	148	148	148	148
Total # of IC Treatments	9,110	10,063	10,363	10,453	10,324
<b>HH Patients</b>					
# of Patients at the Beginning of the Year	0	0	0	0	2
# of Patients at the End of the Year	0	0	0	2	4
Average # of HH Patients during the Year	0	0	0	1	3
# of Treatments / Patient / Year	0	0	0	148	148
Total # of HH Treatments	0	0	0	148	450
<b>PD Patients</b>					
# of Patients at the Beginning of the Year	0	0	0	0	1
# of Patients at the End of the Year	0	0	0	1	2
Average # of PD Patients during the Year	0	0	0	1	2
# of Treatments / Patient / Year	0	0	0	148	148
Total # of PD Treatments	0	0	0	74	225
<b>Total Patients</b>					
# of Patients at the Beginning of the Year	63	67	69	71	73
# of Patients at the End of the Year	67	69	71	73	75
Average # of Total Patients during the Yr	65	68	70	72	74
# of Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments*	9,110	10,063	10,363	10,675	10,999

\*This calculation sums the total # of treatments calculated for IC, HH and PD treatments, as opposed to using the "Average # of Total Patients during the Year" under Total Patients x 148, which would yield the following Total # of Treatments:

Average # of Total Patients during the Year	65	68	70	72	74
# of Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments	9,620	10,064	10,360	10,656	10,952
Difference in Calculation of Treatments	510	1	-3	-19	-47

Based on the applicant's assumptions and methodology (average # patients during the year (# patients beginning of year + # patients end of year/2) x average # of treatments (148) = total # of treatments), it appears that the applicant's calculations for average # of patients during the year are actually based on fractions and not the whole numbers that are presented in the table above and on page 83. Furthermore, the calculations for "average # of patients during the year" should only result in a whole patient or 0.5 of a patient because the beginning and ending census of patients must be a whole number, added together they remain a whole number, which divided by two can only result in a fraction of 0.5. The following table shows the fractions that the applicant had to use to reach the total # of treatments provided in the table on page 83.

<b>Numbers from Form C Utilization, Pg 83</b>	<b>Last Full FY CY2020</b>	<b>Interim FY CY2021</b>	<b>Interim FY CY2022</b>	<b>1st Full FY CY2023</b>	<b>2nd Full FY CY2024</b>
In-Center Patients					
Total # of IC Treatments	9,110	10,063	10,363	10,453	10,324
# of Treatments / Patient / Year	148	148	148	148	148
Average # of IC Patients during the Year	61.55	67.99	70.02	70.63	69.76
HH Patients					
Total # of HH Treatments	0	0	0	148	450
# of Treatments / Patient / Year	0	0	0	148	148
Average # of HH Patients during the Year	0.00	0.00	0.00	1.00	3.04
PD Patients					
Total # of PD Treatments	0	0	0	74	225
# of Treatments / Patient / Year	0	0	0	148	148
Average # of PD Patients during the Year	0.00	0.00	0.00	0.50	1.52
Total Patients					
Total # of Treatments	9,110	10,063	10,363	10,675	10,999
# of Treatments / Patient / Year	148	148	148	148	148
Average # of Total Patients during the Yr	61.55	67.99	70.02	72.13	74.32

The Agency recalculates the projected utilization, utilizing the fractions that the applicant should have used, as shown below.



**Form C Utilization as Recalculated by Agency Based on Applicant's Assumptions**

Form C Utilization	Last Full FY CY2020	Interim FY CY2021	Interim FY CY2022	1st Full FY CY2023	2nd Full FY CY2024
<b>In-Center Patients</b>					
# of Patients at the Beginning of the Year	63	67	69	71	70
# of Patients at the End of the Year	67	69	71	70	69
Average # of Patients during the Year	65	68	70	70.5	69.5
# of Treatments / Patient / Year	148	148	148	148	148
Total # of In-Center Treatments	9,620	10,064	10,360	10,434	10,286
<b>HH Patients</b>					
# of Patients at the Beginning of the Year	0	0	0	0	2
# of Patients at the End of the Year	0	0	0	2	4
Average # of Patients during the Year	0.0	0.0	0.0	1.0	3.0
# of Treatments / Patient / Year	0	0	0	148	148
Total # of HH Treatments	0	0	0	148	444
<b>PD Patients</b>					
# of Patients at the Beginning of the Year	0	0	0	0	1
# of Patients at the End of the Year	0	0	0	1	2
Average # of Patients during the Year	0.0	0.0	0.0	0.5	1.5
# of Treatments / Patient / Year	0	0	0	148	148
Total # of PD Treatments	0	0	0	74	222
<b>Total Patients</b>					
# of Patients at the Beginning of the Year	63	67	69	71	73
# of Patients at the End of the Year	67	69	71	73	75
Average # of Patients during the Year	65	68	70	72	74
# of Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments*	9,620	10,064	10,360	10,656	10,952

