

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 8, 2021

Findings Date: December 8, 2021

Project Analyst: Tanya M. Saporito

Co-signer: Lisa Pittman

Project ID #: M-12129-21

Facility: Fresenius Kidney Care Hope Mills

FID #: 170235

County: Cumberland

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

Project: Develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville

### 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.

NA

Bio-Medical Applications of North Carolina, Inc., hereinafter referred to as “the applicant”, proposes to develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

The applicant does not propose to:

- develop any services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP).
- acquire any medical equipment for which there is a need determination in the 2021 SMFP.

- offer a new institutional health service for which there are any policies in the 2021 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective January 1, 1987.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 develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

**Patient Origin**

The applicant proposes to develop a new 20-station dialysis facility, Fresenius Kidney Care Hope Mills (“FKC Hope Mills”), by relocating eight stations from Fayetteville Kidney Center, six stations from FMC Dialysis Services South Ramsey and six stations from FMC Services of West Fayetteville.

The following table illustrates the projected in-center patient origin at FKC Hope Mills in the second full fiscal year (FY) of operation, calendar year (CY) 2024:

COUNTY	PROJECTED PATIENT ORIGIN IN-CENTER PATIENTS	
	01/01/2024-12/31/2024*	
	PATIENTS	% OF TOTAL
Cumberland	62.0	100.0%
<b>Total</b>	<b>62.0</b>	<b>100.0%</b>

Source: Section C.3, page 26

\*The applicant identifies this year as calendar year (CY) 2025 in the table on page 26; however, based on information in the remainder of the application, the Project Analyst determined that this is a typographical error.

The facility does not presently serve home training patients and does not propose to develop those services as part of this project.

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 includes 56 patient letters of support.... These letters demonstrate that 56 in-center dialysis patients, residing in Cumberland County, desire to transfer their care to the new facility upon completion of the project.”*

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

- The applicant includes letters signed by existing patients dialyzing in a different Cumberland County BMA facility which state the patient would consider transferring their care to the proposed facility.
- The applicant begins the facility census with those 56 patients.
- The applicant projects facility census growth using the 5.2% Five Year Average Annual Change Rate (AACR) for Cumberland County published.
- The applicant uses only existing BMA patients who indicated an intent to transfer their care and does not add any outside patients to the census.

### **Analysis of Need**

In Section C.4, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states the proposal is to develop a new 20-station dialysis facility that will be closer to existing patients’ residences by relocating existing stations from three existing dialysis facilities.
- The applicant states developing the facility as proposed will enhance access to care for BMA patients.
- The applicant provided maps that illustrate existing BMA facilities in Cumberland County and patient residences by ZIP code, which also illustrate the proposed location of the FKC Hope Mills facility.

On page 29, 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. ... The applicant has identified the population to be served as 58.9 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 73.64%, or 2.95 patients per station and exceeds the minimum required by the performance standard.”*

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

- The applicant identifies existing patients currently dialyzing one of three Cumberland County BMA facilities as the beginning patient base for the facility.
- The applicant applies the Cumberland County Five Year AACR as provided in the 2021 SMFP to project utilization.

- The applicant demonstrates that the proposed facility will serve the projected patient population at a rate that exceeds the minimum performance standard set forth at 10A NCAC 14C .2203(7).

Projected Utilization

In Section Q, the applicant provides a table to illustrate projected utilization, as shown below:

FORM C UTILIZATION IN-CENTER PATIENTS	FIRST FULL OY 1/1/23-12/31/23	SECOND FULL OY 1/1/24-12/31/24
# of Patients at the Beginning of the Year	1	56
# of Patients at the End of the Year	56	59
Average # of Patients during the Year	48	57
# of Treatments / Patient / Year	148	148
<b>Total # of Treatments</b>	<b>6,922</b>	<b>8,503</b>

In Section C, pages 26-27 and Section Q, pages 94-95, the applicant provides the assumptions and methodology used to project in-center utilization, summarized below:

- The applicant states 56 in-center dialysis patients who currently dialyze at an existing BMA facility in Cumberland County have signed letters which indicate that patient’s willingness to consider switching their care to the proposed facility because it would be closer to their residence.
- The applicant states it has identified an existing building that can be retrofitted as a dialysis facility.
- The applicant projects facility certification by December 31, 2022.
- The first full FY is OY 1, CY 2023.
- The second full FY is OY 2, CY 2024.
- In-center utilization projections begin with a facility census as of December 31, 2022 of 56 patients, reflecting the 56 existing BMA patients who signed letters indicating a willingness to transfer to FKC Hope Mills.
- The applicant applies the Cumberland County Five Year AACR as published in the 2021 SMFP to project patient utilization.

