

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 27, 2021

Findings Date: April 27, 2021

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: E-11994-20

Facility: FMC Hickory Home Program

FID #: 110873

County: Catawba

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

Project: Relocate no more than 3 dialysis stations from FMC Hickory for a total of no more than 5 dialysis stations to provide home hemodialysis training and support services

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Medical Care Hickory Home Program (hereinafter referred to as “the applicant” or FMC Hickory Home), proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory, an in-center dialysis facility, to FMC Hickory Home, a dialysis facility that provides exclusively home dialysis training and support. Following the proposed station relocation, FMC Hickory will have 30 in-center stations, and FMC Hickory Home will have five dialysis stations to provide home hemodialysis training and support services.

Need Determination

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

stations. According to Table 9D, page 170, the county need methodology shows there is no county need determination for additional dialysis stations in Catawba County. The applicant is proposing to relocate existing dialysis stations; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

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

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

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

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

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

Conclusion

The Agency reviewed the:

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

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

- Neither the county nor facility need methodology is applicable to this review.

- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Catawba County.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program.

Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

The following tables, summarized from data on page 7 of the application, show the projected number of stations at FMC Hickory and FMC Hickory Home upon project completion:

FMC Hickory Home Program

STATIONS	DESCRIPTION	PROJECT ID#
2	Total # existing certified stations in the SMFP in effect on the day the review will begin	
3	Stations to be added as part of this project	E-11994-20
5	Total stations upon completion of proposed project and previously approved projects	

FMC Hickory

STATIONS	DESCRIPTION	PROJECT ID#
33	Total # existing certified stations in the SMFP in effect on the day the review will begin	
-3	Stations to be deleted as part of this project	E-11994-20
20	Total stations upon completion of proposed project and previously approved projects	

The project analyst notes that the table on page 7, reproduced above, incorrectly indicates that there will be a total of 20 stations at FMC Hickory following the proposed three-station relocation. The project analyst concludes that the insertion of the number 20 in the table is in error and the correct number of “*Total stations upon completion of proposed project and previously approved projects*” is 30 [33 – 3 = 30].

Patient Origin

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

The following table illustrates historical and projected patient origin for home hemodialysis (HHD) patients and peritoneal dialysis (PD) patients for calendar years 2019 and 2023 (CY 2019, CY 2023), from application page 17:

COUNTY	LAST FULL OPERATING YEAR (OY) CY 2019				SECOND FULL OPERATING YEAR CY 2023			
	# HHD PTS	% OF TOTAL	# PD PTS	% OF TOTAL	# HHD PTS	% OF TOTAL	# PD PTS	% OF TOTAL
Catawba	8	88.89%	25	83.33%	10.4	83.90%	32.20	75.80%
Alexander	0	0.00%	2	6.67%	1.00	8.10%	3.00	7.30%
Burke	0	0.00%	2	6.67%	0.00	0.00%	6.00	14.50%
Caldwell	1	11.11%	1	3.33%	1.00	8.10%	1.00	2.40%
Total	9	100.00%	30	100.00%	12.40	100.00%	41.20	100.00%

In Section C.3, pages 18-20, the applicant provides the assumptions and methodology used to project its patient origin. On page 18, the applicant begins with the patient origin for existing home dialysis patients for FMC Hickory Home as of June 30, 2020. The applicant’s assumptions are reasonable and adequately supported because they are based on the historical patient origin for home dialysis patients for FMC Hickory Home as of June 30, 2020.

Analysis of Need

In Section C.4, pages 20-21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- Home dialysis patients (both HHD and PD) require the same regular dialysis regimen as those patients who prefer or need in-center dialysis. Home training offers additional methods by which a patient can dialyze.
- The project will enhance patient training opportunities and allow more FMC Hickory Home patients to choose home dialysis.
- Dialysis settings which are not convenient for the patient will adversely affect patient compliance and could lead to missed treatments. Home dialysis affords patients with maximum convenience and improves compliance.

