

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2019

Findings Date: December 17, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: P-11768-19

Facility: FMC Vernon Dialysis

FID #: 990324

County: Lenoir

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

Project: Add no more than 3 dialysis stations for a total of no more than 27 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add three dialysis stations to FMC Vernon Dialysis, an existing facility, for a total of 27 dialysis stations upon completion of this project.

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of four stations in Lenoir County, but because the deficit is less than ten stations, there is no county need determination for new dialysis stations for Lenoir County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for FMC Vernon Dialysis in the July 2019 SDR is 3.3 patients per station per week, or 83.33%, based on 80 in-center dialysis patients and 24 certified dialysis stations [$80 / 24 = 3.33$; $3.33 / 4 = 0.8333$ or 83.33%]. Therefore, FMC Vernon Dialysis is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to six additional stations may be needed at this facility, as illustrated in the following the table:

FMC Vernon Dialysis		
OCTOBER 1 REVIEW-JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		83.33%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		80
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		73
Step	Description	Result
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1918
(ii)	Divide the result of Step (i) by 12	0.0159
(iii)	Multiply the result of Step (ii) by 12	0.1918
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	95.34
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.7945
	and subtract the number of certified and pending stations to determine the number of stations needed	5.7945

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Vernon Dialysis is six, based on rounding allowed in Step (v). Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add three new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.3 (a and d), pages 11 and 13, respectively; Section N.2(b), page 52; Section O, pages 54-57; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.3 (b and d), pages 11-12 and 13, respectively; Section C.7, pages 21-22; Section L, pages 46-49; Section N.2(c), page 52; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3 (c and d), pages 12-13; Section N.2(a), page 52; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

The applicant proposes to add three dialysis stations to FMC Vernon Dialysis for a total of 27 dialysis stations upon completion of this project.

The following table, summarized from data on page 7 of the application and Table B of the July 2019 SDR, illustrates the current and projected number of dialysis stations at FMC Vernon Dialysis.

FMC Vernon Dialysis

# of Stations	Description	Project ID #
24	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
3	# of stations to be added as part of this project	P-11768-19
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
27	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add three dialysis stations at FMC Vernon Dialysis for a total of 27 stations. FMC Vernon Dialysis provides in-center (IC) dialysis, home hemodialysis (HH), and peritoneal dialysis (PD).

Patient Origin

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

In Section C.2, page 16, the applicant provides the patient origin for FMC Vernon Dialysis patients as of December 31, 2018, as summarized in the table below.

**FMC Vernon Dialysis
 1/1/2018/-12/31/2018**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Lenoir	77.0	96.3%	1.0	50.0%	5.0	71.4%
Duplin	1.0	1.3%	1.0	50.0%	1.0	14.3%
Greene	1.0	1.3%	0.0	0.0%	1.0	14.3%
Wayne	1.0	1.3%	0.0	0.0%	0.0	0.0%
Total	80.0	100.0%	2.0	100.0%	7.0	100.0%

Totals may not sum due to rounding

The applicant provides the following patient origin for the second full operating year following project completion, in Section C, page 16.

**FMC Vernon Dialysis
 Projected Patient Origin
 CY2022**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Lenoir	87.8	96.7%	3.6	64.0%	7.1	70.4%
Duplin	1.0	1.1%	2.0	36.0%	1.0	9.9%
Greene	1.0	1.1%	0.0	0.0%	2.0	19.8%
Wayne	1.0	1.1%	0.0	0.0%	0.0	0.0%
Total	90.8	100.0%	5.6	100.0%	10.1	100.0%

Totals may not sum due to rounding

In Section C, pages 17-20, the applicant provides the assumptions and methodology it uses to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In-Center Dialysis

The applicant proposes to add three dialysis stations for a total of 27 dialysis stations upon project completion.

In Section Q, pages 66-67, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant provides a table on page 66 that shows the facility in-center census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC Vernon Dialysis
 In-Center Patients**

COUNTY	12/31/2018	6/30/2019
Lenoir	77	74
Duplin	1	1
Greene	1	1
Wayne	1	1
Total	80	77

- The applicant states that the FMC Vernon Dialysis patient census as of June 30, 2019 was submitted to the Agency on the ESRD Data Collection form in August 2019.
- The applicant states that it assumes the patients from Lenoir County dialyzing at FMC Vernon Dialysis on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 5.0% Lenoir County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR, Table D.
- The applicant assumes that the three patients from Duplin, Greene, and Wayne counties being served in Lenoir County on June 30, 2019 will continue to dialyze at FMC Vernon Dialysis but does not assume any growth in patients from these counties.

- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

In-Center Projected Utilization

In Section Q, page 67, the applicant provides its projected utilization methodology, based on its stated assumptions. The projected in-center utilization is summarized in the following table.

FMC VERNON DIALYSIS IN-CENTER PATIENTS	
Begin with facility census of Lenoir County patients as of June 30, 2019.	74
Project this population forward six months to December 31, 2019, using the Lenoir County Five Year AACR of 5.0%. (5.0% / 12 x 6 = 2.5%)	$74 \times 1.025 = 75.85$
Project Lenoir County patients forward one year to December 31, 2020, using the Lenoir County Five Year AACR of 5.0%.	$75.85 \times 1.05 = 79.64$
Add patients from Duplin, Greene and Wayne counties projected to continue to dialyze at FMC Vernon Dialysis. This is the starting census on January 1, 2021.	$79.64 + 3 = 82.64$
Project Lenoir County patients forward one year to December 31, 2021, using the Lenoir County Five Year AACR of 5.0%.	$79.64 \times 1.05 = 83.62$
Add patients from Duplin, Greene and Wayne counties projected to continue to dialyze at FMC Vernon Dialysis. This is the ending census on December 31, 2021.	$83.62 + 3 = 86.62$
Project Lenoir County patients forward one year to December 31, 2022, using the Lenoir County Five Year AACR of 5.0%.	$83.62 \times 1.05 = 87.81$
Add patients from Duplin, Greene and Wayne counties projected to continue to dialyze at FMC Vernon Dialysis. This is the ending census on December 31, 2022.	$87.81 + 3 = 90.81$

Source: Table in Section Q, page 67

At the end of OY1 (CY2021) FMC Vernon Dialysis is projected to serve 86.6 in-center patients on 27 stations; and at the end of OY2 (CY2022) the facility is projected to serve 90.8 in-center patients on 27 stations.

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

- OY1: 3.2 patients per station per week, or 80.2% utilization [$86.62 / 27 = 3.2$; $3.2 / 4 = 0.8018$].
- OY 2: 3.36 patients per station per week, or 84.1% utilization [$90.8 \text{ patients} / 27 \text{ stations} = 3.36$; $3.36 / 4 = 0.8408$].

The projected utilization of 3.2 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- FMC Vernon Dialysis was operating at 83.33% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects growth in the Lenoir County patient population using the Lenoir County Five Year AACR of 5.0%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Lenoir County.
- Projected IC utilization at the end of OY1 meets the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Home Dialysis Training

In Section Q, pages 67-68, the applicant makes the following assumptions in the projection of home therapies:

- The applicant states that it projects patients forward from the June 30, 2019 census data, which the applicant states was submitted to the Agency on the ESRD Data Collection form in August 2019. The applicant provides a table on page 67 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC Vernon Dialysis
 Home Therapy Patients**

COUNTY	DECEMBER 31, 2018		JUNE 30, 2019	
	HH	PD	HH	PD
Lenoir	1	5	3	6
Duplin	1	1	2	1
Greene	0	1	0	2
Total	2	7	5	9

The applicant states that five HH patients and nine PD patients were served at FMC Vernon Dialysis as reported on the June 30, 2019 patient origin data submitted to the Agency in August 2019.

- The applicant states that it assumes the patients from Lenoir County dialyzing at FMC Vernon Dialysis on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 5.0% Lenoir County Five Year AACR published in the July 2019 SDR.
- The applicant assumes the June 30, 2019 patients outside of Lenoir County will continue to dialyze at FMC Vernon Dialysis but does not assume any growth in patients from these counties.
- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

