

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 20, 2022

Findings Date: April 20, 2022

Project Analyst: Mike McKillip

Co-Signer: Lisa Pittman

Project ID #: J-12169-21

Facility: Zebulon Kidney Center

FID #: 970505

County: Wake

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

Project: Add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project I.D. # J-12133-21 (relocate four stations)

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. (Zebulon Kidney Center), proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project I.D. # J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

Need Determination

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, page 136, the county need methodology shows there is not a county need determination for additional dialysis stations in Wake 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 130, the utilization rate reported for the facility is 82.5% or 3.86 patients per station per week, based on 99 in-center dialysis patients and 30 certified dialysis stations (99 patients / 30 stations = 3.3; $3.3 / 4 = 0.825$).

As shown in Table 9D, page 140, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to four additional stations; thus, the applicant is eligible to apply to add up to four stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than four new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to four 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 72; Section O, page 74-77; 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, pages 30-31; Section L, pages 63-69; Section N, page 73; 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 73; 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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project I.D. # J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

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-Graham counties and Avery-Mitchell-Yancey counties.” Zebulon Kidney Center is located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

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

County	Historical Zebulon Kidney Center Patient Origin (1/1/2020-12/31/2020)	
	Patients	% of Total
Wake	50	58.1%
Franklin	5	5.8%
Johnston	22	25.6%
Nash	9	10.5%
Total	86	100.0%

Source: Section C.2, page 25.

The following table illustrates the projected in-center patient origin at Zebulon Kidney Center in the second full fiscal year of operation (CY2023). The facility does not presently serve home training patients and does not propose develop those services as part of this project.

County	Projected Patient Origin In-Center Patients 01/01/2023-12/31/2023	
	Patients	% of Total
Wake	55.6	57.4%
Franklin	5.0	5.2%
Johnston	27.3	28.1%
Nash	9.0	9.3%
Total	96.9	100.0%

Source: Section C.3, page 26

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported because they are based the historical (CY2020) patient origin for the facility.

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. 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 94.2 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 78.5%, or 3.14 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 four stations at Zebulon Kidney Center.
- The applicant applies the Wake County AACR as provided in the 2021 SMFP to project growth in Wake County patient utilization and projects no growth for the patients from other counties being served at Zebulon Kidney Center.
- Then applicant shows that the facility will need the additional stations to accommodate the existing and projected patient population

Projected Utilization

In Section Q, the applicant provides the projected utilization, as illustrated in the following table.

Form C Utilization	Last Full FY CY2020	Interim CY2021	Interim CY2022	Interim CY2023	1st Full FY CY2024	2nd Full FY CY2025
# of Patients at the Beginning of the Year	99	86	88	91	90	94
# of Patients at the End of the Year	86	88	91	93	94	97
Average # of Patients during the Year	93	87	90	92	92	96
# of Treatments / Patient / Year	148	148	148	148	148	148
Total # of Treatments	13,581	12,904	13,261	13,631	13,659	14,140

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

- The first full fiscal year of operation is CY2024 and the second full fiscal year of operation is CY2025.
- Projections begin with the facility census as of December 31, 2020, as reported to DHSR Healthcare Planning in February 2021.
- The applicant grows the Wake County patient census by 3.3% and the Johnston county patient census by 8.8%, annually, which are the 5-year AACR for those counties as found in the 2021 SMFP, page 133.
- The applicant assumes the facility will continue to serve 14 in-center patients residing in Franklin and Nash counties, but does not project any growth in that patient population.