The applicant provides a table in Section C, page 27, and in Section Q, page 95 to illustrate the application of its assumptions and methodology, as shown below:

Begin with BMA patient population who signed letters indicating willingness to transfer upon project completion, December 31, 2022.	56
Project Cumberland County patient population forward one year to 12/31/2023, using Cumberland County Five Year AACR. This is the end of OY 1.	$56 \times 1.052 = 58.9$
Project Cumberland County patient population forward one year to 12/31/2024, using Cumberland County Five Year AACR. This is the end of OY 2.	$58.9 \times 1.052 = 62.0$

As shown in the table above, the applicant projects FKC Hope Mills will serve 59 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 2.95 patients per station per week or 74.0% (59 patients / 20 stations = 2.95;  $2.95 / 4 = 0.7375$ ). By the end of OY 2 (December 31, 2024), following the applicant's methodology and assumptions, the facility will have 62 in-center patients dialyzing at the center for a utilization rate of 78.0% ( $62 / 20 = 3.1$ ;  $3.1 / 4 = 0.775$ ). 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 number of existing BMA patients currently dialyzing at other Cumberland County BMA facilities who have expressed a willingness to transfer their care to FKC Hope Mills.
- The applicant projects the growth of the patient census using the 5.2% Cumberland County Five-Year AACR as reported in the 2021 SMFP.
- The projected utilization rate by the end of OY 1 exceeds the minimum standard of 2.8 patients per station per week

#### **Access to Medically Underserved Groups**

In Section C.6, page 32, the applicant states:

*“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 32, the applicant provides the estimated percentage for each medically underserved group it will serve during OY 2, as shown in the following table:

<b>MEDICALLY UNDERSERVED GROUPS</b>	<b>PERCENTAGE OF TOTAL PATIENTS OY 2</b>
Low income persons	27.6%
Racial and ethnic minorities	80.4%
Women	42.6%
Persons with disabilities	29.9%
Persons 65 and older	45.2%
Medicare beneficiaries	65.3%
Medicaid recipients	27.6%

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

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

## C

The applicant proposes to develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville. In Section D, pages 37-46, the applicant explains why it believes the needs of the population presently utilizing the dialysis stations proposed to be relocated will continue to be adequately met following the relocation of stations as proposed in this application. The applicant projected utilization at each facility, summarized as follows:

Fayetteville Kidney Center

The applicant states Fayetteville Kidney Center is currently certified for 56 dialysis stations and offers both in-center and home dialysis. The applicant filed an application, Project ID #M-12105-21, that was approved on October 14, 2021 to add one station to the existing facility for a total of 57 stations. Following completion of this proposal, Fayetteville Kidney Center would be certified for 49 dialysis stations. The applicant states 30 existing patients who currently dialyze at Fayetteville Kidney Center signed letters for this project, indicating a willingness to transfer to FKC Hope Mills upon project completion. Fayetteville Kidney Center also serves home hemodialysis and peritoneal dialysis patients.

In-Center Utilization

Following is a summary of the methodology and assumptions used by the applicant to project in-center utilization at Fayetteville Kidney Center following the station relocation and transfer of patients:

- The applicant projects growth of the facility census initially through December 31, 2022, the date the stations will be relocated to FKC Hope Mills.
- The applicant begins with the facility census of Fayetteville Kidney Center as of December 31, 2020 and projects patient growth using the Cumberland County Five Year AACR of 5.2% as published in the 2021 SMFP.
- The applicant states the facility was dialyzing two patients who reside in Hoke County, and five in-center patients who reside in Robeson County. Both counties are contiguous to Cumberland County and the applicant projects that those seven patients will continue to dialyze at Fayetteville Kidney Center; therefore, the applicant adds those patients to the projected facility census at appropriate points in time but does not project growth in that specific patient population.
- Thirty existing patients currently dialyzing at Fayetteville Kidney Center have signed letters indicating a willingness to transfer their care to FKC Hope Mills when that facility is certified. The applicant subtracts thirty patients from the projected patient census as of December 31, 2022, the projected certification date for FKC Hope Mills.

