

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 8, 2020

Findings Date: October 8, 2020

Project Analyst: Kim Meymandi

Team Leader: Fatimah Wilson

Project ID #: J-11937-20

Facility: FMC West Pettigrew

FID #: 956837

County: Durham

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

Project: Add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project and Project ID# J-11373-17 (relocate four stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to add no more than four dialysis stations to the Fresenius Medical Center (FMC) West Pettigrew facility pursuant to Condition 2 of the facility need for a total of no more than 24 in-center (IC) dialysis stations upon completion of this project and Project ID# J-11373-17 (relocate four stations). Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

FMC West Pettigrew provides in-center (IC) dialysis as well as both a peritoneal dialysis (PD) and a home hemodialysis (HH) program.

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

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for FMC West Pettigrew on page 155 of the 2020 SMFP is 77.08 percent or patients per station per week, based on 74 in-center dialysis patients and 24 certified dialysis stations ( $74 \text{ patients} / 24 \text{ stations} = 3.0833$ ;  $3.0833 / 4 = 0.7708$  or 77.08%).

As shown in Table 9E on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Dialysis Services West Pettigrew is up to eight additional stations; thus, the applicant is eligible to apply to add up to eight stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than four new stations to FMC West Pettigrew, which is consistent with the 2020 SMFP calculated facility need determination for up to eight dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

## **Policies**

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, pages 30-31 of the 2020 SMFP, states:

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

**Promote Safety and Quality** – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5, pages 14-16; Section N, pages 53-55, Section O, pages 56-59; and referenced exhibits. The information provided by the applicant is

reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), pages 15-16; Section L, pages 48-51; Section N, pages 53-55, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c), page 16; Sections F and K, and Section N, pages 53-55. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 because the applicant adequately demonstrates how FMC West Pettigrew's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

- (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.

BMA proposes to add no more than four dialysis stations to the FMC West Pettigrew facility pursuant to facility need for a total of no more than 24 in-center (IC) dialysis stations upon completion of this project and Project ID# J-11373-17 (relocate 4 stations).

**Patient Origin**

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” FMC West Pettigrew is in Durham County. Thus, the service area for this application is Durham County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

In Section C.2, page 19, the applicant provides the patient origin for FMC West Pettigrew IC, HH and PD patients as of December 31, 2019, as summarized in the table below.

**FMC West Pettigrew  
 1/1/2019 to 12/31/2019**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Durham	64.00	87.7%	1.00	50.0%	16.00	72.7%
Caswell	0.00	0.00%	0.00	0.00%	1.00	4.5%
Granville	3.00	4.1%	0.00	0.00%	1.00	4.5%
Orange	2.00	2.7%	1.00	50.0%	3.00	13.6%
Person	2.00	2.7%	0.00	0.00%	0.00	0.00%
Wake	2.00	2.7%	0.00	0.00%	1.00	4.5%
<b>Total</b>	<b>73</b>	<b>100.00%</b>	<b>2.00</b>	<b>100.00%</b>	<b>22.0</b>	<b>100.00%</b>

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year following project completion, as provided in Section C, page 20.

**FMC West Pettigrew  
 1/1/2023 to 12/31/2023**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Durham	63.8	87.6%	9.8	90.7%	23.4	79.6%
Caswell	0.00	0.00%	0.00	0.00%	1.00	3.4%
Granville	3.00	4.1%	0.00	0.00%	1.00	3.4%
Orange	2.00	2.7%	1.00	9.3%	3.00	10.2%
Person	2.00	2.7%	0.00	0.00%	0.00	0.00%
Wake	2.00	2.7%	0.00	0.00%	1.0	3.4%
<b>Total</b>	<b>72.8</b>	<b>100.00%</b>	<b>10.8</b>	<b>100.00%</b>	<b>29.4</b>	<b>100.00%</b>

Totals may not sum due to rounding

In Section C, pages 20-23, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C.4, page 24, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

The applicant explains the typical three day per week schedule for in-center patients to receive dialysis and states the failure to receive dialysis services will lead to patient death. On page 24, the applicant states:

*“The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. ... BMA has identified the population to be served as 72.8 in-center dialysis patients, and 35.9 home dialysis patients, projected to be dialyzing with the facility as of the end of the first Operating Year of the project. The in-center utilization rate is calculated to be 3.03 patients per station, or 75.9% utilization.”*

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

- According to the 2020 SMFP, as of December 31, 2018, FMC West Pettigrew was operating at a rate of 3.0833 patients per station per week, or 77.08 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding the facility need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 3.03 in-center patients per station per week dialyzing at FMC West Pettigrew as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standards 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 additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203.