The information is reasonable and adequately supported because the applicant demonstrates that home dialysis provides patients with the necessary dialysis regimen by additional methods and more convenient schedules. This will ultimately lead to a reduction in missed treatments and will improve patient compliance.

Projected Utilization

In Section Q, page 72, the applicant projects to serve the following HHD and PD patients in the first two operating years:

FMC HICKORY HOME PROGRAM	OY 1 (CY 2021)		OY 2 (CY 2022)	
	HHD	PD	HHD	PD
Total patients	11.7	39.0	12.4	41.2

In Section Q, Assumptions for Form C Utilization, pages 70-72, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility, as summarized below:

Home Hemodialysis and Peritoneal Dialysis

- The applicant begins its projections with the FMC Home Hickory facility census as of June 30, 2020, as shown in the following table from page 70:

COUNTY	JUNE 30, 2020	
	HHD Pts	PD Pts
Catawba	8	24
Alexander	1	3
Burke	0	6
Caldwell	1	1
Total	10	34

- The applicant projects growth of the Catawba County patient census using the 7.8% Catawba County Five Year Average Annual Change Rate (AACR) as published in the 2020 SMFP.
- The applicant assumes the patients who utilize the home program at FMC Hickory Home who reside in Alexander and Burke counties, which are contiguous to Catawba County, will continue to utilize the FMC Hickory Home services. However, the applicant projects no growth in that patient population.
- The applicant states that as of June 30, 2020 the facility census included 10 PD patients from Alexander, Burke and Caldwell counties, which are all contiguous to Catawba County. The applicant assumes the patients who utilize the home program at FMC Hickory Home who reside in Alexander, Burke and Caldwell counties will continue to utilize the FMC Hickory Home services. However, the applicant projects no growth in that patient population.
- The applicant states operating year (OY) 1 is CY 2022 and OY 2 is CY 2023.

The following tables, from pages 71 and 72, illustrate the applicant's projections:

FMC Hickory Home Program – Home Hemodialysis Projections

Begin with facility census of HHD patients residing in Catawba County as of June 30, 2020	8
Project this population forward six months to December 31, 2020, using one-half the Catawba County Five Year AACR of 7.8%*	$8 \times 1.078 = 8.3$
Project this population forward one year to December 31, 2021, using the Catawba County Five Year AACR of 7.8%	$8.3 \times 1.078 = 9.0$
Add patients from Alexander and Caldwell counties. This is the beginning census for this facility	$9.0 + 2 = 11.0$
Project Catawba County population forward one year to December 31, 2022, using the Catawba County Five Year AACR of 7.8%	$9.0 \times 1.078 = 9.7$
Add patients from Alexander and Caldwell counties. This is the ending census for this facility for OY 1	$9.7 + 2 = 11.7$
Project Catawba County population forward one year to December 31, 2023, using the Catawba County Five Year AACR of 7.8%	$9.7 \times 1.078 = 10.4$
Add patients from Alexander and Caldwell counties. This is the ending census for this facility for OY 2	$10.4 + 2 = 12.4$

*In the table that appears on application pages 19 and 71 the applicant's mathematical calculations show 7.8% AACR was used for the first six-month period (June 2020 to December 2020), the Catawba County Five Year AACR. However, the project analyst determined that the reference to 7.8% should have been 3.9%, and the applicant correctly projected six months of growth using one-half of 7.8%, or 3.9% [$7.8 / 2 = 3.9$; $8 \times 1.039 = 8.31$].