In Section C, the applicant provides the assumptions and methodology used to project utilization, summarized in the table below:

Begin with Cumberland County in-center patient population as of December 31, 2020.	160
Project population forward to December 31, 2021, using the Cumberland County Five Year AACR.	$160 \times 1.052 = 168.3$
Project population forward to December 31, 2022.	$168.3 \times 1.052 = 177.1$
Subtract 30 patients projected to transfer care to FKC Hope Mills.	$177.1 - 30 = 147.1$
Add 7 patients from Hoke and Robeson Counties. This is projected utilization as of the certification date for FKC Hope Mills.	$147.1 + 7 = 154.1$
Project Cumberland County population forward to December 31, 2023, using the Cumberland County Five Year AACR.	$147.1 \times 1.052 = 154.7$
Add 7 patients from Hoke and Robeson Counties. This is projected utilization for the end of the first OY of FKC Hope Mills.	$154.7 + 7 = 161.7$
Project Cumberland population forward to December 31, 2024, using the Cumberland County Five Year AACR.	$154.7 \times 1.052 = 162.7$
Add 7 patients from Hoke and Robeson Counties. This is projected utilization for the end of the second OY of FKC Hope Mills.	$162.8 + 7 = 169.7$

The applicant projects that Fayetteville Kidney Center will dialyze 154 patients on 49 in-center stations as of December 31, 2022, the projected certification date for FKC Hope Mills, which is 78.6% utilization ( $154 / 49 = 3.14$ ;  $3.14 / 4 = 0.786$ ). The applicant provided utilization for 48 in-center stations as well, because Project ID #M-12105-21 was under review when this application was filed. Project ID #M-12105-21 (add one dialysis station for a total of 49 stations) was approved on October 14, 2021; therefore, the Project Analyst calculated utilization using 49 rather than 48 in-center stations. Additionally, the applicant projects the facility will serve 170 in-center patients at Fayetteville Kidney Center by the end of the second full fiscal year of operation of FKC Hope Mills (CY 2024), which is 82.7% utilization ( $162 / 49 = 3.31$ ;  $3.31 / 4 = 0.8265$ ).

Home Hemodialysis and Peritoneal Dialysis Utilization

- The applicant begins with the home hemodialysis patient census as of December 31, 2020.
- The applicant projects growth in the Cumberland County patient census using the Cumberland County Five Year AACR of 5.2%, as published in the 2021 SMFP.
- The applicant states Fayetteville Kidney Center was serving two home hemodialysis patients from Hoke County and three home hemodialysis patients from Robeson County. The applicant assumes these patients receive their care at this facility by choice, since Hoke and Robeson counties are contiguous to Cumberland County. The applicant does not project growth of this patient population but adds them to the facility census at the appropriate points in time.
- The applicant states Fayetteville Kidney Center was serving two home peritoneal dialysis patients from Hoke County and three home hemodialysis patients from Robeson County. The applicant assumes these patients receive their care at this facility



by choice, since Hoke and Robeson counties are contiguous to Cumberland County. The applicant does not project growth of this patient population but adds them to the facility census at the appropriate points in time.

In Section C, the applicant provides the assumptions and methodology used to project utilization, summarized in the table below:

	HOME HEMODIALYSIS	HOME PERITONEAL DIALYSIS
Begin with Cumberland County in-center patient population as of December 31, 2020.	39	34
Project population forward to December 31, 2021, using the Cumberland County Five Year AACR.	$39 \times 1.052 = 41.0$	$34 \times 1.052 = 35.8$
Project population forward to December 31, 2022.	$41.0 \times 1.052 = 43.2$	$35.8 \times 1.052 = 37.6$
Add patients from Hoke and Robeson counties. This is the projected census as of December 31, 2022, the projected certification date for FKC Hope Mills.	$43.2 + 5 = 48.2$	$37.6 + 5 = 42.6$
Project Cumberland County population forward to December 31, 2023, using the Cumberland County Five Year AACR.	$43.2 \times 1.052 = 45.4$	$37.6 \times 1.052 = 39.6$
Add patients from Hoke and Robeson counties.	$45.4 + 5 = 50.4$	$39.6 + 5 = 44.6$
Project Cumberland County population forward to December 31, 2024, using the Cumberland County Five Year AACR.	$45.4 \times 1.052 = 47.8$	$39.6 \times 1.052 = 41.6$
Add patients from Hoke and Robeson counties.	$47.8 + 5 = 52.8$	$41.6 + 5 = 46.6$

On page 41, the applicant states:

*“This application to develop FKC Hope Mills will not adversely affect the patients remaining at Fayetteville Kidney Center.*

*...BMA notes 2021 SMFP, [sic] Table 9D...indicates that Fayetteville Kidney Center is eligible to apply for up to nine additional stations in 2021. BMA has already applied for one station. BMA now commits to applying to replace the eight stations being relocated to FKC Hope Mills. BMA of Fayetteville, Inc. will apply for eight stations on November 1, 2021, for the review planned to begin on December 1, 2021.”*

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

- The applicant projects growth of the Cumberland County patients remaining at the facility using the Cumberland County Five Year AACR from the 2021 SMFP.
- The applicant adds Hoke and Robeson county to the facility census at the appropriate points in time, thereby accounting for the patient population dialyzing at the facility who are not Cumberland County residents.
- The applicant subtracts those patients who signed letters indicating an intent to transfer their care to FKC Hope Mills.