\*This calculation results in the same total regardless of whether or not the total # of treatments calculated for IC, HH and PD patients are summed for total treatments or the sum of the average # of patients is multiplied by 148, as should be the case

**Difference in Form C Utilization Between Application, page 83, and Recalculated by Agency**

Form C Utilization	Last Full FY CY2020	Interim FY CY2021	Interim FY CY2022	1st Full FY CY2023	2nd Full FY CY2024
Total # of Treatments, Application Pg. 83	9,110	10,063	10,363	10,675	10,999
Total # of Treatments, Agency Calculation	9,620	10,064	10,360	10,656	10,952
Difference	510	1	-3	-19	-47

The difference in projected total # of treatments appears to be in the use of improper fractions for “average # of patients during the year” in all years except for CY2020, which has no impact on the future years. The applicant overstates total # of treatments by 19 and 47 in CY2023 and CY2024, respectively. This has no impact on the number of patients projected to utilize the facility. It may however have an impact on the financial feasibility of the project.

In-Center Utilization

In Section C, pages 26-27 and Section Q, pages 84-85, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is Operating Year 1, the period from January 1-December 31, 2023
- The second full FY is Operating Year 2, the period from January 1-December 31, 2024
- Projections begin with the facility census as of December 31, 2020
- The applicant grows the Rockingham County patient census by 3.9%, the 5-year AACR for as found in the 2021 SMFP, page 135
- The applicant expects three Rockingham County patients in both CY2023 and CY2024 to transition their in-center care to home training care
- The facility also serves 16 in-center patients residing outside of Rockingham County, which the applicant states are assumed to continue to dialyze at the facility, but the utilization will not grow

The applicant provides a table in Section C, page 27, and in Section Q, page 85, illustrating the application of its assumptions and methodology.

<b>Projected RKC In-Center Patients</b>	
Project the Rockingham County patient population forward one year to December 31, 2021, using the Five-Year AACR (3.9%).	51 x 1.039 = 53.0
Project the Rockingham County patient population forward one year to December 31, 2022, using the Five-Year AACR (3.9%).	53 x 1.039 = 55.1
Add the 16 patients from other counties. This is the projected starting census for this project on December 31, 2022.	55.1 + 16 = 71.1
Project the Rockingham County patient population forward one year to December 31, 2023, using the Five-Year AACR (3.9%).	55.1 x 1.039 = 57.2
Subtract 3 patients projected to change to home dialysis	57.2 - 3 = 54.2
Add the 16 patients from other counties. This is the projected ending census for Operating Year 1, CY2023.	54.2 + 16 = 70.2
Project the Rockingham County patient population forward one year to December 31, 2023, using the Five-Year AACR (3.9%).	54.2 x 1.039 = 56.3
Subtract 3 patients projected to change to home dialysis	56.3 - 3 = 53.3
Add the 16 patients from other counties. This is the projected ending census for Operating Year 2, CY2024.	5.3 + 16 = 69.3

Totals may not sum due to rounding

As the table above shows, using conventional rounding, the applicant’s methodology achieves a projection of 70 in-center patients by the end of the first full FY, OY1 (December 31, 2023), for a utilization rate of 2.8 patients per station per week or 70% (70 patients / 25 stations = 2.8 patients per station per week / 4 = 0.702). By the end of OY2 (December 31, 2024), following the applicant’s methodology and assumptions, the facility will have 69.3 in-center patients dialyzing at the center for a utilization rate of 69% (69 / 33 = 2.8 / 4 = 0.693). The projected

utilization of 2.8 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census of the previous year, CY2020, the most recent historical patient census, as submitted to the DHSR HealthCare Planning Section in February 2021
- The new stations are expected to be certified as of December 31, 2022, which makes CY2023 the first full FY and CY2024 the second full FY
- The applicant projects the growth of the Rockingham County patient census using the Five-Year AACR of 3.9%, as reported in the 2021 SMFP and does not grow the census of the patients from outside Rockingham County
- The projected utilization rate by the end of OY1 meets the minimum standard of 2.8 patients per station per week

#### Home Training Utilization

In Section C, pages 27-28 and Section Q, pages 85-86, the applicant provides the assumptions and methodology used to project home training utilization, which are summarized below.