Home Training Projected Utilization

**FMC VERNON DIALYSIS
 HH AND PD PATIENTS**

	HH	PD
Begin with facility census of Lenoir County patients as of June 30, 2019.	3	6
Project Lenoir County population forward six months to December 31, 2019, using the Lenoir County Five Year AACR of 5.0% (5.0% /12 x 6 = 2.5%)	$3 \times 1.025 = 3.08$	$6 \times 1.025 = 6.15$
Project Lenoir County population forward one year to December 31, 2020, using the Lenoir County AACR of 5.0%.	$3.08 \times 1.05 = 3.23$	$6.15 \times 1.05 = 6.46$
Add the patients from Duplin and Greene counties. This is the ending census on December 31, 2020.	$3.23 + 2 = 5.23$	$6.46 + 3 = 9.46$
Project the Lenoir County population forward one year to December 31, 2021, using the Lenoir County AACR 5.0%.	$3.26 [3.23] \times 1.05 = 3.39$	$6.46 \times 1.05 = 6.78$
Add the patients from Duplin and Greene counties. This is the ending census on December 31, 2021.	$3.39 + 2 = 5.39$	$6.78 + 3 = 9.78$
Project Lenoir County population forward one year to December 31, 2021, using the Lenoir County AACR of 5.0%.	$3.39 \times 1.05 = 3.56$	$6.78 \times 1.05 = 7.12$
Add the patients from Duplin and Greene counties. This is the ending census on December 31, 2022.	$3.56 + 2 = 5.56$	$7.12 + 3 = 10.12$

Source: Table in Section Q, page 67
 Totals may not sum due to rounding

At the end of OY1 (CY2021) FMC Vernon Dialysis is projected to serve 5.39 HH patients and 9.78 PD patients; and at the end of OY2 (CY2022) the facility is projected to serve 5.56 HH patients and 10.12 PD patients.

Projected utilization of the home training program is reasonable and adequately supported for the following reasons:

- The applicant projects growth in the Lenoir County home training patient population using the Lenoir County Five Year AACR of 5.0%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Lenoir County.

The total IC, HH, and PD projected utilization is shown in Section Q, page 69, and summarized below.

**FMC Vernon Dialysis
 Projected Patient Utilization**

COUNTY	December 31, 2021			December 31, 2022		
	# IC PATIENTS	# HH Patients	# PD Patients	# IC PATIENTS	# HH Patients	# PD Patients
Lenoir	83.62	3.39	6.78	87.80	3.56	7.12
Duplin	1.00	2.00	1.00	1.00	2.00	1.00
Greene	1.00	0.00	2.00	1.00	0.00	2.00
Wayne	1.00	0.00	0.00	1.00	0.00	0.00
Total	86.62	5.39	9.78	90.81	5.56	10.12

Totals may not sum due to rounding

Projected utilization of the total proposed IC, HH, and PD program at FMC Vernon Dialysis is reasonable and adequately supported for the reasons stated above.

Access

In Section C.7, page 22, the applicant states:

“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.

...

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.”

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**FMC Vernon Dialysis
 Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.33	0.37%	0.00	0.00%	0.13	1.30%
Commercial Insurance*	5.60	6.16%	0.80	14.38%	3.82	37.72%
Medicare*	67.82	74.68%	4.47	80.39%	4.97	49.14%
Medicaid*	7.78	8.57%	0.00	0.00%	0.55	5.41%
Medicare/Commercial	6.04	6.65%	0.29	5.23%	0.65	6.43%
Miscellaneous (Incl. VA)	3.24	3.57%	0.00	0.00%	0.00	0.00%
Total	90.81	100.00%	5.56	100.00%	10.12	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

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

NA

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

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

CA

The applicant proposes to add three dialysis stations to FMC Vernon Dialysis for a total of 27 dialysis stations upon completion of this project.

In Section E, page 27, the applicant states it considered the following three alternatives related to serving the needs of the patients in the area:

1. Maintain the status quo – the applicant states this is not a reasonable alternative because it fails to recognize the growth of the ESRD patient population residing in the area of FMC Vernon Dialysis. The applicant states that failure to add stations will result in higher utilization rates at the facility and fewer opportunities for patient admission.
2. Apply for fewer than three stations – the applicant states that the facility need methodology indicates a need for six stations and applying for fewer stations would result in higher utilization rates at the facility; thus given the growth of the patients, BMA believes an application to add fewer than three stations at FMC Vernon Dialysis would be inappropriate.
3. Relocate stations from FMC Kinston Dialysis in Lenoir County – the applicant states that FMC Kinston Dialysis was operating at 75% utilization with 117 patients dialyzing on 39 stations with an annualized growth rate of 8.547% as of June 30, 2019. The applicant states that it would not be appropriate to relocate stations from this facility given its high utilization rate and the fact that the growth rate is above the county average of 5.0%

On page 28, the applicant states that it elected to add three stations because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at FMC Vernon Dialysis.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided 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, and
- information publicly available during the review and used by the Agency.

