

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2019

Findings Date: September 27, 2019

Project Analyst: Mike McKillip

Team Leader: Gloria Hale

Project ID #: J-11738-19

Facility: Fresenius Medical Care White Oak

FID #: 160405

County: Wake

Applicant: Fresenius Medical Care White Oak, LLC

Project: Relocate no more than four dialysis stations from Wake Dialysis Clinic pursuant to Policy ESRD-2 to FMC White Oak for a total of no more than 16 stations upon project completion

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, Fresenius Medical Care White Oak, LLC (FMC White Oak), proposes to relocate four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak and 46 dialysis stations at Wake Dialysis Clinic upon project completion.

Need Determination

The 2019 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 D in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for additional dialysis stations in Wake County. An applicant is eligible to apply for additional stations in its existing facility based on the

facility need methodology if the facility's utilization rate as reported in the latest SDR is at least 3.2 patients per station per week. According to Table B of the July SDR, FMC White Oak reported an average of 2.5 patients per station per week as of December 31, 2018. Therefore, neither of the two need determination methodologies in the 2019 SMFP apply to this proposal.

Policies

There is one policy in the 2019 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2, on page 25 of the 2019 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 Semiannual Dialysis Report; 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 Semiannual Dialysis Report.”*

Both FMC White Oak and Wake Dialysis Clinic are in located in Wake County. The application is conforming to 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 that the application is conforming to this criterion because the relocation of four dialysis stations within Wake County will have no effect on the number of dialysis stations within the county.

- (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 relocate four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak upon project completion. Both facilities are located in Wake County.

The following tables, summarized from Section A.4, page 7 of the application, show the FMC White Oak facility, and the Wake Dialysis Clinic facility from which the applicant plans to relocate four stations.

FMC White Oak		
Stations	Description	Project ID #
12	Total existing certified stations as of the July 2018 SDR	
+4	Stations to be added as part of this project	J-11738-19
16	Total stations upon completion of above project	
Wake Dialysis Clinic		
Stations	Description	Project ID #
50	Total existing certified stations as of the July 2019 SDR	
-4	Stations to be deleted as part of another project	J-11270-16
+4	Stations to be added but not yet certified	J-11315-17
-4	Stations to be deleted as part of this project	J-11738-19
46	Total stations upon completion of above projects	

As shown in the table above, upon project completion, FMC White Oak will be certified for 16 dialysis stations, and Wake Dialysis Clinic will be certified for 46 dialysis stations.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” 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 14, the applicant provides the historical patient origin for FMC White Oak for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients as of December 31, 2018 as follows:

County	IC Patients	HHD Patients	PD Patients
Wake	26	0	0
Johnston	2	0	0
Other States	2	0	0
Totals	30	0	0

Source: Section C.2, page 14.

In Section C.3, page 16, the applicant provides a table showing projected patient origin for FMC White Oak in the first two operating years, which is summarized below:

COUNTY	FIRST FULL FY OF OPERATION (CY2021)		SECOND FULL FY OF OPERATION (CY2022)	
	IN-CTR. PTS.	% OF TOTAL	IN-CTR. PTS.	% OF TOTAL
Wake	52.9	100.0%	54.8	100.0%
Total	52.9	100.0%	54.8	100.0%

Note: numbers may not sum due to rounding

In Section C.1, page 15, the applicant states FMC White Oak does not currently provide home therapies, and does not plan to offer home therapies following completion of the proposed project. In Section C, pages 14-16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 14-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which is summarized below:

- The applicant begins the projections for FMC White Oak by using the ending in-center patient census of 38 Wake County patients as of June 30, 2019.
- The applicant assumes that no out-of-state patients will continue to utilize the FMC White Oak facility in future years.
- The applicant uses the Wake County Five Year Average Annual Change Rate (AACR) of 3.6 percent to project utilization in the future years.
- The applicant identifies 11 existing patients who have written letters expressing their intention to transfer their care from other facilities to FMC White Oak. Exhibit C-3.3 contains copies of the patient letters of support.
- Operating Year 1 (OY1) = January 1 through December 31, 2021 (CY2021).
 Operating Year 2 (OY2) = January 1 through December 31, 2022 (CY2022).

