

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 25, 2022

Findings Date: March 25, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Micheala Mitchell

Project ID #: M-12166-21

Facility: FMC Services of West Fayetteville

FID #: 011019

County: Cumberland

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

Project: Add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6)

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., proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

Need Determination

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, page 133, the county need methodology shows there is not a county need determination for additional dialysis stations in Cumberland County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 121, the utilization rate reported for the facility is 106.25% or 4.25 patients per station per week, based on 170 in-center dialysis patients and 40 certified dialysis stations [$170 \text{ patients} / 40 \text{ stations} = 4.25$; $4.25 / 4 = 1.0625$].

As shown in Table 9D, page 138, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to nine additional stations; thus, the applicant is eligible to apply to add up to 18 dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than six new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 18 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

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

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, page 73; Section O, pages 75-77; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality in the delivery of dialysis services.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, pages 30-31; Section L, pages 65-69; Section N, page 73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access to dialysis services.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, pages 72-73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value for dialysis services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

(2) Repealed effective January 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

Patient Origin

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* FMC Services of West Fayetteville is located in Cumberland County. Thus, the service area for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant provides the following historical in-center (IC) patient origin for FMC Services of West Fayetteville for the last full calendar year (CY), CY 2020, as shown in the table below:

**Historical Patient Origin
 FMC Services of West Fayetteville, CY 2020**

COUNTY	# IN-CTR. PTS.	% OF TOTAL
Cumberland	151	87.3%
Hoke	16	9.2%
Robeson	4	2.3%
Sampson	1	0.6%
Wake	1	0.6%
Total	173	100.0%

Source: application page 25
 Numbers may not sum due to rounding

On page 30, the applicant states the facility does not offer home dialysis therapies.

The following table illustrates the projected IC patient origin for FMC Services of West Fayetteville in the second full fiscal year of operation (CY 2024):

**Historical Patient Origin
 FMC Services of West Fayetteville, CY 2020**

COUNTY	# IN-CTR. PTS.	% OF TOTAL
Cumberland	170.6	89.0%
Hoke	16	8.4%
Robeson	4	2.1%
Sampson	1	0.5%
Total	190.6	100.0%

Source: application page 26
 Numbers may not sum due to rounding

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

“The applicant begins projections of the future patient population to be served with the facility census as of December 31, 2020.”

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

- The applicant begins with the December 31, 2020 patients who are currently served at FMC Services of West Fayetteville.
- The applicant projects growth of the Cumberland County patient population using the Cumberland County Five Year AACR as published in the 2021 SMFP.
- The applicant accounts for the patients who reside in counties other than Cumberland County and adds those patients to the patient projections at appropriate points in time.

Analysis of Need

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 183.1 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 104.05%, or 4.16 patients per station and exceeds the minimum required by the performance standard.”

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

- The 2021 SMFP shows a facility need determination for up to 18 stations at FMC Services of West Fayetteville.
- The application is to add six in-center dialysis stations.
- The applicant projects growth of the Cumberland County dialysis patient population using the Five Year AACR as provided in the 2021 SMFP and projects no growth for the patients from other counties who are dialyzing at the facility by choice, according to the applicant.
- The applicant demonstrates that the facility will need the additional stations to accommodate the existing and projected patient population

Projected Utilization

In Section Q Form C, the applicant provides the projected utilization for two interim and two PYs, as illustrated in the following table:

FMC Services of West Fayetteville Projected Utilization

FORM C	INTERIM PY CY 2021	INTERIM PY CY 2022	INTERIM PY CY 2023	INTERIM PY CY 2024
# Pts. Beginning	173	180	188	183
# Pts at End of Year	180	188	183	192
Average # Pts in Year	176	184	186	187
# of Treatments / Pt. / Year	148	148	148	148
Total # Treatments	26,111	27,229	27,472	27,727

