

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

- C = Conforming
- CA = Conditional
- NC = Nonconforming
- NA = Not Applicable

Decision Date: February 22, 2021
Findings Date: February 22, 2021

Project Analyst: Mike McKillip
Team Leader: Fatimah Wilson

Project ID #: J-11996-20
Facility: FMC White Oak
FID #: 160405
County: Wake
Applicant: Fresenius Medical Care White Oak, LLC
Project: Relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 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

Fresenius Medical Care White Oak, LLC (hereinafter referred to as “the applicant” or FMC White Oak), proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 169, the county need methodology shows there is no county need determination for additional dialysis stations in Wake County. The applicant is proposing to relocate existing dialysis stations; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

There is one policy in the 2020 SMFP that is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan.”*

The applicant proposes to relocate existing dialysis stations within Wake County, pursuant to Policy ESRD-2. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

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

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

- Neither the county nor facility need methodology is applicable to this review.
 - The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Wake County.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations. BMA of Raleigh will be certified for 46 stations upon completion of this project.

The following table, summarized from data on page 7 of the application, shows the projected number of stations at FMC White Oak upon project completion.

FMC White Oak		
Stations	Description	Project ID #
16	Total existing certified stations in the SMFP in effect on the day the review will begin	
+4	Stations to be added as part of this project	J-11996-20
20	Total stations upon completion of proposed project and previously approved projects	

The following table, summarized from information on page 7 of the application, shows the current and projected number of dialysis stations at BMA of Raleigh upon completion of this project.

BMA of Raleigh		
Stations	Description	Project ID #
50	Total existing certified stations in the SMFP in effect on the day the review will begin	
-4	Stations to be deleted as part of this project	J-11996-20
46	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2020 SMFP defines the service area dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Both facilities referred to in this application are located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 17, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for FMC White Oak for CY2019, as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wake	46	86.79%	0.0		0.0	
Brunswick	1	1.89%	0.0		0.0	
Johnson	3	5.66%	0.0		0.0	
Richmond	1	1.89%	0.0		0.0	
Other States	2	3.77%	0.0		0.0	
Total	53	100.00%	0.0	0.0%	0.0	0.0%

In Section C.3, page 18, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for FMC White Oak for the second full operating year following project completion, January 1, 2023 – December 31, 2023 (CY2023), as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wake	63.4	92.69%	0.0		0.0	
Johnston	4	5.85%	0.0		0.0	
Wayne	1	1.46%	0.0		0.0	
Total	68.4	100.00%	0.0	0.0%	0.0	0.0%

In Section C.3, pages 18-19, the applicant provides the assumptions and methodology used to project its patient origin. On page 18, the applicant begins with the patient origin for existing in-center dialysis patients for FMC White Oak as of June 30, 2020. The applicant’s assumptions are reasonable and adequately supported because it is based on the historical patient origin for in-center dialysis patients for FMC White Oak as of June 30, 2020.

Analysis of Need

In Section C.3, pages 18-19, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the June 30, 2020 census data. The applicant states that it assumes the patients from Wake County dialyzing at FMC White Oak on June 30, 2020 will continue to dialyze there and will increase at a rate equal to the Wake County Five Year Average Annual Change Rate (AACR) of 3.6% as published in the 2020 SMFP.
- The applicant assumes the patients from Johnston and Wayne Counties will continue to dialyze at FMC White Oak but does not assume any growth in patients from those counties.
- The project is scheduled for completion on December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In-Center Projected Utilization

In Section C.3, page 19, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Wake County in-center patients as of June 30, 2020.	56
The applicant projects the Wake County in-center patients forward six months to December 31, 2020 using the Wake County AACR.	$56 \times 1.018 = 57.0$
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County AACR.	$57.0 \times 1.036 = 59.1$
The applicant adds five patients from Wayne and Johnston counties. This is the projected starting census for the project.	$59.1 + 5 = 64.1$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County AACR.	$59.1 \times 1.036 = 61.2$
The applicant adds five patients from Wayne and Johnston counties. This is the projected ending census for Operating Year 1.	$61.2 + 5 = 66.2$
The applicant projects the Wake County in-center patients forward one year to December 31, 2023 using the Wake County AACR.	$61.2 \times 1.036 = 63.4$
The applicant adds five patients from Wayne and Johnston counties. This is the projected ending census for Operating Year 2.	$63.4 + 5 = 68.4$

The applicant projects to serve 66 in-center patients in OY1 and 68 in-center patients in OY2. Thus, the applicant projects that FMC White Oak will have a utilization rate of 82.5% or 3.3 patients per station per week ($66 \text{ patients} / 20 \text{ stations} = 3.3 / 4 = 0.825$ or 82.5%) in OY1. The projected utilization of 3.3 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing Wake County FMC White Oak patient census as of June 30, 2020.
- The applicant projects the Wake County patient census at FMC White Oak will increase by the Wake County Five Year AACR of 3.6 percent, as reported in the 2020 SMFP.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access

In Section C.7, page 21, the applicant states:

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

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

In Section C.7, page 22, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operating following completion of the project, as illustrated in the following table.