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

	Wake	Johnston
Begin with the Wake and Johnston County patient census as of December 31, 2020.	50	22
Project the Wake and Johnston County patient census forward one year to December 31, 2021, using the Five-Year AACR.	$50 \times 1.033 = 51.7$	$22 \times 1.088 = 22.7$
Project the Wake and Johnston County patient population forward one year to December 31, 2022, using the Five-Year AACR.	$51.7 \times 1.033 = 53.4$	$22.7 \times 1.088 = 23.5$
Project the Wake and Johnston County patient census forward one year to December 31, 2023, using the Five-Year AACR.	$53.4 \times 1.033 = 55.1$	$23.5 \times 1.088 = 24.3$
Subtract three Wake County patients planned to transfer to the new FKC Knightdale facility (Project I.D. # J-12133-21).	$55.1 - 3 = 52.1$	24.3
Add the 14 patients from other counties.	$52.1 + 24.3 + 14 = 90.4$	
Project the Wake and Johnston County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$52.1 \times 1.033 = 53.8$	$24.3 \times 1.088 = 26.4$
Add the 14 patients from other counties. This is the projected ending census for Operating Year 1.	$53.8 + 26.4 + 14 = 94.2$	
Project the Wake and Johnston County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$53.8 \times 1.033 = 55.6$	$26.4 \times 1.088 = 27.3$
Add the 14 patients from other counties. This is the projected ending census for Operating Year 2.	$55.6 + 27.3 + 14 = 96.9$	

Totals may not sum due to rounding

As shown in the table above, the applicant projects Zebulon Kidney Center will serve 94 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 3.13 patients per station per week or 78.3% ($94 \text{ patients} / 30 \text{ stations} = 3.13 \text{ patients per station per week}$)

week / 4 = 0.783). By the end of OY2 (December 31, 2025), the applicant projects the facility will have 97 in-center patients dialyzing at the center for a utilization rate of 81% ($97 / 30 = 3.23 / 4 = 0.81$). The projected utilization exceeds 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, the most recent historical patient census
- The applicant projects the growth of the Wake and Johnston County patient census using the Five-Year AACR for those counties as reported in the 2021 SMFP.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week

Access to Medically Underserved Groups

In Section C.6, pages 30-31, the applicant discusses access to the facilities' services, stating:

“Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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

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

On page 31, the applicant provides the estimated percentage for each medically underserved group it will serve during OY2, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	49.3%
Racial and ethnic minorities	81.3%
Women	36.0%
Persons with disabilities	37.3%
Persons 65 and older	50.7%
Medicare beneficiaries	56.0%
Medicaid recipients	38.7%

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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project I.D. # J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

In Section E, page 39, 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 rate of 3.7 patients per station per week by the end of the second operating year. 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.

Based on the explanations above, the applicant states that its proposal is the most effective alternative.

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. The certificate holder shall develop no more than four in-center stations for a total of no more than 30 stations at Zebulon Kidney Center upon completion of this**

project and Project ID # J-12133-21 (Relocate no more than four dialysis stations to FKC Knightdale).

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 fourth month. The first progress report shall be due on September 1, 2022. The second progress report shall be due on January 1, 2023 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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project I.D. # J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

Capital and Working Capital Costs

In Section F.1, page 40, and Section F.3, page 42, the applicant states it will not incur any capital or working capital costs for this project.

Financial Feasibility

In Section Q, the applicant provides 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 of operation following completion of the proposed project, as shown in the table below.

Zebulon Kidney Center	1 st Full FY CY2024	2 nd Full FY CY2025
Total Billable Treatments	13,659	14,140
Total Gross Revenue (charges)	\$85,930,817	\$88,957,304
Total Net Revenue	\$3,559,160	\$3,684,514
Average Net Revenue per Treatment	\$260.57	\$260.57
Total Operating Expenses (costs)	\$3,570,223	\$3,652,498
Average Operating Expense per Treatment	\$261.38	\$258.31
Net Income	(\$11,063)	\$32,016

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.
- 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 sufficient funds for the operating needs of the proposal.
- The applicant adequately demonstrates 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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project I.D. # J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

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-Graham counties and Avery-Mitchell-Yancey counties.”* Zebulon Kidney Center is located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

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

Wake County Dialysis Facilities

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

Source: 2021 SMFP, Table 9A.