- The first full FY is Operating Year 1, the period from January 1-December 31, 2023
- The second full FY is Operating Year 2, the period from January 1-December 31, 2024
- Projections begin with the facility census as of December 31, 2020.
- The applicant grows the Rockingham County patient census by 3.9%, the 5-year AACR for as found in the 2021 SMFP, page 135
- The applicant expects three Rockingham County patients in both CY2023 and CY2024 to transition their in-center care to home training care (two to HH in 2023; one to PD)

The applicant provides a table in Section C, page 28, and in Section Q, page 86, illustrating the application of its assumptions and methodology for projecting home dialysis patients.

**Projected RKC Home Dialysis Patients\***

	HH Patients	PD Patients
The applicant projects 3 Rockingham County patients to change to home dialysis in the first operating year. This is the ending census on December 31, 2023.	2	1
Project the Rockingham County patient population forward one year to December 31, 2024, using the Five-Year AACR (3.9%).	$2 \times 1.039 = 2.08$	$1 \times 1.039 = 1.04$
Add the 3 patients changing to home dialysis in the second operating year. This is the projected ending census for the second operating year, December 31, 2024.	$2.08 + 2 = 4.08$	$1.04 + 1 = 2.04$

Totals may not sum due to rounding

\*This is not the number of patients trained in a year. Provide the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

As the table above shows, using conventional rounding, the applicant’s methodology achieves a projection of two HH patients and one PD patient by the end of the first full FY, December 31, 2023; and four HH patients and two PD patients by the end of the second full FY, December 31, 2024. In Section C.5, page 31, the applicant provides a table showing six HH patients and four PD patients being “trained” at RKC during both CY2023 and CY2024.

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

- CY2023 is the first full FY and CY2024 is the second full FY
- The applicant expects three Rockingham County patients to transition their care from in-center to home training in both CY2023 and CY2024; two to HH and one to PD
- The applicant grows the Rockingham County patient census by 3.9%, the 5-year AACR for as found in the 2021 SMFP, page 135

**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.”*

The applicant provides the estimated percentage for each medically underserved group on page 33, as summarized in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	52.24%
Racial and ethnic minorities	58.21%
Women	43.28%
Persons with Disabilities	35.82%
Persons 65 and older	37.31%
Medicare beneficiaries	48.16%
Medicaid recipients	4.86%

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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

In Section E, page 41, 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:

- Maintain the status quo – the applicant states that failure to apply for additional stations would result in utilization rates of 4.0 patients per station and potentially interrupt patient admissions. Therefore, the applicant states this alternative is less effective.
- Add fewer stations – the applicant states that this alternative would also result in higher utilization rates; therefore, the applicant determined that this was not the most effective alternative.
- Do not add home therapies at the facility – the applicant states that this alternative would leave patients little option for home dialysis – patients could continue to be referred to the BMA Greensboro Kidney Center for home training or they could continue with in-center dialysis at RKC. The applicant states that failure to add home therapies is not consistent with contemporary standards of care and is not in the best interest of the dialysis patient.

Based on the explanations above, the applicant states that its proposal is the most effective alternative because the facility will be able to accommodate the existing patients and projected patients, both in-center and home therapy.

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 application is conforming or conditionally conforming to all statutory and regulatory review criteria
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative

## **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. 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. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than six additional in-center dialysis stations for a total of no more 25 stations at Rockingham Kidney Center upon completion of this project and add home training and support for home hemodialysis and peritoneal dialysis.**
  - 3. 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 third month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.**
  - 4. 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

**Capital and Working Capital Costs**

In Section Q Form F.1a Capital Cost, page 88, the applicant projects the total capital cost of the project, as summarized below.

Construction Costs	\$1,408,761
Furniture /Fixtures Costs	\$67,189
<b>Total</b>	<b>\$1,475,950</b>

In Section Q, page 88, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Construction costs estimated based on experience in developing additional stations and home therapy programs at existing facilities
- Cost of furniture and fixtures estimated based on experience purchasing furniture and fixtures at existing facilities

In Sections F.3, page 45, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

**Availability of Funds**

In Section F.2, page 43, the applicant states that the capital cost will be funded as shown in the table below.

Type	Bio-Medical Applications of North Carolina, Inc.
Loans	
Accumulated reserves or OE *	\$1,475,950
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$1,475,950</b>

\* OE = Owner's Equity

Exhibit F-2 contains a letter dated March 15, 2021 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care



Holdings (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2019 Consolidated Balance Sheet for FMCH reflects more than \$446 million in cash, and total assets exceeding \$25 billion.