In Section C, pages 26-27 and Section Q, pages 82-83, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- The applicant states that Table 9D in the 2021 SMFP indicates FMC Services of West Fayetteville is eligible to apply for up to 18 stations. On December 9, 2021, the applicant was approved to add four stations to FMC Services of West Fayetteville pursuant to Project ID #M-12106-21.
- The applicant begins with the December 31, 2020 patients who are currently served at FMC Services of West Fayetteville.
- The applicant uses the 5.2% Cumberland County Average Annual Change Rate (AACR) as published in the 2021 SMFP to project patient growth for the Cumberland County patient population.
- The applicant notes the facility was serving 21 patients from Hoke Robeson and Sampson counties, which are contiguous to Cumberland County. The applicant does not project growth in that patient population but does add those patients to its patient projections at the appropriate points in time.
- The applicant notes the facility was serving one patient from Wake County, which is not contiguous to Cumberland County. The applicant assumes this patient is a transient patient and does not project that this patient will continue to dialyze at the facility.
- The applicant states this application follows Project ID #M-12129-21, in which the applicant was approved to develop a new facility (Fresenius Kidney Care Hope Mills) by relocating existing dialysis stations. In that application, the applicant projected that 13 Cumberland Count dialysis patients would transfer their care to that facility. The applicant subtracts those patients from its projections in this application as of December 31, 2022, the projected certification date for Fresenius Kidney Care Hope Mills.
- The applicant projects the stations proposed in this application to be certified as of December 31, 2022. The project proposes to install the proposed dialysis stations in existing space.
- The applicant states Operating Year (OY) one is calendar year (CY) 2023, and OY 2 is CY 2024.

The applicant provides a table in Section C, page 27, and in Section Q, page 83 to illustrate the application of its assumptions and methodology, as shown below:

FMC SERVICES OF WEST FAYETTEVILLE IN-CENTER PATIENTS	
Begin with Cumberland County patient population as of December 31, 2020.	151
Project the Cumberland County patient population forward one year to December 31, 2021, using the Cumberland County Five-Year AACR (5.2%).	$151 \times 1.052 = 158.9$
Project the Cumberland County patient population forward one year to December 31, 2022, using the Cumberland County Five-Year AACR (5.2%).	$158.9 \times 1.052 = 167.1$
Subtract the 13 patients projected to transfer their care to FKC Hope Mills.	$167.1 - 13 = 154.1$
Add the 21 patients from other counties. This is the projected starting census for this project.	$154.1 + 21 = 175.1$
Project the Cumberland County patient population forward one year to December 31, 2023, using the Cumberland County Five-Year AACR (5.2%).	$154.1 \times 1.052 = 162.1$
Add the 21 patients from other counties. This is the projected ending census for Operating Year 1.	$162.1 + 21 = 183.1$
Project the Cumberland County patient population forward one year to December 31, 2024, using the Five-Year AACR (5.2%).	$162.17 \times 1.052 = 170.6$
Add the 21 patients from other counties. This is the projected ending census for Operating Year 2.	$170.6 + 21 = 191.6$

Totals may not sum due to rounding

As shown in the tables above, the applicant projects FMC Services of West Fayetteville will serve 183.1 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 4.16 patients per station per week or 104% [$183.1 \text{ patients} / 44 \text{ stations} = 4.161 \text{ patients per station per week}$. $4.161 / 4 = 1.04$]. By the end of OY2 (December 31, 2024), following the applicant’s methodology and assumptions, the facility will have 191.6 in-center patients dialyzing at the center for a utilization rate of 108% [$191.6 / 44 = 4.354$; $4.354 / 4 = 1.08$]. The projected utilization exceeds the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census of the most recent historical patient census for the facility prior to submission of the application.
- The applicant projects the growth of the Cumberland County patient census using the Five-Year AACR of 5.2%, as reported in the 2021 SMFP.
- The projected utilization rate by the end of OY 1 is above the minimum standard of 2.8 patients per station per week

Access to Medically Underserved Groups

In Section C.6, page 31, the applicant discusses access to the facility’s services, stating:

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

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

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

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

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	41.5%
Racial and ethnic minorities	77.4%
Women	42.1%
Persons with disabilities	23.8%
Persons 65 and older	43.9%
Medicare beneficiaries	51.2%
Medicaid recipients	22.0%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The Fresenius corporate policy commits to provide services to all patients referred for ESRD services
- Fresenius’ facilities have historically provided care to all in need of ESRD services, including underserved persons

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

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

NA

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

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

CA

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

In Section E, page 39, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states that failure to apply for additional stations would result in higher utilization rates because the projected number of patients to be served would be dialyzing on 38 rather than 44 dialysis stations. This would result in higher utilization and would potentially interrupt patient admission to the facility. The applicant states this is the least effective alternative.
- Add fewer stations – The applicant states that this alternative would also result in high utilization rates at the facility. Therefore, the applicant determined that this was not an effective alternative.
- Apply for more than six stations – The applicant states this alternative would result in significantly higher expenditures to expand the building. Therefore, the applicant states this is not an effective alternative.