Projected Utilization

In Section C, page 16, 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, 2019.	38
The applicant projects the Wake County patients forward six months to December 31, 2019 using one-half of the Wake County AACR of 3.6 percent, which is 1.8 percent.	$38 \times 1.018 = 38.7$
The applicant projects the Wake County in-center patients forward one year to December 31, 2020 using the Wake County AACR.	$38.7 \times 1.036 = 40.1$
The applicant adds 11 Wake County patients who have expressed their intention to transfer their care from other facilities to the FMC White Oak facility.	$40.1 + 11 = 51.1$
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County AACR. This is the projected ending census for Operating Year 1 .	$51.1 \times 1.036 = 52.9$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County AACR. This is the projected ending census for Operating Year 2 .	$52.9 \times 1.036 = 54.8$

The applicant projects to serve 53 in-center patients in OY1 and 55 in-center patients in OY2. Thus, the applicant projects that FMC White Oak will have a utilization rate of 82.81% or 3.3 patients per station per week ($53 \text{ patients} / 16 \text{ stations} = 3.3 / 4 = 0.8281$ or 82.81%) in OY1. The projected utilization of 3.3 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 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 FMC White Oak patient census as of June 30, 2019.
- 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 July 2019 SDR.
- The utilization rate by the end of OY1 is above the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

FMC White Oak does not offer home hemodialysis or peritoneal dialysis training nor does the applicant propose to add those services. In Section I, page 48, the applicant states those patients that require home hemodialysis or peritoneal dialysis will be referred to Wake Dialysis Clinic. In Exhibit I.1, the applicant provides a copy of the home training agreement.

Access

In Section C.3, pages 22-23, the applicant states that each of the 127 Fresenius-related facilities in 47 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Services are provided to all patients, regardless of their ability to pay. In Section Q, page 89, the

applicant provides the projected payor mix during the second full fiscal year of operation following completion of the project (CY2022) for FMC White Oak, as illustrated below.

Payor Source	Percent of Total Revenue
Self Pay	2.00%
Insurance	10.00%
Medicare	53.56%
Medicaid	4.00%
Medicare / Commercial	28.32%
Misc. (VA)	2.12%
Total	100.00%

As illustrated in the table above, the applicant projects that 85.88% of all FMC White Oak patients will be Medicare or Medicaid recipients in CY2022. On page 58, the applicant states its projected payor mix in Operating Year 2 is based on the FMC White Oak facility's recent history, the payor mix for FMC Stallings Station, which is located nearby, and the recent history of Wake Dialysis Clinic, from which the four dialysis stations will be transferred. The projected payor mix is reasonable and adequately supported.

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.

- (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.

The applicant proposes to relocate four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak upon project completion. Both facilities are located in Wake County.

In Section D, pages 26-27, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project.

The applicant assumes that the number of in-center patients at Wake Dialysis Clinic who live in Wake County will increase at 3.6 percent per year based on the Five Year AACR for Wake County, as reported in Table D of the July 2019 SDR. The applicant serves six patients from others counties and assumes those patients will continue to dialyze at Wake Dialysis Clinic, but does not project any increase in the number of out-of-county patients to be served at Wake Dialysis Clinic. In Section D.1, page 28, the applicant calculates the in-center patient census for Wake Dialysis starting June 30, 2019 through December 31, 2020, summarized as follows:

The applicant begins with the Wake County in-center patients as of June 30, 2019.	185
The applicant projects the Wake County patients forward six months to December 31, 2019 using one-half of the Wake County AACR of 3.6 percent, or 1.8 percent.	$185 \times 1.018 = 188.3$
The applicant projects the Wake County in-center patients forward one year to December 31, 2020 using the Wake County AACR of 3.6 percent.	$188.3 \times 1.036 = 195.1$
The applicant adds six patients from other counties.	$195.1 + 6 = 201.1$
The applicant subtracts six patients projected to transfer to FMC Rock Quarry (Project I.D. # J-11270-16).	$201.1 - 6 = 195.1$

In Section D, pages 28-29, the applicant projects the Wake Dialysis Clinic patient population of 195 in-center patients for a utilization of 106% or 4.24 patients per station, per week. This is based on 195 in-center patients dialyzing on 46 certified dialysis stations ($195 / 46 = 4.24$; $4.24 / 4 = 1.06$ or 106%). On page 29, the applicant states,

“As previously noted, the facility does qualify to apply for additional stations in September 2019. The facility will apply to replace the four stations being relocated. Assuming an approval of that application, the utilization rate would be calculated as 3.9 patients per station, or 97.50% utilization.”

Home Hemodialysis and Peritoneal Dialysis

Home hemodialysis and peritoneal dialysis are currently offered at Wake Dialysis Clinic, but the applicant states the proposed relocation of dialysis stations will have no impact on the home dialysis patients.

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

- The applicant begins its utilization projection with the existing Wake County patient census currently served at Wake Dialysis Clinic.
- The applicant projects the Wake County in-center patient census at Wake Dialysis Clinic will increase at the Wake County Five Year AACR of 3.6 percent, as reported in the July 2019 SDR.
- The applicant projects the number of patients from other counties that are dialyzing at Wake Dialysis Clinic will remain constant.

On page 30, the applicant states the proposed relocation of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care, that the proposed relocation of stations will not have an effect upon access to care for any patient.

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 demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or 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 four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak and 46 dialysis stations at Wake Dialysis Clinic upon project completion.