**Financial Feasibility**

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

**RKC Projected Revenue and Operating Expenses**

	Interim Full FY	Interim Full FY	1 <sup>st</sup> Full FY	2 <sup>nd</sup> Full FY
	12/1/21-12/31/21	12/1/22-12/31/22	12/1/23-12/31/23	12/1/24-12/31/24
Total In-Center Treatments	10,063	10,363	10,453	10,324
Total HH Treatments	0	0	148	450
Total PD Treatments	0	0	74	225
Total Billable Treatments	10,063	10,363	10,675	10,999
Total Gross Revenues (Charges)	\$ 63,307,503	\$ 65,195,509	\$ 67,157,148	\$ 69,195,291
Total Net Revenue	\$ 3,626,645	\$ 3,734,801	\$ 3,858,660	\$ 3,998,832
Average Net Revenue per Treatment	\$ 360	\$ 360	\$ 361	\$ 364
Total Operating Expenses (Costs)	\$ 2,413,649	\$ 2,469,852	\$ 2,855,761	\$ 2,923,887
Avg Operating Expense per Treatment	\$ 240	\$ 238	\$ 268	\$ 266
Net Income	\$ 1,212,995	\$ 1,264,949	\$ 1,002,899	\$ 1,074,945

As discussed in Criterion (3), the applicant overestimates the number of treatments by 19 and 47 in CY2023 and CY2024, respectively. However, with 1) such a small difference in the number of treatments, 2) the average net revenue per treatment being \$364 or less, and 4) the net income being greater than \$1 million, the result of the difference in number of treatments is insignificant.

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

- Charges and expenses are based on historical facility operations projected forward
- Payor percentages are based on historical facility operations
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 2.5%
- 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
- The result of the small overstatement of treatments is insignificant to the project

## **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions
  - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal
  - The applicant adequately demonstrates the availability of 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* The facility in this application is in Rockingham County. Thus, the service area for this application is Rockingham County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are three existing or approved dialysis facilities in Rockingham County, two of which are owned and operated by DaVita and one by Fresenius. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

<b>Rockingham County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Dialysis Care of Rockingham County	DaVita	Eden	25	88.00%
Reidsville Dialysis	DaVita	Rockingham	27	68.52%
Rockingham Kidney Center	Fresenius	Rockingham	19	82.89%

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 Rockingham County. On page 50, the applicant states that this application is based upon facility performance and demonstrated need at RKC and is not specific to Rockingham County as a whole. The applicant also states that the 2021 SMFP indicates that the DaVita facilities in Rockingham County offer peritoneal dialysis, but do not offer home hemodialysis. The applicant further states:

*“BMA has proposed to add home therapies for both home modalities. BMA suggests that this is not duplication of services because the physicians that round and admit at the DaVita facilities do not round and admit at the BMA facility; further, the physicians rounding and admitting at the BMA facility do not have privileges at the DaVita facilities in Rockingham County. Physicians can not be expected to have privileges at every facility. Thus, the patients followed by the respective nephrology physician practice will be admitted at only those facilities where the nephrologist has privileges.”*

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 applicant adequately demonstrates that RKC needs additional stations to serve its existing and projected patient population
- The applicant adequately demonstrates that the proposed addition of home therapies is needed in addition to the existing and approved home therapy programs in Rockingham 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 based on 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

In Section Q Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the RKC facility, as summarized in the following table:

POSITION	Current FTE Positions	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
RN	2.00	3.00	3.00
Home Training Nurse	0.00	1.00	1.00
Patient Care Technician (PCT)	6.00	8.00	8.00
Dietician	0.67	0.80	0.80
Social Worker	0.67	0.80	0.80
Maintenance	0.80	0.80	0.80
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
Chief Technician	0.20	0.20	0.20
FMC In-Service	0.20	0.20	0.20
<b>Total</b>	<b>12.69</b>	<b>16.95</b>	<b>16.95</b>

Source: Section Q Form H, page 98

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H.3, pages 52-53, 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 is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility
- The applicant has existing policies in regard to recruitment, training and continuing education

**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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

#### **Ancillary and Support Services**

In the table in Section I, page 54, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 54-59, 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 RKC with the necessary ancillary and support services
- The applicant states that it has agreements in place for lab services, hospital affiliation, and transplant services

#### **Coordination**

In Section I, page 59, 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 and social service providers
- The applicant has agreements in place coordinating lab services, hospital services, and transplant 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.

- (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 January 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

In Section K, page 62, the applicant states that the project will involve new construction of 4,800 square feet. The proposed floor plan is provided in Exhibit K-1.