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

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

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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than six in-center stations for a total of no more than 44 stations at FMC Services of West Fayetteville upon completion of this project, Project ID #M-12106-21 (add four stations) and Project ID #M-12129-21 (relocate six stations to Fresenius Kidney Care Hope Mills).**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on August 1, 2022. The second progress report shall be due on November 1, 2022 and so forth.**

4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

Capital and Working Capital Costs

In Section F.1, page 40, and Section F.3, page 41, the applicant states it will not incur any capital or working capital costs for this project, since the project calls for adding stations to existing space.

Financial Feasibility

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

FMC SERVICES OF WEST FAYETTEVILLE	1 ST FULL FY CY 2023	2 ND FULL FY CY 2024
Total Treatments, including HH and PD Treatments and Training Days	27,472	27,727
Total Gross Revenue (charges)	\$172,824,120	\$174,427,605
Total Net Revenue	\$7,327,125	\$7,395,107
Average Net Revenue per Treatment	\$267	\$267
Total Operating Expenses (costs)	\$6,094,791	\$6,171,564
Average Operating Expense per Treatment	\$222	\$223
Net Income	\$1,232,334	\$1,223,534

The applicant's net income in its Form F.2 appears to contain errors: the applicant lists *Net Income* for PY 1 as \$1,262,134 and PY 2 as \$1,252,344. The errors do not affect the reasonableness of the applicant's projections. The *Net Income* amounts reflected in the table above represent the correct figures.

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

- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* FMC Services of West Fayetteville is located in Cumberland County. Thus, the service area for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina, Inc. (BMA), currently operate five dialysis centers in Cumberland County, and is the only provider of dialysis services in Cumberland County. The following table shows the existing and approved dialysis facilities in Cumberland County, from Table 9A, page 121 of the 2021 SMFP:

Cumberland County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/20	IN-CENTER PATIENTS 12/31/20	UTILIZATION PERCENT 12/31/20
Fayetteville Kidney Center	56	167	74.55%
FMC Dialysis Services North Ramsey	40	152	95.00%
FMC Dialysis Services South Ramsey	47	163	86.70%
FMC Services of West Fayetteville	40	173	108.13%
Fresenius Kidney Care Rockfish	25	68	68.00%

Source: ESRD Data Collection Forms and application Section G, page 47.

In Section G, page 48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County. The applicant states that this application is based upon facility performance and demonstrated need at FMC Services of West Fayetteville and is not specific to Cumberland County as a whole. The applicant states:

“This is an application based upon the facility performance and demonstrated need at the FMC Services West Fayetteville [sic]. The need addressed by this application is not specific to Cumberland County as a whole.

...four of the five dialysis facilities operating in Cumberland County were operating at or above the 70% utilization threshold as of December 31, 2020. Only the FKC Rockfish facility utilization was less than 70%. The FKC Rockfish facility has been utilized at a COVID 19 facility; consequently, utilization is artificially decreased as half of the facility treatment schedule is set aside for COVID 19 patients.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates that FMC Services of West Fayetteville needs the additional stations as proposed to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed addition of six dialysis stations is needed at the facility and would have no adverse impact on the existing and approved stations in Cumberland County as a whole.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

In Section Q, Form H, the applicant provides current (as of November 15, 2021) and projected full-time equivalent (FTE) positions for FMC Services of West Fayetteville, as shown in the following table:

POSITION	CURRENT FTE POSITIONS	INTERIM CY 2022	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00	1.00
RN	8.00	8.00	8.00	8.00
Patient Care Technician (PCT)	21.00	21.00	21.00	21.00
Dietician	1.00	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00	1.00
Administration/Business Office	2.00	2.00	2.00	2.00
FMC Director Operations	0.15	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15	0.15
FMC In-Service	0.25	0.25	0.25	0.25
Total	35.55	35.55	35.55	35.55

Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 50-51, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at this facility.
- The applicant has existing policies in place regarding recruitment, training and continuing education, and will continue to abide by those policies.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

Ancillary and Support Services

In Section I, page 52, the applicant identifies each ancillary and support service listed in the application as necessary for the existing and proposed dialysis services. On pages 52-57, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at FMC Services of West Fayetteville and ancillary and support services are currently in place.
- The applicant explains how it provides each necessary ancillary and support service at the facility and how it will continue to provide the same services following the addition of stations.