In Section E.1, pages 31-33, 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 maintaining the status quo is not an effective alternative because it ignores the increasing numbers of patients who would benefit from additional dialysis stations closer to their residence.

- Relocate dialysis stations from a Wake County facility – The applicant states each of the facilities operated by the applicant in Wake County are well utilized.
- Relocate more or fewer dialysis stations – The applicant states that fewer stations would be inadequate to meet the projected need and that the FMC White Oak facility does not currently have the capacity to accommodate more than four additional stations.

The applicant adequately demonstrates that the alternative proposed in this application 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 shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Fresenius Medical Care White Oak, LLC shall relocate four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of no more than 16 dialysis stations at FMC White Oak.**
 - 3. Upon completion of this project, Fresenius Medical Care White Oak, LLC shall take the necessary steps to decertify four dialysis station at Wake Dialysis Clinic for a total of no more than 46 dialysis stations at Wake Dialysis Clinic upon project completion.**
 - 4. Fresenius Medical Care White Oak, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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 four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak upon project completion.

Capital and Working Capital Costs

In Form F.1(a), page 84, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$0
Equipment	\$15,000
Miscellaneous Costs	\$0
Total	\$15,000

In Section F.3, pages 36-38, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because FMC White Oak is an operational facility.

Availability of Funds

In Section F.2, page 35, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SOURCE
Loans	0
Accumulated Reserves or OE*	\$15,000
Other (Specify)	0
Total	\$15,000

*OE = Owner's Equity

Exhibit F-1 contains a letter dated July 15, 2019 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. (FMCH), parent company of FMC White Oak, authorizing and committing cash reserves in the amount of \$15,000 for the capital costs of the project. The letter states that FMCH currently has \$1.8 billion in cash and cash equivalents and \$20 billion in total assets.

Financial Feasibility

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

	OY 1 (CY2021)	OY 2 (CY2022)
Total In-Center Treatments	7,695	7,972
Total Gross Revenues (Charges)	\$48,411,827	\$50,154,652
Total Net Revenue	\$2,758,774	\$2,858,090
Average Net Revenue per Treatment	\$358.50	\$358.50
Total Operating Expenses (Costs) (From Form A)	\$2,666,642	\$2,745,788
Average Operating Expense per Treatment	\$346.54	\$344.43
Net Income	\$92,132	\$112,301

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - 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.
 - The applicant adequately demonstrates sufficient funds for the capital needs of the proposal.
- (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 four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak upon project completion. Both facilities are located in Wake County.

On page 369, the 2019 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service

area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by Fresenius Medical Care (FMC). DaVita operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

WAKE COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 12/31/18	UTILIZATION AS OF 12/31/18
FMC New Hope Dialysis	FMC	Raleigh	36	86.11%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	84.82%
BMA of Raleigh Dialysis	FMC	Raleigh	50	90.50%
Cary Kidney Center	FMC	Cary	24	89.58%
FMC Apex	FMC	Apex	20	82.50%
FMC Central Raleigh	FMC	Raleigh	19	67.11%
FMC Eastern Wake	FMC	Rolesville	17	64.71%
FMC Millbrook	FMC	Raleigh	17	76.47%
FMC Northern Wake	FMC	Wake Forest	14	87.50%
Southwest Wake County Dialysis	FMC	Raleigh	30	95.00%
Wake Dialysis Center	FMC	Raleigh	50	98.50%
Zebulon Kidney Center	FMC	Zebulon	30	86.67%
FMC Morrisville	FMC	Morrisville	10	45.00%
FMC White Oak	FMC	Garner	12	62.50%
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	98.86%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, July 2019 SDR.

*Indicates dialysis stations at facilities that were approved but not operational as of December 31, 2018.

As shown in the table above, three of the 14 operational dialysis facilities owned by FMC were being utilized at 90% or higher and 10 of the 14 were being utilized at greater than 70.0%.

In Section G.2, page 43, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County.

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 relocates four existing dialysis stations from one Fresenius Medical Care facility to another in Wake County, and therefore would not result in an increase in the number of dialysis stations in Wake County.
- The applicant adequately demonstrates that the proposed dialysis stations are needed.

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

In Form H, page 94, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

POSITION	CURRENT FTE POSITIONS	PROJECTED FTE POSITIONS
Medical Director	NA*	NA*
Registered Nurse	1.50	2.50
Patient Care Technician	5.00	6.50
Dietician	0.40	0.50
Social Worker	0.40	0.50
Clinical Manager	1.00	1.00
Director of Operations	0.15	0.15
In-Service	0.15	0.15
Business Office	0.50	0.75
Chief Technician	0.15	0.15
Equipment Technician	0.40	0.40
Total	9.65	12.60

*The applicant states the medical director is a contract position and not an employee.