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than three additional dialysis stations at FMC Vernon Dialysis for a total on no more than 27 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add three dialysis stations to FMC Vernon Dialysis for a total of 27 dialysis stations upon completion of this project.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 72, the applicant projects a total capital cost of \$15,000 for furniture and non-medical equipment.

In Section Q, page 73, the applicant provides the assumptions used to project the capital cost.

In Sections F.3, page 29, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 29, the applicant states that the capital cost of \$11,250 will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans		
Accumulated reserves or OE *	\$11,250	\$11,250
Bonds		
Other (Specify)		
Total Financing	\$11,250	\$11,250

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing \$11,250 of accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion. Obviously, there is a discrepancy of \$3,750 in the capital cost amounts provided by the applicant in Section Q and in Section F. However, the discrepancy is insignificant considering the \$1.8 billion reflected as cash on the FMCH Consolidated Balance Sheet and the projected net income for the facility in the historical, interim, and project years.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

FMC Vernon Dialysis Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total Treatments	14,735.17	15,412.73
Total Gross Revenue (charges)	\$92,698,963	\$96,961,484
Total Net Revenue	\$4,238,859	\$4,430,192
Average Net Revenue per Treatment	\$287.67	\$287.44
Total Operating Expenses (costs)	\$3,611,594	\$3,731,985
Average Operating Expense per Treatment	\$245.10	\$242.14
Net Income / Profit	\$627,265	\$698,207

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

Conclusion

The Agency reviewed the:

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

C

The applicant proposes to add three dialysis stations to FMC Vernon Dialysis for a total of 27 dialysis stations upon completion of this project.

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

According to the July 2019 SDR, there are two existing dialysis facilities in Lenoir County, both of which are Fresenius related facilities, as follows:

Lenoir County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
FMC of Kinston Dialysis	39	75.00%	3.0000
FMC Vernon Dialysis	24	83.33%	3.3333

Source: July 2019 SDR, Table B.

Per the July 2019 SDR, as of December 31, 2018, Fresenius related entities own and operate the two existing dialysis facilities in Lenoir County with a total of 63 certified stations. Both facilities are well-utilized, operating at or above 3.0 patients per station.

The applicant provides the same data as above in Section G, page 34. On page 34, the applicant also provides the facility data submitted on the Fresenius ESRD Data Collection Forms in August 2019, as summarized below:

Lenoir County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	39	78.21%	3.1282
Northwest Greensboro Kidney Center (FMC)	24	80.21%	3.2083

In Section G, page 35, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Lenoir County. The applicant states:

“This is an application to add three dialysis stations to FMC Vernon.

The July 2019 SDR does report a deficit of four dialysis stations in Lenoir County. Additional stations are needed by the dialysis patient population of the county.

Approval of this application does not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists fo [sic] the ESRD patient population of the 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:

- There is a facility need determination at FMC Vernon Dialysis, as calculated using the methodology in the July 2019 SDR, for up to six additional dialysis stations.
- The applicant adequately demonstrates that the three proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Form H Staffing, page 83, the applicant provides a table illustrating current and projected OY2 staffing in full time equivalent (FTE) positions for FMC Vernon Dialysis, as summarized below.

POSITION	FTE Positions as of 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	4.00	4.50	4.50
Home Training RN	2.00	2.00	2.00
Patient Care Technician	9.00	10.00	10.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Equipment Technician	1.00	1.00	1.00
Administration	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.20	0.20	0.20
Chief Technician	0.15	0.15	0.15
Total	20.50	22.00	22.00

Source: Section Q Form H

The assumptions and methodology used to project existing and projected staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 37, the applicant identifies the current medical director for the facility as Dr. Rekha John. In Exhibit H-4, the applicant provides a letter from Rekha E John, MD indicating his intent in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section I, page 39, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On site
Home training	
HH	
PD Accessible follow-up program	
Psychological counseling	Referral to PORT Kinston, ECU Psychiatry, and Eastern North Carolina Psychiatry
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	UNC Lenoir Hospital or Vidant Medical Center
Emergency care	Provided by staff until ambulance transport to hospital
Blood bank services	Referral to UNC Lenoir Hospital
Diagnostic and evaluation services	Referral to UNC Lenoir Hospital
X-ray services	Referral to UNC Lenoir Hospital
Laboratory services	Provided on site by applicant
Pediatric nephrology	Referral to Vidant Medical Center, or FMC ECU Dialysis
Vascular surgery	Eastern Nephrology Access Center Greenville / Lenoir
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	Vocational Rehabilitation of Kinston
Transportation	Lenoir County Transient, Elite Transport, and H2GO Transport

Source: Table in Section I, page 39

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

Conclusion

The Agency reviewed the:

- application, and
- 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 July 1, 1987.