FMC Dialysis Services South Ramsey

FMC Dialysis Services South Ramsey (FMC South Ramsey) is currently certified for 47 in-center stations and was approved in August 2021 to add nine dialysis stations, for a total of 56 in-center stations. In this application, the applicant proposes to relocate six stations to FKC Hope Mills; therefore, the following utilization projections for FMC South Ramsey is based on 50 in-center stations [47 + 9 – 6 = 50].

- The applicant states it will project growth of FMC South Ramsey through December 31, 2022, the date the stations are projected to be relocated to FKC Hope Mills.
- The applicant begins with the facility census as of December 31, 2020.
- The applicant projects growth in the Cumberland County patient census using the Cumberland County Five Year AACR of 5.2%, as published in the 2021 SMFP.
- The applicant states the facility was serving two in-center patients who reside in Hoke and Robeson counties, and assumes these patients will continue to dialyze at the facility, since Hoke and Robeson counties are contiguous to Cumberland County. The applicant does not project growth in this patient population but adds these patients to the facility census at the appropriate points in time.
- The applicant states 13 existing in-center patients signed letters indicating a willingness to transfer their care to FKC Hope Mills when that facility is certified. The applicant subtracts those 13 patients from the projected census at the appropriate point in time.

In Section C, the applicant provides the assumptions and methodology used to project utilization, summarized in the table below:

Begin with Cumberland County in-center patient population as of December 31, 2020.	161
Project population forward to December 31, 2021, using the Cumberland County Five Year AACR. This is the date the nine new stations (Project ID #M-12038-21) are projected to be certified.	$161 \times 1.052 = 169.4$
Project Cumberland County population forward to December 31, 2022.	$169.4 \times 1.052 = 178.2$
Subtract 13 patients projected to transfer care to FKC Hope Mills.	$178.2 - 13 = 165.2$
Add 2 patients from Hoke and Robeson Counties. This is projected utilization as of the date the stations are projected to be relocated.	$165.2 + 2 = 167.2$
Project Cumberland County population forward to December 31, 2023, using the Cumberland County Five Year AACR.	$165.2 \times 1.052 = 173.8$
Add 2 patients from Hoke and Robeson Counties.	$173.8 + 2 = 175.8$
Project Cumberland population forward to December 31, 2024, using the Cumberland County Five Year AACR.*	$173.8 \times 10.52 = 182.8$
Add 2 patients from Hoke and Robeson Counties.	$182.8 + 2 = 184.8$

\*The applicant's table includes verbiage that is repeated from one table cell to the next. The Project Analyst determined this to be a typographical error and has no bearing on the analysis or the outcome of this decision.

The applicant states projected utilization of FMC South Ramsey as of December 31, 2022, the projected certification date for FKC Hope Mills, is 167.2 patients dialyzing on 50 in-center stations, which is an 83.5% utilization rate [ $167 / 50 = 3.34$ ;  $3.34 / 4 = 0.835$ ].

On page 43, the applicant states:

*“This application to develop FKC Hope Mills will not adversely affect the patients remaining at FMC South Ramsey.*

*...BMA notes again that the 2021 SMFP ... indicates that FMC South Ramsey is eligible to apply for up to 20 additional stations in 2021. BMA has already applied for nine stations. BMA now commits to applying to replace the six stations being relocated to FKC Hope Mills. BMA will apply for six stations on November 15, 2021, for the review planned to begin on December 1, 2021.”*

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

- The applicant projects growth of the Cumberland County patients remaining at the facility using the Cumberland County Five Year AACR from the 2021 SMFP.
- The applicant adds Hoke and Robeson county to the facility census at the appropriate points in time, thereby accounting for the patient population dialyzing at the facility who are not Cumberland County residents.
- The applicant subtracts those patients who signed letters indicating an intent to transfer their care to FKC Hope Mills.