Estimated Percentages of Patients by Group		
a	Low income persons	24.6%
b	Racial and ethnic minorities	67.2%
c	Women	47.5%
d	Handicapped persons	19.7%
e	The elderly	47.5%
f	Medicare beneficiaries	77.0%
g	Medicaid recipients	13.1%

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.

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 projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations. BMA of Raleigh will be certified for 46 stations upon completion of this project.

In Section D.2, pages 25-26, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 29, the applicant provides a table which shows projected BMA of Raleigh utilization assuming the relocation of 4 stations to the FMC White Oak facility, which is summarized below:

The applicant begins with 177 total Wake County in-center patients at BMA of Raleigh as of June 30, 2020.	177
The applicant projects the Wake County in-center patients forward six months to December 31, 2020 using one half the Wake County Five-Year AACR.	$177 \times 1.018 = 180.2$
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County Five-Year AACR.	$180.2 \times 1.036 = 183.4$
The applicant adds four patients from outside of Wake County to the facility's census, for a total year-end census as of December 31, 2021, which is the projected certification date for the project.	$183.4 + 4 = 187.4$

As shown in the table above, BMA of Raleigh is projected to have a utilization rate of 4.07 patients per station per week or 101.6% ($187 \text{ patients} / 46 \text{ stations} = 4.07 / 4 = 1.016$) at the time the proposed stations will be relocated and certified at FMC White Oak. The applicant states that the population presently served at BMA of Raleigh will continue to have their needs adequately met by the remaining stations and proposed addition of dialysis stations in 2021. On page 25, the applicant states:

“The patients currently utilizing the stations will not be adversely impacted by this relocation. Fresenius Medical Care is the parent of BMA of Raleigh and majority owner in FMC White Oak. Fresenius Medical Care will apply for a Certificate of Need to replace the stations at BMA of Raleigh. ... The current draft 2021 SFMP indicates that BMA of Raleigh will qualify to apply for as many as 20 dialysis stations in 2021. Fresenius Medical Care commits to submit an application for four dialysis stations; the application will be filed March 15, 2021 for the review commencing April 1, 2021.”

In Section D.3, page 27, the applicant states the relocation of four stations from BMA of Raleigh to FMC White Oak will not have any impact on the access to services by low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare beneficiaries or Medicaid recipients.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The needs of the population currently using the services to be relocated will be adequately met following project completion.

- The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

In Section E.2, page 29, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because FMC White Oak is highly utilized and has experienced significant growth.
- *Relocate fewer than four stations* – The applicant states that relocating fewer than four stations is less effective because FMC White Oak is highly utilized and has experienced significant growth.
- *Relocate more than four stations* – The applicant states that relocating more than four stations is not cost-effective because the FMC White Oak facility does not have adequate capacity to accommodate more than four stations and would require significant capital expenditure to develop additional space.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Fresenius Medical Care White Oak, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, the certificate holder shall relocate no more than four stations from BMA of Raleigh to FMC White Oak for a total of no more than 20 in-center and home hemodialysis stations at FMC White Oak upon completion of the project.**
 - 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify four stations at BMA of Raleigh for a total of no more than 46 in-center and home hemodialysis stations upon completion of the project.**
 - 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on August 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**
 - 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

Capital and Working Capital Costs

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

	Total Costs
Nonmedical Equipment	\$3,000
Furniture	\$12,000
Total Capital Costs	\$15,000

In Section F, page 32, the applicant states there will be no working capital costs because FMC White Oak is an operational facility.

In Section Q, page 72, 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 information on projected capital costs provided by the applicant in Form F.1a on page 72 of the application.

Availability of Funds

In Section F, page 31, the applicant states that the capital costs will be funded by Fresenius Medical Care White Oak, LLC, as shown in the table below.

Type	Fresenius Medical Care White Oak, LLC
Loans	
Accumulated reserves or OE *	\$15,000
Bonds	
Other (Specify)	
Total Financing	\$15,000

* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated October 15, 2020, from the Senior Vice President and Treasurer for Fresenius Medical Care documenting its commitment to fund the capital costs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Section F and Exhibit F-2, as described above.

Financial Feasibility

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

FMC White Oak Revenue and Expenses		
	CY2022	CY2023
Treatments	9,683	9,959
Gross Patient Revenue	\$60,634,289	\$62,649,531
Net Patient Revenue	\$3,826,966	\$3,954,159
Average Net Revenue per Treatment	\$397	\$397
Total Operating Expenses	\$2,837,506	\$2,907,286
Average Operating Expense per Treatment	\$294	\$292
Net Income	\$989,461	\$1,046,873

Totals may not sum due to rounding

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate 14 dialysis centers and have been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2018. 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. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table 9B, pages 163-164 of the 2020 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Oak City Dialysis (DaVita)	0	0	NA
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Wake Forest Dialysis Center (DaVita)	22	87	98.86%
Zebulon Kidney Center (BMA)	30	104	86.67%

Source: 2020 SMFP, Table 9B.