On page 62, 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 addition of six stations requires the expansion of the building to provide necessary access to the existing and projected patients
- Fresenius Medical Care has extensive experience developing dialysis facilities
- Line drawings are provided in Exhibit K-1

On page 63, 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 based on the following:

- The proposed project to add stations and home therapies is necessary to ensure continued convenient access to care for the patients in the area
- The cost of adding stations is not passed on the patient - the costs are borne by BMA  
The applicant states that the proposed project will not increase costs or charges to the public for the proposed services

On pages 63-64, the applicant provides the applicable energy saving features that are incorporated Fresenius related dialysis facilities.

**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.

- (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

In Section L, page 67, the applicant provides the historical payor mix for in-center dialysis during CY2020 for RKC, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	0.5	0.75%
Insurance *	9.7	14.52%
Medicare *	32.3	48.16%
Medicaid *	3.3	4.86%
Other (Medicare Advantage, VA and Misc.)	21.2	31.71%
<b>Total</b>	<b>67.0</b>	<b>100.00%</b>

\*Including any managed care plans

Source: Section L, page 67. RKC does not currently provide home training

In Section L, page 68, the applicant provides the following comparison.

RKC	Percentage of Total Patients Served by the Facility or Campus during the Last Full CY2020	Percentage of the Population of the Service Area
Female	43.3%	51.4%
Male	56.7%	48.6%
Unknown		
64 and Younger	62.7%	88.0%
65 and Older	37.3%	1.0%
American Indian	0.0%	0.8%
Asian	3.0%	7.7%
Black or African-American	53.7%	21.0%
Native Hawaiian or Pacific Islander	1.5%	0.1%
White or Caucasian	41.8%	59.6%
Other Race	0.0%	10.8%
Declined / Unavailable	0.0%	

The Agency reviewed the:

- Application
- Exhibits to the application



- Information which was publicly available during the review and used by the Agency

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 69, the applicant states that RKC 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 69, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

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 70, 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 summarized in the table below.

**RKC Projected Payor Mix**

County	Second Full FY of Operation following Project Completion 1/1/24-12/31/24					
	IC Patients		HH Patients		PD Patients	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Self-Pay	0.5	0.75%	0.0	0.68%	0.0	0.00%
Insurance *	10.1	14.52%	0.8	19.31%	0.6	27.46%
Medicare *	33.4	48.16%	2.8	67.82%	1.0	48.01%
Medicaid *	3.4	4.86%	0.0	0.00%	0.0	0.00%
Other (Medicare Adv, VA and Misc.)	22.0	31.71%	0.5	12.18%	0.5	24.53%
<b>Total</b>	<b>69.3</b>	<b>100.00%</b>	<b>4.1</b>	<b>100.00%</b>	<b>2.0</b>	<b>100.00%</b>

Rounding has an insignificant effect on totals and percentages

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.5% of IC dialysis services will be provided to self-pay patients, 48.16% to Medicare recipients and 4.86% to Medicaid recipients.

On page 70, 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:

- The applicant bases payor mix upon treatment volumes rather than patients
- The applicant bases future payor mix percentages on CY2020 payor mix percentages for treatment volumes
- The applicant includes Medicare Advantage treatments in Other, rather than including it in Medicare, as the application directs

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 72, 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

In Section M, page 73, 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. 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 add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations at RKC upon project completion and add home training and support for HH and PD.

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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* The facility in this application is in Rockingham County. Thus, the service area for this application is Rockingham County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are three existing or approved dialysis facilities in Rockingham County, two of which are owned and operated by DaVita and one by Fresenius. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

<b>Rockingham County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Dialysis Care of Rockingham County	DaVita	Eden	25	88.00%
Reidsville Dialysis	DaVita	Rockingham	27	68.52%
Rockingham Kidney Center	Fresenius	Rockingham	19	82.89%

Source: 2021 SMFP, Table 9A.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Rockingham 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 75, the applicant states:

*“Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, 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 75, the applicant states:

*“Quality of 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 75, 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, ability to pay 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 January 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 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility has been 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 January 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 promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

**10 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.*

-NA- RKC is an existing facility. Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in:*

(1) *an existing dialysis facility; or*

(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-C- In Section C, page 28, and on Section Q Form C Utilization, the applicant projects that RKC will serve 70 in-center patients on 25 stations, a utilization rate of 2.8 ( $70 / 25 = 2.8$ ) patients per station per week, as of the end of the first operating year following project completion, meeting the 2.8 patients per station per week requirement. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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