#### FMC Services of West Fayetteville

FMC Services of West Fayetteville (FMC West Fayetteville) is currently certified for 40 in-center stations. The applicant filed an application, Project ID #M-12106-21, to add four dialysis stations, for a total of 44 in-center stations, with a projected certification date of December 31, 2022. That application is currently under review by the Agency. In this application, the applicant proposes to relocate six stations to FKC Hope Mills; therefore, the following utilization projections for FMC West Fayetteville is based on 38 in-center stations [ $40 + 4 - 6 = 38$ ].

- The applicant states it will project growth of FMC West Fayetteville through December 31, 2022, the date the stations are projected to be relocated to FKC Hope Mills.
- The applicant begins with the facility census as of December 31, 2020.
- The applicant projects growth in the Cumberland County patient census using the Cumberland County Five Year AACR of 5.2%, as published in the 2021 SMFP.
- The applicant states the facility was serving 21 in-center patients who reside in Hoke, Sampson and Robeson counties, and assumes these patients will continue to dialyze at the facility, since Hoke, Sampson and Robeson counties are contiguous to Cumberland County. The applicant does not project growth in this patient population but adds these patients to the facility census at the appropriate points in time.
- The applicant states the facility was serving one patient who resides in Wake County but assumes this patient to be a transient patient since Wake County is not contiguous

to Cumberland County. The applicant does not project growth of that one patient or add that patient to the facility census.

- The applicant states 13 existing in-center patients signed letters indicating a willingness to transfer their care to FKC Hope Mills when that facility is certified. The applicant subtracts those 13 patients from the projected census at the appropriate point in time.

In Section C, the applicant provides the assumptions and methodology used to project utilization, summarized in the table below:

Begin with Cumberland County in-center patient population as of December 31, 2020.	151
Project population forward to December 31, 2021, using the Cumberland County Five Year AACR.	$151 \times 1.052 = 158.9$
Project Cumberland County population forward to December 31, 2022.	$158.9 \times 1.052 = 167.1$
Subtract 13 patients projected to transfer care to FKC Hope Mills.	$167.1 - 13 = 154.1$
Add 21 patients from Hoke, Sampson and Robeson Counties. This is projected utilization as of the date the stations are projected to be relocated.	$154.1 + 21 = 175.1$
Project Cumberland County population forward to December 31, 2023, using the Cumberland County Five Year AACR.	$154.1 \times 1.052 = 162.1$
Add 21 patients from Hoke and Robeson Counties.*	$162.1 + 21 = 183.1$
Project Cumberland population forward to December 31, 2024, using the Cumberland County Five Year AACR.*	$162.1 \times 1.052 = 170.6$
Add 21 patients from Hoke, Sampson and Robeson Counties.	$170.6 + 21 = 191.6$

\*The applicant's table includes verbiage that is repeated from one table cell to the next. The Project Analyst determined this to be a typographical error and has no bearing on the analysis or the outcome of this decision.

The applicant states projected utilization of FMC West Fayetteville as of December 31, 2022, the projected certification date for FKC Hope Mills, is 175.1 patients dialyzing on 38 in-center stations, which is a 115% utilization rate [ $175 / 38 = 4.61$ ;  $4.61 / 4 = 1.151$ ].

On page 45, the applicant states it operates a third shift at FMC West Fayetteville to accommodate its patients and avoid facility overcrowding.

On page 46, the applicant states:

*"This application to develop FKC Hope Mills will not adversely affect the patients remaining at FMC West Fayetteville.*

*...BMA further notes that FMC West Fayetteville does qualify to apply for 14 additional stations in 2021. The 2021 SMFP ... indicates the facility may apply for up to 18 stations in 2021; the facility has already applied for four stations. BMA commits to applying to replace the six stations being relocated to FKC Hope Mills.*

*BMA will apply for six stations on November 15, 2021, for the review planned to begin on December 1, 2021.”*

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

- The applicant projects growth of the Cumberland County patients remaining at the facility using the Cumberland County Fiver Year AACR from the 2021 SMFP.
- The applicant adds Hoke, Sampson and Robeson county to the facility census at the appropriate points in time, thereby accounting for the patient population dialyzing at the facility who are not Cumberland County residents.
- The applicant subtracts those patients who signed letters indicating an intent to transfer their care to FKC Hope Mills.