FMC Hickory Home Program – Peritoneal Projections

Begin with facility census of PD patients residing in Catawba County as of June 30, 2020	24
Project this population forward six months to December 31, 2020, using the Catawba County Five Year AACR of 7.8%*	$24 \times 1.078 = 24.9$
Project this population forward one year to December 31, 2021, using the Catawba County Five Year AACR of 7.8%	$24.9 \times 1.078 = 26.9$
Add patients from Alexander, Burke and Caldwell counties. This is the beginning census for this facility	$26.9 + 10 = 36.9$
Project Catawba County population forward one year to December 31, 2022, using the Catawba County Five Year AACR of 7.8%	$26.9 \times 1.078 = 29.0$
Add patients from Alexander, Burke and Caldwell counties. This is the ending census for this facility for OY 1	$29.0 + 10 = 39.0$
Project Catawba County population forward one year to December 31, 2023, using the Catawba County Five Year AACR of 7.8%	$29.0 \times 1.078 = 31.2$
Add patients from Alexander, Burke and Caldwell counties. This is the ending census for this facility for OY 2	$31.2 + 10 = 41.2$

*In the table that appears on application pages 19 and 72 the applicant's mathematical calculations show 7.8% AACR was used for the first six-month period (June 2020 to December 2020), the Catawba County Five Year AACR. However, the project analyst determined that the reference to 7.8% should

have been 3.9%, and the applicant correctly projected six months of growth using one-half of 7.8%, or 3.9% [$7.8 / 2 = 3.9$; $24 \times 1.039 = 24.9$].

As the tables above show, the applicant projects 12 home hemodialysis and 41 peritoneal dialysis patients by the end of the second operating year.

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

- The applicant bases the beginning HH and PD patient census on existing FMC Hickory Home patients as June 30, 2020.
- The applicant projects the growth of the Catawba County patient census using the Catawba County Five-Year AACR of 7.8%, as reported in the 2020 SMFP.

Access

In Section C.7, page 24, the applicant states:

“The applicant, and its parent organization, Fresenius Medical Care Holdings, Inc., has [sic] a long history of providing dialysis services to the underserved populations of 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.”

In Section C.7, page 24, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as summarized in the following table.

ESTIMATED PERCENTAGES OF PATIENTS BY GROUP		
a	Low income persons	38.46%
b	Racial and ethnic minorities	20.51%
c	Women	30.77%
d	Handicapped persons	7.69%
e	The elderly	41.03%
f	Medicare beneficiaries	64.10%
g	Medicaid recipients	12.82%

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 applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.
- The applicant’s assumptions are based on an existing patient population and the applicant’s in providing similar services in the service area.

Conclusion

The Agency reviewed the:

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

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

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

FMC Hickory is currently certified for 33 dialysis stations and will be certified for 30 dialysis stations upon project completion. In Section D.2, pages 28-29, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 28, the applicant states,

“The patients remaining at FMC Hickory will not be adversely impacted by this proposal. The draft 2021 SMFP indicates that FMC Hickory qualifies to apply for up to four additional dialysis stations in 2021.

...

FMC Hickory could provide dialysis care and treatment for up to 120 in-center patients on 30 dialysis stations, on traditional shifts (Monday-Wednesday-Friday, Tuesday-Thursday-Saturday, morning and afternoon shifts). The census at FMC Hickory was 112 patients as of June 30, 2020.”

The applicant’s assumptions used to project utilization at FMC Hickory are summarized below, from pages 28-29:

- The applicant assumes the Catawba County patient population dialyzing at FMC Hickory will increase by 7.8%, the Catawba County Five Year AACR published in the 2020 SMFP.
- The applicant states as of June 30, 2020 FMC Hickory was serving nine patients residing in Burke, Caldwell and Lincoln counties. The applicant assumes the patients will continue to dialyze at this facility but projects no growth in that patient population.
- The applicant states as of June 30, 2020 FMC Hickory was serving one patient residing in “other states”. The applicant assumes that patient is a transient patient and does not project that patient will continue to dialyze at the facility, because it would not be reasonable to project a patient from outside North Carolina to continue to travel to this facility three times per week for dialysis treatments.