### *Projected Utilization*

#### *In-Center Patients*

In Section C., pages 19-21, and in Section Q, pages 68-70, the applicant provides projected utilization, as illustrated in the following table.

**FMC WEST PETTIGREW IN-CENTER PATIENTS**

Begin with facility census of Durham County patients as of December 31, 2019.	64
Project Durham County patients forward one year to December 31, 2020, using the Durham County AACR of 4.6%	$64 \times 1.046 = 66.9$
Subtract three patients projected to change to home dialysis	$66.9 - 3 = 63.9$
Project Durham County patients forward for one year to December 31, 2021, using the Durham county AACR of 4.6%.	$63.9 \times 1.046 = 66.9$
Subtract three patients projected to change to home dialysis and add nine patients from Granville, Orange, Person and Wake Counties projected to continue dialysis at FMC West Pettigrew. <b>This is the starting census for the project.</b>	$66.9 - 3 + 9 = 72.9$
Project Durham County patients forward one year to December 31, 2022, using the Durham County AACR of 4.6%	$63.9 \times 1.046 = 66.8$
Subtract three patients projected to change to home dialysis and add nine patients from Granville, Orange, Person and Wake Counties projected to continue dialysis at FMC West Pettigrew. <b>This is the census on December 31, 2022 at the end of OY1.</b>	$66.8 - 3 + 9 = 72.8$
Project Durham County patients forward one year to December 31, 2023, using the Durham County AACR of 4.6%	$63.8 \times 1.046 = 66.8$
Subtract three patients projected to change to home dialysis and add nine patients from Granville, Orange, Person and Wake Counties projected to continue dialysis at FMC West Pettigrew. <b>This is the census on December 31, 2023 at the end of OY2.</b>	$66.8 - 3 + 9 = 72.8$

In both Section C, pages 19-21, and Section Q, pages 68-70, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the FMC West Pettigrew patient census as of December 31, 2019 which was 64 total IC patients: 63.8 Durham County patients; 3 Granville County patients; 2 Orange County patients; 2 Person County patients and 2 Wake County patients.
- The Granville County, Orange County, Person County and Wake County patients will be carried forward into projections of future patient census however, the applicant does not project any growth of the Granville County, Orange County, Person County and Wake County patients.
- The applicant projects that three patients per year will change from in-center dialysis to home dialysis. The applicant projects that two patients will choose home hemodialysis and one patient will choose peritoneal dialysis. These patients will be subtracted from future in center patient populations and added to home patient populations.

- The applicant projects the facility patients who reside in Durham County will grow at the Five Year Average Annual Change Rate (AACR) for Durham County, 4.6%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 167, of the 2020 SMFP.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2022) FMC West Pettigrew is projected to serve 73 in-center patients on 24 stations; and at the end of OY2 (CY2023) the facility is projected to serve 73 in-center patients on 24 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.04 patients per station per week, or 76.0% utilization [73 patients/ 24 stations = 3.04;  $3.04 / 4 = 0.76$  or 76.0%].
- OY 2: 3.04 patients per station per week, or 76.0% utilization [73 patients/ 24 stations = 3.04;  $3.04 / 4 = 0.76$  or 76.0%].

The projected utilization of 3.04 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.6 percent for Durham County patients which reflects the Durham County Five-Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Granville, Orange, Person and Wake County patients.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

#### *Peritoneal and Home Hemodialysis Patients*

In both Section C, pages 21-23, and Section Q, pages 71-72, the applicant provides the assumptions and methodology used to project PD and HH utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).

- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the FMC West Pettigrew PD and HH patient census as of December 31, 2019 which was:
  - 22 total PD patients: 16 Durham County patients and a total of six patients from Caswell, Granville, Orange and Wake Counties, and
  - Two total HH patients: one Durham County patient and one patient from Orange County.
- The non-Durham County PD and HH patients will be carried forward into projections of future patient census however, the applicant does not project any growth of the non-Durham County PD and HH patients.
- The applicant projects two IC patients will switch to HH and one IC patient will switch to home PD.
- The applicant projects the facility patients who reside in Durham County will grow at the Five-Year AACR for Durham County, 4.6%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 167, of the 2020 SMFP.

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.6 percent for Durham County patients which reflects the Durham County Five-Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its non-Durham County PD and HH patients.

### Access

In Section C.7, page 25, the applicant states,

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

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

On page 26, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**FMC West Pettigrew**  
**Estimated Percentage of Patients by Group CY 2023**

Medically Underserved Groups	Percentage of Total Patients
Low income persons	33.7%
Racial and ethnic minorities	89.2%
Women	45.8%
Handicapped persons	34.9%
The elderly	48.2%
Medicare beneficiaries	75.9%
Medicaid recipients	33.7%

Totals may not sum due to rounding

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.

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

NA

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

BMA proposes to add no more than four dialysis stations to the FMC West Pettigrew facility pursuant to facility need for a total of no more than 24 in-center (IC) dialysis stations upon completion of this project and Project ID# J-11373-17 (relocate 4 stations).

In Section E, page 31, 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 this alternative fails to address the in-center utilization at the facility. Failure to expand would result in higher utilization rates and fewer opportunities for patient admission.
- Apply for fewer than four stations- The applicant states that this alternative did not adequately address the utilization rate and therefore was less effective.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Pursuant to the facility need determination in the 2020 SMFP, Bio-Medical Applications of North Carolina, Inc. shall add no more than four additional in-center dialysis stations for a total of no more than 24 in-center stations at FMC West Pettigrew upon completion of this project and Project ID# J-11373-17 (relocate four stations).**
  3. **Bio-Medical Applications of North Carolina, Inc. 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

BMA proposes to add no more than four dialysis stations to the FMC West Pettigrew facility pursuant to facility need for a total of no more than 24 in-center (IC) dialysis stations upon completion of this project and Project ID# J-11373-17 (relocate 4 stations).

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 73, the applicant projects no capital costs associated with this project. In Section F.3, pages 33-34, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two full operating years of operation following completion of the project. In Section Q, Form F.2, page 78, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Operating Year</b>	<b>2<sup>nd</sup> Full Operating Year</b>
Total Treatments	15,785.9	16,403.2
Total Gross Revenues (Charges)	\$99,309,327	\$103,192,290
Total Net Revenue	\$5,016,400	\$5,262,197
Average Net Revenue per Treatment	\$318	\$321
Total Operating Expenses (Costs)	\$4,275,322	\$4,397,793
Average Operating Expense per Treatment	\$271	\$268
Net Income	\$741,079	\$864,404

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 based on the following:

- 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 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

BMA proposes to add no more than four dialysis stations to the FMC West Pettigrew facility pursuant to facility need for a total of no more than 24 in-center (IC) dialysis stations upon completion of this project and Project ID# J-11373-17 (relocate 4 stations).

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

According to Table B of the 2020 SMFP, there are 13 existing or approved dialysis facilities in Durham County, four of which are owned and operated by FMC. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

**Durham County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations</b>	<b># of IC Patients</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
Bull City Dialysis (DaVita)	16	44	68.75%	2.75
Downtown Durham Dialysis (DaVita)	10	0	0.00%	0.0
Durham Dialysis (DaVita)	25	98	98.0%	3.92
Durham Regional Dialysis (DaVita)	10	14	35.0%	1.40
Durham West Dialysis (DaVita)	27	79	73.15%	2.93
FMC Dialysis Services of Briggs Avenue (BMA)	29	105	90.52%	3.62
FMC Dialysis Services West Pettigrew (BMA)	24	74	77.08%	3.08
Freedom Lake Dialysis (BMA)	26	94	90.38%	3.61
Fresenius Kidney Care Eno River (BMA)	0	0	0.00%	0.0
Fresenius Medical Care South Durham Dialysis (BMA)	18	66	91.67%	3.67
Hope Valley Dialysis (DaVita)	0	0	0.00%	0.00
Research Triangle Park Dialysis (DaVita)	10	21	52.50%	2.1
Southpoint Dialysis (DaVita)	16	69	107.81%	4.31
<b>Total</b>	<b>201</b>	<b>664</b>		

Source: 2020 SMFP, Table B.