In Section G.2, page 37, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“This is a proposal to relocate four dialysis stations to an existing dialysis facility. The stations are needed by the patient population projected to be served by the facility. The projections of future patient population to be served begins with the current patient population of the facility and an increase of that population at a rate of 3.6%. The applicant has not projected to serve patients currently served in another facility, or served by another provider. The stations are needed at FMC White Oak to support the growing patient census at the facility.”

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

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Wake County.
- The applicant adequately demonstrates that the proposed relocation of the four stations to FMC White Oak is needed in addition to the operational facilities in Wake County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

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

POSITION	PROJECTED FTE POSITIONS CY2022	PROJECTED FTE POSITIONS CY2023
Administrator	1.00	1.00
Registered Nurse	3.00	3.00
Technicians (PCT)	9.00	9.00
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administrative/Business Office	1.00	1.00
FMC Director Operations	0.15	0.15
In-Service	0.20	0.20
Chief Technician	0.25	0.25
Total	16.10	16.10

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the

applicant are budgeted in the pro forma financials found in Section Q. In Section H, page 38, 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 information provided in Section H, pages 38-39, and in Section Q, Form H, as described above.

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 relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

Ancillary and Support Services

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 40, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1, as described above.

Coordination

In Section I.2, pages 40-41, the applicant describes its existing and proposed 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 information provided in Section I.2, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.

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

NA

In Section K.1, page 43, the applicant states that the project will not involve new construction or renovation of existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations. In Section L.1, page 48, the applicant provides FMC White Oak's historical payor mix for CY2019, as shown in the table below.

Payor Source	In-Center Patients	Percent of Total
Self Pay	0.77	1.45%
Insurance	10.45	19.71%
Medicare	26.04	49.13%
Medicaid	1.16	2.19%
Medicare/Commercial	12.94	24.41%
VA	1.65	3.11%
Total	53.00	100.00%

Totals may not sum due to rounding

In Section L.1(a), page 47, the applicant provides comparison of the demographical information on FMC White Oak patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total Wake Forest Dialysis Center Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	47.5%	51.4%
Male	52.5%	48.6%
Unknown	0.0%	0.0%
64 and Younger	52.5%	88.0%
65 and Older	47.5%	12.0%
American Indian	0.0%	0.8%
Asian	1.6%	7.7%
Black or African-American	60.7%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	31.1%	59.6%
Other Race	6.6%	10.8%
Declined / Unavailable	0.0%	0.0%

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

Conclusion

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 48, the applicant states that the facility is not obligated to provide uncompensated care or community service.

In Section L.2, page 49, the applicant states there have been no civil rights access complaints filed against any of the applicant's facilities within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**FMC White Oak
Projected Payor Mix CY2023**

Payor Source	In-Center Patients	Percent of Total
Self Pay	1.0	1.45%
Insurance	13.5	19.71%
Medicare	33.6	49.13%
Medicaid	1.5	2.19%
Medicare/Commercial	16.7	24.41%
VA	2.1	3.11%
Total	68.4	100.00%

Totals may not sum due to rounding

As shown in the table above, during the second full calendar year of operation, the applicant projects that 1.45% of the in-center dialysis patients will be self-pay patients and 76% will have all or part of their services paid for by Medicare or Medicaid.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's projected patient payor mix is based on the historical payor mix for FMC White Oak.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 50, 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 relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

In Section M., the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 51, and Exhibit M-2, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to relocate no more than 4 dialysis stations pursuant to Policy ESRD-2 from BMA of Raleigh to FMC White Oak for a total of no more than 20 stations.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate 14 dialysis centers and have been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2018. 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. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table 9B, pages 163-164 of the 2020 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Oak City Dialysis (DaVita)	0	0	NA
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Wake Forest Dialysis Center (DaVita)	22	87	98.86%
Zebulon Kidney Center (BMA)	30	104	86.67%

Source: 2020 SMFP, Table 9B.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 52, 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. The projected patient population for the FMC White Oak facility begins with the current patient population and projects growth of that population consistent with the Wake County Five Year Average Annual Change Rate published in the 2020 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N.2, page 53, the applicant states:

“This is a proposal to relocate four stations to the FMC White Oak facility. The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the FMC White Oak 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 C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N.2, page 53, the applicant states:

“Quality of care is always in the forefront at Fresenius related facilities. 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.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N.2, page 53, the applicant states:

“All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. The Form A identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. ... 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. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

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

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by Fresenius Medical Care (FMC) or a related entity.

In Section O.2, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any FMC-related facility. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all FMC and related facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.
- NA- The applicant is not proposing to establish a new kidney disease treatment center or dialysis 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 C.3, pages 19-20, the applicant projects 66 in-center patients will be served by the FMC White Oak facility by the end of the first operating year, CY2022, for a utilization rate of 3.3 patients per station per week or 82.5% ($66 \text{ patients} / 20 \text{ stations} = 3.3 \text{ patients per station} / 4 = 0.825$). The projected utilization of 3.3 patients per station per week exceeds the 2.8 in-center patients per station threshold required in this Rule. 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.3, pages 19-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.