In Section G, pages 47-48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. On page 49, the applicant states that this application is based upon facility performance and demonstrated need at Zebulon Kidney Center and is not specific to Wake County as a whole. The applicant states:

“It is not uncommon for a facility to have lower utilization while another facility in the same county is well utilized. Facilities have been intentionally developed to place stations in close proximity to the patient residence; the intent is to provide dialysis treatment in convenient settings. While some capacity does exist at BMA facilities in Wake County, these facilities are not proximate to the Zebulon Kidney Center location. Within Raleigh and Wake County, traffic congestion is also a concern. Congestion leads to longer commute times, even when the travel distance may be relatively short.”

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 Zebulon Kidney Center needs additional stations to serve its existing and projected patient population

- The applicant adequately demonstrates that the proposed addition of four stations is needed in addition to the existing and approved stations in Wake County

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion 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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project ID #J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the Zebulon Kidney Center 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	4.00	4.00	4.00
Patient Care Technician (PCT)	10.00	10.00	10.00
Dietician	0.75	0.75	0.75
Social Worker	0.75	0.75	0.75
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
FMC In-Service	0.15	0.15	0.15
Total	18.95	18.95	18.95

Source: Section Q Form H

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 Sections H.2 and H.3, pages 49-50, the applicant

describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The 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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project ID #J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

Ancillary and Support Services

In the table in Section I, page 51, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 51-56, 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 Zebulon Kidney Center.
- The applicant discusses how it provides each necessary ancillary and support service at Zebulon Kidney Center.

Coordination

In Section I, page 56, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective 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.

NA

The applicant states there is no construction associated with the proposed project. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 64, the applicant provides the historical payor mix for in-center dialysis during CY2020 for Zebulon Kidney Center, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	2.4	2.8%
Insurance *	4.0	4.7%
Medicare *	61.5	71.5%
Medicaid *	13.8	16.0%
Other (Medicare Advantage, VA and Misc.)	4.3	5.0%
Total^	86.0	100.0%

*Including any managed care plans

In Section L, page 65, the applicant provides the following comparison for facility patients and the service area population.

Zebulon Kidney Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY, CY2020	Percentage of the Population of the Service Area
Female	36.0%	51.4%
Male	64.0%	48.6%
Unknown		
64 and Younger	49.3%	88.0%
65 and Older	50.7%	12.0%
American Indian	0.0%	0.8%
Asian	1.3%	7.7%
Black or African-American	60.0%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	18.7%	59.6%
Other Race	20.0%	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 66, the applicant states that Zebulon Kidney Center 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 66, the applicant states that during the last 18 months 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(a), page 67, 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.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	2.7	2.8%
Insurance *	4.5	4.7%
Medicare *	69.3	71.5%
Medicaid *	15.5	16.0%
Other (Medicare Advantage, VA and Misc.)	4.8	5.0%
Total^	96.9	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.8% of IC dialysis services will be provided to self-pay patients, 71.5% to Medicare recipients and 16% to Medicaid recipients.

On pages 67-68, 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 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.5, page 69, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project ID #J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

In Section M, page 70, 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 four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon completion of this project and Project ID #J-12133-21 (Relocate four dialysis stations to FKC Knightdale).

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-Graham counties and Avery-Mitchell-Yancey counties. Zebulon Kidney Center is located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.*

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

Wake County Dialysis Facilities

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

Source: 2021 SMFP, Table 9A.

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

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

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

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

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

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

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

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

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

See also Sections B, C and L of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective 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 77, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility was found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*". After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective 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 or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- Zebulon Kidney Center is an existing facility.

- (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 Q, Form C, the applicant projects that Zebulon Kidney Center will serve 94 in-center patients on 30 dialysis stations. The projected utilization of 3.13 ($94 / 30 = 3.13$) 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 this Rule.

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

-C- In Section C, pages 26-27, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.