Access to Medically Underserved Groups

On page 46, the applicant provides a table, reproduced below, to illustrate the effects of the proposed relocation of stations from each of the facilities:

	FAYETTEVILLE KIDNEY CENTER	FMC SOUTH RAMSEY	FMC WEST FAYETTEVILLE	AVERAGE
Low Income Persons	20.0%	45.3%	21.8%	27.7%
Racial/Ethnic Minorities	77.1%	88.2%	77.6%	80.4%
Women	38.0%	49.1%	43.0%	42.6%
Handicapped	29.4%	37.3%	23.6%	29.9%
Elderly	39.2%	54.0%	45.5%	45.2%
Medicare	65.7%	79.5%	50.9%	65.3%
Medicaid	20.0%	45.3%	21.8%	27.7%
American Indian	3.3%	2.5%	0.0%	2.1%
Asian	1.2%	0.0%	0.6%	0.7%
African American	65.3%	80.1%	77.0%	72.9%
Hawaiian	2.4%	0.0%	0.0%	1.1%
White	22.9%	11.8%	22.4%	19.6%
Other	4.1%	5.6%	0.0%	3.3%
Declined	0.8%	20.0%	0.0%	0.4%

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use the dialysis facilities will be adequately met following completion of the project for all of the reasons described above.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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 develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

In Section E, pages 49-50, 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 develop FKC Hope Mills would fail to bring dialysis treatments close to patients' residences, thereby lessening commute time and reducing stress for patients. Therefore, the applicant states this alternative is less effective.
- Develop FKC Hope Mills with more than 20 stations – The applicant states that this alternative would not meet its goal of making dialysis treatments more convenient for patients and would necessarily draw patients who reside further away from FKC Hope Mills; therefore, the applicant determined that this was not the most effective alternative.
- Develop FKC Hope Mills with fewer than 20 stations – The applicant states that this alternative would not meet its goal of making dialysis treatments more convenient for patients because it would not meet the need of existing dialysis patients residing in the area of the proposed facility; therefore, the applicant determined that this was not the most effective alternative.
- Include home therapies at FKC Hope Mills – The applicant states that this alternative would not help contain costs at the proposed facility, because it would require more space and necessarily more capital to develop space for home therapies. The chosen location and facility has the available space for the project as proposed, and Fayetteville Kidney Center has sufficient capacity to meet the home patients it serves.

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

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

## **Conclusion**

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.**
- 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 April 1, 2021. The second progress report shall be due on July 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 develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below:

Construction	\$1,686,310
Architect/Engineering Fees	\$151,768
Miscellaneous Costs	\$611,011
<b>Total</b>	<b>\$2,449,079</b>

In Section Q, Form F.1a, page 87, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the applicant's experience regarding what is required to add the nine additional dialysis stations, including water treatment system, patient TVs, and dialysis chairs.

In Section F, page 53, the applicant projects that start-up costs will be \$170,601 and initial operating expenses will be \$954,961 for a total working capital of \$1,125,562. On page 54, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant describes each item that makes up the projected capital cost.
- The applicant provides the individual and combined cost of each item that makes up the projected capital cost.
- The applicant describes how it projects start-up costs and initial operating expenses, including allowance for salaries and the time to be allotted.

**Availability of Funds**

In Section F, page 51, the applicant states that the capital cost will be funded as shown in the table below.



**Sources of Capital Cost Financing**

TYPE	BMA	TOTAL
Loans	\$0	\$0
Cash/Cash Equivalents/Accumulated reserves or OE *	\$2,449,079	\$2,449,079
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$2,449,079</b>	<b>\$2,449,079</b>

\*OE = Owner's Equity

Exhibit F-2 contains a September 15, 2021 letter from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., confirming the availability of sufficient funds and authorizing the use of accumulated reserves for the capital needs of the project. The letter states that in their 2020 Consolidated Balance Sheet, Fresenius Medical Care Holdings, Inc. had over \$446 million in cash and over \$25 billion in assets to fund the capital cost of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The availability of funds in accumulated reserves provided in Exhibit F-2.
- Documentation of the applicant's intent to fund the project provided in Exhibit F-2.

**Financial Feasibility**

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

	1 <sup>ST</sup> FFY (CY 2023)	2 <sup>ND</sup> FFY (CY 2024)
Total Treatments	6,922	8,946
Total Gross Revenues (Charges)	\$43,547,403	\$56,277,206
Total Net Revenue	\$1,821,169	\$2,353,534
Average Net Revenue per Treatment	\$263	\$263
Total Operating Expenses (Costs)	\$1,833,016	\$2,079,433
Average Operating Expense per Treatment	\$265	\$232
Net Income	(\$61,847)	\$274,101

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 the applicant's experience in developing and operating similar dialysis facilities.

- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing at similar dialysis facilities operated by the applicant and projected average annual salary increases of 2.0%
- 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
- Supplemental information requested 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 demonstrates sufficient funds for the operating needs of the proposal
  - The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

The applicant proposes to develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

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.”* FKC Hope Mills is proposed to be 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 (BMA), currently operate five dialysis facilities 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, pages 130-131 of the 2021 SMFP:

**Cumberland County Dialysis Facilities**

<b>DIALYSIS FACILITY</b>	<b>CERTIFIED STATIONS 12/31/20</b>	<b>IN-CENTER PATIENTS 12/31/20</b>	<b>UTILIZATION PERCENT 12/31/20</b>
FMC West Fayetteville	40	173	108.13%
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%
Fresenius Kidney Care Rockfish	25	68	68.00%
<b>Total</b>	<b>208</b>	<b>723</b>	<b>86.90%</b>

Source: 2021 SMFP, Table 9A.

\*Project ID #M-12101-21, currently under review, proposes to add four in-center stations to this facility.

In Section G, page 59, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County, stating that the application proposes to relocate existing dialysis stations to develop a new facility. Therefore, there are no new dialysis stations proposed and the application does not seek to duplicate existing dialysis services in the county.

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 FKC Hope Mills is needed to serve existing and projected Cumberland County dialysis patient patients served by BMA.
- The applicant adequately demonstrates that the proposed location would better serve existing and projected patients, and is needed in Cumberland County

**Conclusion**

The Agency reviewed the:

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

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

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

The applicant proposes to develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the BMA Raleigh facility, as summarized in the following table:

<b>Position</b>	<b>FTE Positions OY 1</b>	<b>FTE Positions OY 2</b>
Administrator	1.00	1.00
Registered Nurse	2.00	2.00
Patient Care Technician (PCT)	4.00	4.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.25	0.25
Administration/Business Office	0.50	0.50
FMC Director of Operations	0.15	0.15
Chief Technician	0.15	0.15
FMC In-Service	0.15	0.15
<b>Total</b>	<b>9.20</b>	<b>9.20</b>

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.3, page 62, 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 applicant bases its staffing on its historical experience providing dialysis services at similar facilities operated by the applicant.
- The applicant has existing policies in regard to recruitment, training and continuing education for its staff.

**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 develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

**Ancillary and Support Services**

In Section I, page 63, the applicant identifies each ancillary and support service identified in the application as necessary for the proposed dialysis services. On pages 63-68, 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 other facilities in Cumberland County and North Carolina.
- The applicant discusses how it will provide each necessary ancillary and support service at FKC Hope Mills.

**Coordination**

In Section I, page 68, the applicant describes its existing relationships with other local health care and social service providers.

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

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective January 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

The applicant proposes to develop the facility in an existing shell building and upfit existing space to accommodate the dialysis stations.

In Section K, page 71, the applicant states that the project involves renovating 9,421 square feet in the shell building. Line drawings are provided in Exhibit K-2.

In Exhibit K-4, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. The site appears to be suitable for the proposed dialysis facility based on the applicant's representations and supporting documentation.

On pages 71-72, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal, stating it relies on the expertise of the Fresenius Medical Care Real Estate and Construction Services team to develop this and similar projects, and this team utilizes a national data base to ensure project costs are reasonable and accurate.

On page 72, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the applicant states the project is a necessary part of doing business and providing dialysis services to the patients in Cumberland County it serves. The applicant states the costs of development are not passed to the patient, but are borne by the applicant and will not increase costs of providing dialysis to the patients.

On page 72, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-4.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 76, the applicant provides the historical payor mix for in-center dialysis during CY 2020 for Fayetteville Kidney Center, FMC Dialysis Services South Ramsey and FMC Services of West Fayetteville, the facilities located in Cumberland County that will be donating stations, as summarized in the table below:

Fayetteville Kidney Center, in-center patients, home hemodialysis (HD) patients and peritoneal dialysis (PD) patients:

PAYOR SOURCE	IN-CENTER PTS.		HD PATIENTS		PD PATIENTS	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Self-Pay	2.4	1.43%	0.1	0.32%	0.3	0.74%
Insurance*	5.6	3.35%	8.8	19.92%	6.7	17.10%
Medicare*	138.8	83.09%	28.0	63.58%	28.2	72.37%
Medicaid*	11.9	7.14%	1.1	2.53%	0.4	0.93%
Other (incl. VA)	8.3	4.98%	6.0	13.65%	3.5	8.86%
<b>Total</b>	<b>167</b>	<b>100.00%</b>	<b>44</b>	<b>100.00%</b>	<b>39</b>	<b>100.00%</b>