Coordination

In Section I, page 57, the applicant describes its existing relationships with other local health care and social service providers.

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

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

- The applicant states the same relationships will be in place following the proposed addition of stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective January 1, 1987.

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

NA

In Section K, page 60, the applicant states there is no construction or renovation associated with the proposed project, since the proposed stations will replace stations relocated from this facility. 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 65, the applicant provides the in-center dialysis historical payor mix during CY 2020 for FMC Services of West Fayetteville, as illustrated in the table below:

**Historical Payor Mix (CY 2020)
 FMC Services of West Fayetteville**

PRIMARY PAYOR SOURCE AT ADMISSION	IN-CENTER DIALYSIS	
	# Pts.	% OF TOTAL
Self-Pay	1.9	1.1%
Insurance*	7.2	4.2%
Medicare*	147.6	85.3%
Medicaid*	9.1	5.2%
Other (Misc., includes VA)	7.3	4.2%
Total	173	100.0%

*Includes any managed care plans

In Section L, page 66, the applicant provides the following comparison of facility patients and the service area population:

FMC SERVICES OF WEST FAYETTEVILLE	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY, CY2020	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	42.1%	50.4%
Male	57.9%	49.6%
Unknown	--	--
64 and Younger	56.1%	87.8%
65 and Older	43.9%	12.2%
American Indian	0.0%	1.9%
Asian	0.6%	2.7%
Black or African-American	76.8%	39.1%
Native Hawaiian or Pacific Islander	0.0%	0.4%
White or Caucasian	22.6%	42.4%
Other Race	0.0%	13.5%
Declined / Unavailable	0.0%	--

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 67, the applicant states that FMC Services of West Fayetteville is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 67, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3(a), page 68, the applicant projects payor mix for the proposed services during the second full fiscal year of operation following project completion, as summarized in the table below:

Projected Payor Mix (CY 2024)
FMC Services of West Fayetteville

PRIMARY PAYOR SOURCE AT ADMISSION	IN-CENTER PATIENTS	
	# PTS.	% OF TOTAL
Self-Pay	2.1	1.1%
Insurance*	8.0	4.2%
Medicare*	163.4	85.3%
Medicaid*	10.0	5.2%
Other (Misc., includes VA)	8.0	4.2%
Total	191.6	100.0%

*Includes any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.1% of IC dialysis services will be provided to self-pay patients, 85.3% to Medicare recipients and 5.2% to Medicaid recipients.

On page 68, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant bases payor mix on current and historical treatment volumes at the facility.
- The applicant bases future payor mix percentages on CY 2020 payor mix percentages for treatment volumes.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 70, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

In Section M, page 71, 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-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides documentation of its willingness to provide applicable health professional training programs in the area with access to the facility.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

The applicant proposes to add no more than six dialysis stations to FMC Services of West Fayetteville pursuant to Condition 2 of the facility need methodology for a total of no more than 44 stations upon completion of this project, Project ID# M-012106-21 (add 4) and Project ID# M-012129-21 (relocate 6).

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* FMC Services of West Fayetteville is located in Cumberland County. Thus, the service area for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina, Inc. (BMA), currently operate five dialysis centers in Cumberland County, and is the only provider of dialysis services in Cumberland County. The following table shows the existing and approved dialysis facilities in Cumberland County, from Table 9A, page 121 of the 2021 SMFP:

Cumberland County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/20	IN-CENTER PATIENTS 12/31/20	UTILIZATION PERCENT 12/31/20
Fayetteville Kidney Center	56	167	74.55%
FMC Dialysis Services North Ramsey	40	152	95.00%
FMC Dialysis Services South Ramsey	47	163	86.70%
FMC Services of West Fayetteville	40	173	108.13%
Fresenius Kidney Care Rockfish	25	68	68.00%

Source: ESRD Data Collection Forms and application Section G, page 47.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 72, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Cumberland 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 73, the applicant states:

“The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 773, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 73, the applicant states:

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

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

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section Q Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility was found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*". After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective January 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may

vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility.

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

(1) *an existing dialysis facility; or*

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

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

-C- In Section C and Section Q, Form C, the applicant documents the need for the six stations as proposed. The applicant projects to serve 183.1 patients at the end of the first 12 months of operation following certification of the proposed additional stations, which is 4.16 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 26-27, and in the Assumptions following Form C in Section Q, pages 82-83, the applicant provides the assumptions and methodology it used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.