On page 29, the applicant provides a table which shows projected FMC Hickory utilization following the proposed relocation of three stations to FMC Hickory Home, as shown below:

Begin with facility census at FMC Hickory residing in Catawba County as of June 30, 2020	102
Project this population forward six months to December 31, 2020, using one-half of the Catawba County Five Year AACR of 7.8%	$102 \times 1.039 = 106.0$
Project this population forward one year to December 31, 2021, using the Catawba County Five Year AACR of 7.8%	$106.0 \times 1.078 = 114.2$
Add patients from other counties. This is the projected census for this facility as of the certification date for this project	$114.2 + 9 = 123.2$

As shown in the table above, FMC Hickory is projected to have a utilization rate of 4.11 patients per station per week or 102.7% ($123 \text{ patients} / 30 \text{ stations} = 4.11$; $4.11 / 4 = 1.027$) at the time of the proposed relocation of stations on December 31, 2021.

The applicant states it will apply for three additional stations at FMC Hickory in March 2021. The applicant submitted an application in March 2021 to add three stations to FMC Hickory. That application is currently under review.

In Section D.3, page 30, the applicant states the relocation of three stations as proposed in this application will not have any effect access by low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare beneficiaries or Medicaid recipients.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

CA

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

In Section E.1, page 32, the applicant states considered the following alternatives to this proposal:

- Do not file an application – the applicant considered not filing an application to expand the home program at FMC Hickory Home, but an increasing number of patients are electing home dialysis. To ignore this increasing demand would not be an effective alternative to meet patient need.
- Relocating fewer than three stations – the applicant states this is not an effective alternative because it fails to enhance access to care for patients who desire home dialysis.
- Relocating more than three stations – the applicant states this is not an effective alternative because the FMH Hickory Home program facility does not currently have capacity for more than three additional stations for training purposes. Relocating more than three stations would require a significant capital expenditure for renovating and adding space to the facility to accommodate the extra stations. Therefore, 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 to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. FMC Hickory Home Program (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, the certificate holder shall relocate no more than three in-center dialysis stations from Fresenius Medical Care of Hickory.**
 - 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify three stations at Fresenius Medical Care of Hickory for a total of no more than 30 in-center and home hemodialysis stations upon project completion.**
 - 4. 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 October 1, 2021. The second progress report shall be due on February 1, 2022 and so forth.**
 - 5. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

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

Projected Capital Costs	
	TOTAL COSTS
Construction Costs	
Architect/Engineering Fees	
Nonmedical Equipment	\$2,250
Furniture	\$9,000
Other: Contingency	
Total Capital Costs	\$11,250

In Section Q, page 76, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the information on projected capital costs provided by the applicant in Form F.1a on page 76 of the application.

In Section F, page 35, the applicant states that the stations proposed to be relocated are existing, and the destination facility is operational; therefore, there are neither start-up costs nor initial operating expenses associated with this project.

Availability of Funds

In Section F, page 36, the applicant states that the capital cost will be funded by FMS ENA Home, LLC. In Section F.1, page 34, the applicant provides a table that illustrates the proposed source of capital funding for the project and identifies FMS ENA Home, LLC. However, the project analyst notes that this is a typographical error. In Section A, the applicant is identified as Bio-Medical Applications of North Carolina, Inc. In Exhibit F.2, the applicant provides a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. that confirms the availability of funds in the amount required for this project's capital cost. The project analyst concludes that, since the applicant submits many applications for certificates of need annually, and since the application provides a stock format for applicants to use, the applicant in this instance did not cut and replace the information in the tables and in Section F.1 as noted. See the following table that illustrates the sources of capital financing for this project:

Sources of Capital Financing

TYPE	FRESENIUS MEDICAL CARE HOLDINGS, INC.
Loans	
Accumulated reserves or OE *	\$11,250
Bonds	
Other (Specify)	
Total Financing	\$11,250

* OE = Owner's Equity

In Exhibit F-1, the applicant provides a letter dated November 15, 2020, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company to Bio-Medical Applications of North Carolina, Inc., documenting its commitment to fund the capital costs of the project. Additionally, the letter states that Fresenius Medical Care Holdings, Inc.'s 2019 consolidated balance sheets reflect more than \$446 million in cash, and total assets in excess of \$25 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation provided in Exhibit F-1 and Exhibit F-2, as described above.