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 47, the applicant provides the historical payor mix during CY2018 for its existing services, as shown in the table below.

**FMC Vernon Dialysis
 Historical Payor Mix CY 2018**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.29	0.37%	0.00	0.00%	0.09	1.30%
Commercial Insurance*	4.93	6.16%	0.29	14.38%	2.64	37.72%
Medicare*	59.75	74.68%	1.61	80.39%	3.44	49.14%
Medicaid*	6.86	8.57%	0.00	0.00%	0.38	5.41%
Medicare/Commercial	5.32	6.65%	0.10	5.23%	0.45	6.43%
Miscellaneous (Incl. VA)	2.86	3.57%	0.00	0.00%	0.00	0.00%
Total	80.00	100.00%	2.00	100.00%	7.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 46, the applicant provides comparison of the demographical information on FMC Vernon Dialysis patients and the service area patients during CY2018, as summarized below.

	Percentage of Total FMC Vernon Dialysis Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations will be Located*
Female	48.3%	52.4%
Male	51.7%	47.6%
Unknown		
64 and Younger	62.9%	80.2%
65 and Older	37.1%	19.8%
American Indian	0.0%	0.6%
Asian	0.0%	0.8%
Black or African-American	65.2%	41.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	29.2%	49.2%
Other Race	5.6%	7.7%
Declined / Unavailable	0.0%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, pages 47-48, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons. The applicant further states that BMA facilities are responsible and do provide care to both minorities and handicapped persons.

In Section L, page 48, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any related BMA facilities located in North Carolina.

Conclusion

The Agency reviewed the:

- application, and
- 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 48, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**FMC Vernon Dialysis
 Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.33	0.37%	0.00	0.00%	0.13	1.30%
Commercial Insurance*	5.60	6.16%	0.80	14.38%	3.82	37.72%
Medicare*	67.82	74.68%	4.47	80.39%	4.97	49.14%
Medicaid*	7.78	8.57%	0.00	0.00%	0.55	5.41%
Medicare/Commercial	6.04	6.65%	0.29	5.23%	0.65	6.43%
Miscellaneous (Incl. VA)	3.24	3.57%	0.00	0.00%	0.00	0.00%
Total	90.81	100.00%	5.56	100.00%	10.12	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 0.37% of in-center dialysis services will be provided to self-pay patients, 81.33% to Medicare patients (includes Medicare and Medicare/Commercial), and 8.57% to Medicaid patients.

On pages 48-49, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the

project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of FMC Vernon Dialysis.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M, page 50, 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.

Conclusion

The Agency reviewed the:

- application, and

- exhibits to the application.

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

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

C

The applicant proposes to add three dialysis stations to FMC Vernon Dialysis for a total of 27 dialysis stations upon completion of this project.

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

According to the July 2019 SDR, there are two existing dialysis facilities in Lenoir County, both of which are Fresenius related facilities, as follows:

Lenoir County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
FMC of Kinston Dialysis	39	75.00%	3.0000
FMC Vernon Dialysis	24	83.33%	3.3333

Source: July 2019 SDR, Table B.

Per the July 2019 SDR, as of December 31, 2018, Fresenius related entities own and operate the two existing dialysis facilities in Lenoir County with a total of 63 certified stations. Both facilities are well-utilized, operating at or above 3.0 patients per station.

According to Table D in the July 2019 SDR, there is a deficit of four dialysis stations in Lenoir County. The applicant proposes to add three dialysis stations to the existing facility in Lenoir County.

In Section N, pages 51-53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Lenoir County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Vernon facility begins with the current patient population.

...

Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.

...

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

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

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .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 End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- FMC Vernon Dialysis is an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section Q Form C, page 65, the applicant projects that FMC Vernon Dialysis will serve 86.62 in-center patients on 27 stations, or a rate of 3.2 patients per station per week, as of the end of the first operating year following project completion. This meets the minimum performance standard of 3.2 patient per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section Q, pages 66-67, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.