The assumptions and methodology used to project staffing are provided in Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 45, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 46, the applicant identifies the medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating his interest in serving in that capacity.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 48, the applicant includes a list of providers of the necessary ancillary and support services.

FMC WHITE OAK ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	FMC White Oak
Self-care training (in-center)	Refer to other FMC facilities
Home training	
HH PD Accessible follow-up program	Refer to other FMC facilities
Psychological counseling	Wake County Crisis and Assessment or WakeMed
Isolation – hepatitis	FMC White Oak
Nutritional counseling	FMC White Oak
Social Work services	FMC White Oak
Acute dialysis in an acute care setting	Rex Hospital or WakeMed
Emergency care	FMC White Oak or Hospital
Blood bank services	Rex Hospital
Diagnostic and evaluation services	Rex Hospital
X-ray services	Rex Hospital
Laboratory services	FMC White Oak
Pediatric nephrology	UNC Healthcare
Vascular surgery	Rex Hospital or Raleigh Access Center
Transplantation services	UNC Healthcare
Vocational rehabilitation & counseling	Wake County Vocational Rehabilitation Services
Transportation	Go Wake Transportation Services

In Section I.2, page 48, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.2, I-1.3 and I-1.4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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 does not propose to construct any new space associated with the relocation of four stations as proposed in this application. 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.1, page 56, the applicant provides the historical payor mix during CY2018 at FMC White Oak, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL
Medicare	53.56%
Medicaid	0.22%
Commercial Insurance	13.64%
Medicare/Commercial	28.32%
Miscellaneous (Incl. VA)	4.27%
Total	100.00%

Numbers may not sum due to rounding

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wake	11%	51%	40%	11%	6%	10%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The applicant adequately demonstrates that it currently provides access to medically underserved populations. 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, page 57, the applicant states:

"Fresenius related dialysis facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. BMA facilities are responsible and do provide care to both minorities and

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”

In Section L, page 57, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

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 Q, page 89, the applicant provides the projected payor mix during the second full fiscal year of operation following completion of the project (CY2022) for FMC White Oak, as illustrated below.

Payor Source	Percent of Total Revenue
Self Pay	2.00%
Insurance	10.00%
Medicare	53.56%
Medicaid	4.00%
Medicare / Commercial	28.32%
Misc. (VA)	2.12%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.0% of total services will be provided to self-pay patients, 81.88% to Medicare patients (including Medicare/commercial) and 4.0% to Medicaid patients.

On page 58, 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 because the projected payor mix is based on the historical experience of FMC White Oak, Wake Dialysis Clinic and FMC Stallings Station.

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 59, 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

In Section M, page 61, 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 Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective January 1, 1987.
(16) Repealed effective January 1, 1987.
(17) Repealed effective January 1, 1987.
(18) Repealed effective January 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 four dialysis stations from Wake Dialysis Clinic to FMC White Oak for a total of 16 dialysis stations at FMC White Oak upon project completion. Both facilities are located in Wake County.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by Fresenius Medical Care (FMC). DaVita operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

WAKE COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 12/31/18	UTILIZATION AS OF 12/31/18
FMC New Hope Dialysis	FMC	Raleigh	36	86.11%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	84.82%
BMA of Raleigh Dialysis	FMC	Raleigh	50	90.50%
Cary Kidney Center	FMC	Cary	24	89.58%
FMC Apex	FMC	Apex	20	82.50%
FMC Central Raleigh	FMC	Raleigh	19	67.11%
FMC Eastern Wake	FMC	Rolesville	17	64.71%
FMC Millbrook	FMC	Raleigh	17	76.47%
FMC Northern Wake	FMC	Wake Forest	14	87.50%
Southwest Wake County Dialysis	FMC	Raleigh	30	95.00%
Wake Dialysis Center	FMC	Raleigh	50	98.50%
Zebulon Kidney Center	FMC	Zebulon	30	86.67%
FMC Morrisville	FMC	Morrisville	10	45.00%
FMC White Oak	FMC	Garner	12	62.50%
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	98.86%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, July 2019 SDR.

*Indicates dialysis stations at facilities that were approved but not operational as of December 31, 2018.

In Section N, pages 62-64, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 62, the applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Wake County. The applicant does not project to serve dialysis patients currently being served by another provider. ... Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available 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.

- (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 A, the applicant provides a list of Fresenius related dialysis facilities located in North Carolina.

In Section O.2, page 68, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no quality of care incidents that resulted in a finding of “*Immediate Jeopardy*” (IJ) in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius-related facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant does not propose to establish a new End Stage Renal Disease facility. Therefore, this performance standard is not applicable to this review.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.3, page 16, the applicant projects to serve 53 in-center patients on 16 in-center stations by the end of OY 1, which is 3.3 patients per station per week [53 / 16 = 3.3]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 15-16, 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.