Financial Feasibility

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

FMC Hickory Home Program Revenue and Expenses

	LAST OY	INTERIM YEAR	INTERIM YEAR	1 ST OY	2 ND OY
	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
Total Treatments	5,548	6,251.8	6,886.6	7,287.4	7,713.3
Gross Patient Revenue	\$34,902,468	\$39,329,846	\$43,336,255	\$45,845,003	\$48,549,433
Net Patient Revenue	\$2,534,881	\$2,816,464	\$3,105,084	\$3,284,092	\$3,477,062
Average Net Revenue per Treatment	\$456.90	\$450.50	\$450.89	\$450.65	\$450.79
Total Operating Costs	\$1,555,488	\$2,069,023	\$2,173,422	\$2,460,097	\$2,545,443
Average Operating Cost per Treatment	\$280.37	\$330.95	\$315.60	\$337.58	\$330.01
Net Income	\$979,393	\$747,441	\$931,662	\$823,995	\$931,619

Totals may not sum due to rounding

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

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

The applicant operates three of the four existing dialysis centers in Catawba County. Table 9B, pages 152-153 of the 2020 SMFP shows the following Catawba County dialysis facilities, the number of stations and utilization:

FACILITY	# IN-CTR. PTS.	# STATIONS	PTS/STATION	% UTILIZATION
Catawba County Dialysis	10	25	2.5	62.5%
FMC Dialysis Services of Hickory	122	35	3.5	87.1%
FMC of Catawba County	97	25	3.9	97.0%
Fresenius Kidney Care Newton	0	0	0.0	0.0%
Total	229	85		

In Section G.2, page 38, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Catawba County. The applicant states:

“The project does not create new dialysis stations but merely relocates existing dialysis stations. The dialysis stations are needed at FMC Home Hickory Program in order to enhance access to home hemodialysis training and support services to the ESRD patient population of Catawba county.”

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

- The proposal would not result in a surplus or deficit of stations or increase an existing surplus or deficit of stations in Catawba County.
- The applicant adequately demonstrates that the proposed relocation of the three stations to the FMC Hickory Home Program is needed in addition to the existing stations at the facility.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

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

POSITION	CURRENT FTE POSITIONS	PROJECTED FTE POSITIONS CY 2022	PROJECTED FTE POSITIONS CY 2023
Administrator	1.00	1.00	1.00
Home Training Nurse	6.00	8.00	8.00
Dietician	0.75	0.75	0.75
Social Worker	0.75	0.75	0.75
Maintenance	0.25	0.25	0.25
Administrative/Business Office	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.15	0.15	0.15
Chief Technician	0.05	0.05	0.05
Total	10.10	12.10	12.10

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 39-40, and in Section Q, Form H, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

Ancillary and Support Services

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed dialysis services. On page 41, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1.

Coordination

In Section I.2, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (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

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

NA

The applicant does not propose to:

- construct any new space
- renovate any existing space

Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 49, the applicant provides the historical payor mix during CY 2019 for both FMC Hickory Home Program and FMC Hickory, as shown in the tables below:

FMC Hickory Home Program CY 2019

PAYOR CATEGORY	HHD DIALYSIS AS % OF TOTAL	PD DIALYSIS AS % OF TOTAL
Self-Pay	1.74%	0.25%
Insurance*	24.20%	27.57%
Medicare*	61.85%	42.19%
Medicaid*	0.65%	7.78%
Medicare/Commercial	1.20%	15.68%
Other Miscellaneous (incl. VA)	10.36%	6.53%
Total	100.00%	100.00%

*Includes managed care plans
 Numbers may not sum due to rounding

FMC Hickory CY 2019

PAYOR CATEGORY	IN-CTR DIALYSIS AS % OF TOTAL
Self-Pay	1.98%
Insurance*	5.78%
Medicare*	59.11%
Medicaid*	6.25%
Medicare/Commercial	21.26%
Other Miscellaneous (incl. VA)	5.61%
Total	100.00%

*Includes managed care plans
 Numbers may not sum due to rounding

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

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	30.8%	51.1%
Male	69.2%	48.9%
Unknown	--	--
64 and Younger	59.0%	81.7%
65 and Older	41.0%	18.3%
American Indian	0.0%	0.6%
Asian	2.6%	4.5%
Black or African-American	15.4%	8.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	79.5%	74.9%
Other Race	2.6%	11.0%
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 50, the applicant states that the facility is not obligated to provide uncompensated care or community service.