In Section G, page 37, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states it is not projecting to serve patients currently served in another facility but rather the stations are needed to serve the rapidly growing patient census at it's facility. Projected utilization starts with the current patient population of the facility and grows that patient census.

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:

- There is a facility need determination in the 2020 SMFP at FMC West Pettigrew for more than the proposed four dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 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 Section Q, Form H, page 86, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	OY1 (1/1/2022 to 12/31/2022)	OY2 (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
RNs	1.50	1.50	1.50
LPNs	0.25	0.25	0.25
Home Training Nurse	4.00	4.00	4.00
Technicians (PCT)	9.50	9.50	9.50
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Admin/Business Office	1.00	1.00	1.00
Other: FMC Dir. Operations	0.15	0.15	0.15
Other: In-Service	0.20	0.20	0.20
Other: Chief Tech	0.20	0.20	0.20
<b>TOTAL</b>	<b>20.80</b>	<b>20.80</b>	<b>20.80</b>

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 Form F.4, which is found in Section Q. In Section H.2 and H.3, page 39, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 40, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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, page 41, the applicant states that the following ancillary and support services are necessary for the proposed services:

<b>ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
Self-care training	Provided by the facility
Home training	
HH	
PD Accessible follow-up program	
Psychological counseling	Referral to Carolina Behavioral Care, Alliance Behavioral Healthcare, Blue Moon Senior Counseling, or Silver Linings
Isolation – hepatitis	Referral to Freedom Lake Dialysis or FMC South Durham Dialysis
Nutritional counseling	FMC on site
Social Work services	FMC on site
Acute dialysis in an acute care setting	Duke Regional Hospital
Emergency care	Duke Regional Hospital
Blood bank services	Duke Regional Hospital
Diagnostic and evaluation services	Duke Regional Hospital
X-ray services	Duke Regional Hospital
Laboratory services	On site blood draw; analysis by Spectra Labs
Pediatric nephrology	Referral to UNC Hospitals
Vascular surgery	Referral to Carolina Vascular Associates, or Duke Regional Radiology
Transplantation services	Duke UMC, UNC Hospital, or UVA Medical Center
Vocational rehabilitation & counseling	NCDHHS Vocational Rehabilitation Services
Transportation	Go Durham Access, Absolute Transportation, H2Go

On page 41, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, pages 41- 42, 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.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (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

The applicant does not propose to construct any new space or renovate any 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

In Section L, page 49, the applicant provides the historical payor mix for FMC West Pettigrew patients during the last full operating year (CY2019) for the proposed services, as shown in the table below.

**FMC West Pettigrew  
 Historical Payor Mix CY 2019**

Payor Source	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.44	0.60%	0.00	0.00%	0.00	0.00%
Insurance*	1.69	2.31%	0.02	1.09%	8.48	38.53%
Medicare*	60.28	82.58%	1.51	75.70%	9.46	42.98%
Medicaid*	3.55	4.86%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	5.84	8.00%	0.38	19.11%	4.07	18.49%
Miscellaneous (Incl. VA)	1.21	1.66%	0.08	4.11%	0.00	0.00%
<b>Total</b>	<b>73.00</b>	<b>100%</b>	<b>2.00</b>	<b>100%</b>	<b>22.00</b>	<b>100%</b>

Totals may not sum due to rounding

\*Including any managed care plans

In Section L, page 48, the applicant provides the following comparison.