\*Includes managed care plans

FMC Dialysis Services South Ramsey:

PAYOR SOURCE	IN-CENTER PATIENTS	
	# PTS.	% OF TOTAL
Self-Pay	2.3	1.41%
Insurance*	6.7	4.01%
Medicare*	136.2	81.58%
Medicaid*	9.9	5.93%
Other (incl. VA)	11.8	7.07%
<b>Total</b>	<b>167</b>	<b>100.00%</b>

\*Includes managed care plans

FMC Dialysis Services of West Fayetteville:

PAYOR SOURCE	IN-CENTER PATIENTS	
	# PTS.	% OF TOTAL
Self-Pay	1.9	1.08%
Insurance*	7.2	4.17%
Medicare*	147.6	85.32%
Medicaid*	9.1	5.23%
Other (incl. VA)	7.3	4.20%
<b>Total</b>	<b>173</b>	<b>100.00%</b>

\*Includes managed care plans



In Section L, page 77, the applicant provides the following comparison for facility patients and the service area population:

<b>BMA RALEIGH</b>	<b>PERCENTAGE OF TOTAL PATIENTS TO BE SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY, CY2020</b>	<b>PERCENTAGE OF THE POPULATION OF THE SERVICE AREA</b>
Female	42.6%	50.4%
Male	57.4%	49.6%
Unknown	--	--
64 and Younger	54.8%	87.8%
65 and Older	45.2%	12.2%
American Indian	2.10%	1.9%
Asian	0.7%	2.7%
Black or African-American	72.9%	39.1%
Native Hawaiian or Pacific Islander	1.1%	0.4%
White or Caucasian	19.6%	42.4%
Other Race	3.3%	13.5%
Declined / Unavailable	--	--

On pages 78-79, the applicant provides the same comparison for each of the three facilities that will donate stations to FKC Hope Mills.

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 79, the applicant states that FKC Hope Mills 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 79, 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 80, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

PAYOR SOURCE	IN-CENTER PATIENTS	
	# PTS.	% OF TOTAL
Self-Pay	0.8	1.3%
Insurance*	2.4	3.8%
Medicare*	51.6	83.3%
Medicaid*	3.8	6.1%
Other (incl. VA)	3.4	5.4%
<b>Total</b>	<b>62.0</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.3% of in-center dialysis services will be provided to self-pay patients, 83.3% to Medicare recipients and 6.1% to Medicaid recipients.

On page 80, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant bases payor mix upon treatment volumes rather than patients.
- The applicant bases future payor mix percentages on CY 2020 payor mix percentages for treatment volumes in its other Cumberland County facilities.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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, pages 81-82, 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 develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

In Section M, page 83, 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. 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
- 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 develop a new 20-station dialysis facility by relocating no more than eight stations from Fayetteville Kidney Center, no more than six stations from FMC Dialysis Services South Ramsey and no more than six stations from FMC Services of West Fayetteville.

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.” FKC Hope Mills is proposed to be 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 (BMA), currently operate five dialysis facilities 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, pages 130-131 of the 2021 SMFP:

**Cumberland County Dialysis Facilities**

<b>DIALYSIS FACILITY</b>	<b>CERTIFIED STATIONS 12/31/20</b>	<b>IN-CENTER PATIENTS 12/31/20</b>	<b>UTILIZATION PERCENT 12/31/20</b>
FMC West Fayetteville	40	173	108.13%
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%
Fresenius Kidney Care Rockfish	25	68	68.00%
<b>Total</b>	<b>208</b>	<b>723</b>	<b>86.90%</b>

Source: 2021 SMFP, Table 9A.

\*Project ID #M-12101-21, currently under review, proposes to add four in-center stations to this facility.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, 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 85, the applicant states:

*“This is a proposal to relocate 20 in-center dialysis stations to develop a new facility in Hope Mills, Cumberland County. 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 of the area in a convenient setting.”*

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

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

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

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

See also Sections B, 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 85, the applicant states:

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

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

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

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

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

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

## C

The 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.*
- C- In Section C and Section Q, Form C, the applicant documents that the proposed facility will dialyze 59 in-center patients on 20 stations as of the end of the first 12 months of operation following certification of the facility, which is 2.95 patients per station per week [59 / 20 = 2.95].
- (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.*

- NA- The applicant does not propose to increase the number of dialysis stations in an existing facility, or a facility that has been issued a certificate of need as of the date this application was submitted but is not operational.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-29, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.