In Section L.2, page 50, the applicant states there have been no civil rights access complaints filed against any of the applicant's facilities within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 51, 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 shown in the table below:

FMC Hickory Home Program CY 2023

PAYOR CATEGORY	HHD DIALYSIS AS % OF TOTAL	PD DIALYSIS AS % OF TOTAL
Self-Pay	1.74%	0.25%
Insurance*	24.20%	27.57%
Medicare*	61.85%	42.19%
Medicaid*	0.65%	7.78%
Medicare/Commercial	1.20%	15.68%
Other Miscellaneous (incl. VA)	10.36%	6.53%
Total	100.00%	100.00%

*Includes managed care plans
 Numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.74% of total HHD services will be provided to self-pay patients and 0.25% to PD patients; 61.85% of HHD services to will be provided Medicare patients and 42.19% to PD patients; and 0.65% of HHD services and 7.78% to PD patients will be provided to Medicaid patients.

On page 51, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant’s proposed patient payor mix is based on the historical payor mix for FMC Hickory Home Program.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory, an in-center dialysis facility, to FMC Hickory Home, a dialysis facility that provides exclusively home dialysis training and support. Following the proposed station relocation, FMC Hickory will have 30 in-center stations, and FMC Hickory Home will have five home training stations.

In Section M, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 53, and Exhibit M-2, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory to FMC Hickory Home Program. Following the proposed station relocation, FMC Hickory will have 30 in-center stations and FMC Hickory Home will have five dialysis stations dedicated to home hemodialysis training and support. FMC Hickory Home also provides peritoneal dialysis (PD).

The applicant proposes to relocate no more than three existing dialysis stations pursuant to Policy ESRD-2 from FMC Hickory, an in-center dialysis facility, to FMC Hickory Home, a dialysis facility that provides exclusively home dialysis training and support. Following the proposed station relocation, FMC Hickory will have 30 in-center stations, and FMC Hickory Home will have five home training stations.

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

The applicant operates three of the four existing dialysis centers in Catawba County. Table 9B, pages 152-153 of the 2020 SMFP shows the following Catawba County dialysis facilities, the number of stations and utilization:

FACILITY	# IN-CTR. PTS.	# STATIONS	PTS/STATION	% UTILIZATION
Catawba County Dialysis	10	25	2.5	62.5%
FMC Dialysis Services of Hickory	122	35	3.5	87.1%
FMC of Catawba County	97	25	3.9	97.0%
Fresenius Kidney Care Newton	0	0	0.0	0.0%
Total	229	85		

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 54, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Catawba County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Hickory Home Program facility begins with the current home patient population, residing in Catawba County and surrounding areas. The applicant projects growth of that population consistent with the Catawba County Five Year Average Annual Change Rate published in the 2020 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N.2, page 55, the applicant states:

“This is a proposal to relocate three hemodialysis stations from FMC Hickory to FMC Hickory Home Program, where the stations will be utilized exclusively for home

hemodialysis training and support. 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, while also offering enhanced access to home hemodialysis, another choice of dialysis modality, for Catawba County dialysis patients.”

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

Regarding the impact of the proposal on quality, in Section N.2, page 55, the applicant states:

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

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N.2, page 55, the applicant states:

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

...

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

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

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

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

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

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

C

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

In Section O.2, page 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of "*Immediate Jeopardy*" occurred in any Fresenius related facility. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Carolina Dialysis and related facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (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.

NA

The applicant proposes relocate three existing dialysis stations to FMC Hickory Home Program, a kidney disease treatment center dedicated to providing home training and support services exclusively for home hemodialysis and peritoneal dialysis patients. The application does not propose to add any in-center stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.