	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	45.8%	52.3%
Male	54.2%	47.7%
Unknown		
64 and Younger	51.8%	86.4%
65 and Older	48.2%	13.6%
American Indian	0.0%	0.9%
Asian	0.0%	5.5%
Black or African-American	85.5%	36.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	10.8%	43.0%
Other Race	3.6%	13.6%
Declined / Unavailable	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 which was publicly available during the review and used by the Agency

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, the applicant states in Section L, page 49, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**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.

- (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 50, 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 West Pettigrew  
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	.40	0.60%	0.00	0.00%	0.00	0.00%
Insurance*	1.7	2.31%	0.12	1.09%	11.34	38.53%
Medicare*	60.1	82.58%	8.15	75.70%	12.65	42.98%
Medicaid*	3.5	4.86%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	5.8	8.00%	2.06	19.11%	5.44	18.49%
Miscellaneous (incl. VA)	1.2	1.66%	0.44	4.11%	0.00	0.00%
<b>Total</b>	<b>72.8</b>	<b>100.0%</b>	<b>10.8</b>	<b>100.0%</b>	<b>29.4</b>	<b>100.0%</b>

Totals may not sum due to rounding

\*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 0.60% of in-center dialysis services will be provided to self-pay patients, 82.58% to Medicare patients, and 4.86% to Medicaid patients.

On page 50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of FMC West Pettigrew.

**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.

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

C

In Section L, page 51, the applicant adequately describes the range of means by which patients will have access to 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.

- (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 52, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

## C

FMC proposes to add no more than four dialysis stations to the FMC West Pettigrew facility pursuant to facility need for a total of no more than 24 in-center (IC) dialysis stations upon completion of this project and Project ID# J-11373-17 (relocate 4 stations).

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

According to Table B of the 2020 SMFP, there are 13 existing or approved dialysis facilities in Durham County, four of which are owned and operated by FMC. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

**Durham County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations</b>	<b># of IC Patients</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
Bull City Dialysis (DaVita)	16	44	68.75%	2.75
Downtown Durham Dialysis (DaVita)	10	0	0.00%	0.0
Durham Dialysis (DaVita)	25	98	98.0%	3.92
Durham Regional Dialysis (DaVita)	10	14	35.0%	1.40
Durham West Dialysis (DaVita)	27	79	73.15%	2.93
FMC Dialysis Services of Briggs Avenue (BMA)	29	105	90.52%	3.62
FMC Dialysis Services West Pettigrew (BMA)	24	74	77.08%	3.08
Freedom Lake Dialysis (BMA)	26	94	90.38%	3.61
Fresenius Kidney Care Eno River (BMA)	0	0	0.00%	0.0
Fresenius Medical Care South Durham Dialysis (BMA)	18	66	91.67%	3.67
Hope Valley Dialysis (DaVita)	0	0	0.00%	0.00
Research Triangle Park Dialysis (DaVita)	10	21	52.50%	2.1
Southpoint Dialysis (DaVita)	16	69	107.81%	4.31
<b>Total</b>	<b>201</b>	<b>664</b>		

Source: 2020 SMFP, Table B.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 53, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 54, the applicant states:

*“Approval of this application will allow the FMC West Pettigrew 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.”*

Regarding the impact of the proposal on quality, in Section N, page 54, the applicant states:

*“Quality of care is not negotiable. ... Our organizational mission statement captures this sentiment very well:*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 54, the applicant states:

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

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

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

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

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

- (19) Repealed effective 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 Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 120 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O.2, page 59, 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 of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2203 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

#### **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- FMC West Pettigrew is an existing facility. Therefore, this Rule is not applicable to this review.

- (b) An applicant proposing to increase the number of dialysis stations in:
- (1) an existing dialysis facility; or
  - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;
- shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, pages 20-22, and Form C in Section Q, the applicant projects that FMC West Pettigrew will serve 72.8 in-center patients on 24 stations, or a rate of 3 patients per station per week or 80.0% ( $72.8 / 24 = 3.03/4 = 0.76$  or 76.0%), as of the end of the first operating year (CY2021) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

-C- In Section C, pages 20-22, in Section Q, Form C, pages 68-70, the applicant provides the assumptions and methodology it used to project utilization of the facility.