

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 28, 2017
Findings Date: December 28, 2017

Project Analyst: Celia C. Inman
Team Leader: Lisa Pitman

Project ID #: K-11396-17
Facility: FMC Dialysis Services Neuse River
FID #: 170422
County: Granville
Applicant(s): Bio-Medical Applications of North Carolina, Inc.
Project: Relocate the entire dialysis facility to a new site in Oxford

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate FMC Dialysis Services Neuse River (FMC Neuse River) to a new site in Oxford, Granville County.

Need Determination

The 2017 State Medical Facilities Plan (SMFP) provides a County Need Methodology and a Facility Need Methodology for determining the need for new dialysis stations. The applicant proposes to replace and relocate the existing 25-station dialysis facility and is not proposing to increase the number of dialysis stations; therefore, there are no need determinations in the 2017 SMFP applicable to the review of this application.

Policies

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 33 of the 2017 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure is greater than \$2 million, but less than \$5 million; therefore Policy GEN-4 is applicable to this review.

In Section B.5, pages 10-11, and Section K.1, pages 41-42, the applicant provides written statements describing how design and construction of the replacement facility will assure improved energy efficiency and water conservation.

The information in the application, including any exhibits, is reasonable and adequately supports a finding of conformity.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to Policy GEN-4.

(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 replace and relocate the existing 25-station facility within the same county. In Section C.1, page 12, the applicant states:

“BMA is proposing to relocate the entire FMC Neuse River facility. The facility is planned to have a total of 25 dialysis stations, and a home therapies suite for home training. The facility is not planning to offer home hemodialysis training and support, but will offer peritoneal dialysis training and support.”

In Section C.5, page 17, the applicant states:

“Both the primary and secondary sites for the new facility are within two blocks of the existing facility.”

There are no current projects under development at FMC Neuse River that affect the number of certified stations at the facility.

Patient Origin

On page 373, the 2017 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 consists of Granville County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant provides the historical patient origin for FMC Neuse River patients as of December 31, 2016, which is summarized in the following table:

FMC Neuse River Historical Patient Origin

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Granville	59	0	3
Vance	13	0	1
Warren	2	0	0
Virginia	1	0	0
TOTAL	75	0	4

In Section C.1, page 12, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

**FMC Neuse River
 Projected Patient Origin by County**

County	Operating Year 1 7/1/19 –6/30/20		Operating Year 2 7/1/20-6/30/21		County In-Center Patients as Percent of Total In-Center	
	In-Center Patients	Peritoneal Patients	In-Center Patients	Peritoneal Patients	OY1	OY2
Granville	69.90	3.56	74.00	3.80	81.2%	82.1%
Vance	13.00	1.00	13.00	1.00	15.5%	14.8%
Warren	2.00	0.00	2.00	0.00	2.2%	2.1%
Virginia	1.00	0.00	1.00	0.00	1.1%	1.1%
Total	85.90	4.6 [4.56]	90.00	4.80	100.0%	100.0%

In Section C.1, pages 12-15, the applicant provides the assumptions and methodology used to project utilization and patient origin.

The applicant adequately identifies the population to be served.

Analysis of Need

As stated above, the applicant proposes to replace and relocate the existing 25-station facility and provide peritoneal home training. In Section C.1, pages 12-15, the applicant provides the assumptions used to project need:

- The applicant projects the first two full operating years of the project will be July 1, 2019 – June 30, 2020 and July 1, 2020 – June 30, 2021.
- The applicant assumes that the FMC Neuse River Granville County patients will increase at the Granville County Five Year Average Annual Change Rate (AACR) of 5.8%, as published in the July 2017 SDR.
- The applicant assumes the 16 patients from outside Granville County are dialyzing at the facility as a matter of choice and will continue treatment at the

facility. The applicant does not project an increase in the 16 patients, but will add them to the census projection at appropriate points in time.

Projected Utilization

In Section C.1, page 13, the applicant provides the methodology used to project utilization for in-center patients and PD patients, as summarized in the tables below:

FMC Neuse River In-Center Patient Utilization	In-Center
Begin with the Granville County patients dialyzing at FMC Neuse River, as of June 30, 2017.	59
Project the Granville County patient population forward six months to December 31, 2017, using half the annual increase of 5.80% ($5.80\% / 12 \times 6 = 2.90\%$).	$59.0 \times 1.029 = 60.7$
Project the Granville County patient population forward twelve months to December 31, 2018, using an annual increase of 5.80%	$60.7 \times 1.058 = 64.2$
Project the Granville County patient population forward six months to June 30, 2019, using half the annual increase of 5.80% ($5.80\% / 12 \times 6 = 2.90\%$).	$64.2 \times 1.029 = 66.1$
Add the 16 patients from outside of Granville County. This is the starting census for this project.	$66.1 + 16 = 82.1$
Project the Granville County patient population forward twelve months to June 30, 2020, using an annual increase of 5.80%.	$66.1 \times 1.058 = 69.9$
Add the 16 patients from outside of Granville County. This is the ending census for OY1.	$69.9 + 16 = 85.9$
Project the Granville County patient population forward twelve months to June 30, 2021 (end of OY2), using the an annual increase of 5.80%	$69.9 \times 1.058 = 74.0$
Add the 16 patients from outside of Granville County. This is the end of OY2 census.	$74.0 + 16 = 90.0$

FMC Neuse River Peritoneal Patient Utilization	Peritoneal Patients
Begin with the Granville County patients dialyzing at FMC Neuse River, as of June 30, 2017.	3
Project the Granville County patient population forward six months to December 31, 2017, using half the annual increase of 5.80% ($5.80\% / 12 \times 6 = 2.90\%$).	$3.0 \times 1.029 = 3.09$
Project the Granville County patient population forward twelve months to December 31, 2018, using an annual increase of 5.80%	$3.09 \times 1.058 = 3.27$
Project the Granville County patient population forward six months to June 30, 2019, using half the annual increase of 5.80% ($5.80\% / 12 \times 6 = 2.90\%$).	$3.27 \times 1.029 = 3.36$
Add the 1 patient from outside of Granville County. This is the starting census for this project.	$3.36 + 1 = 4.36$
Project the Granville County patient population forward twelve months to June 30, 2020, using an annual increase of 5.80%.	$3.36 \times 1.058 = 3.56$
Add the 1 patient from outside of Granville County. This is the ending census for OY1.	$3.56 + 1 = 4.56$
Project the Granville County patient population forward twelve months to June 30, 2021 (end of OY2), using the an annual increase of 5.80%	$3.56 \times 1.058 = 3.76$
Add the 1 patient from outside of Granville County. This is the ending OY2 census.	$3.76 + 1 = 4.76$

The methodology assumes the Vance County patient will continue to be treated at the facility, but will not be projected to increase and will be added to the projected census at appropriate points in time.

Therefore, based on the tables above, the applicant projects that at the end of OY1, 85.9 in-center patients, rounded down to 85 patients will be dialyzing on 25 stations for a projected utilization rate of 3.4 patients per station per week ($85 \text{ in-center patients} / 25 \text{ stations} = 3.4$) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

Projected utilization appears to be based on reasonable and adequately supported assumptions regarding continued growth.

In Section C.2, page 15, the applicant states:

“The patient population projected to utilize the FMC Neuse River facility indeed has a need for the stations at this location. The needs of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”

In Section E, page 22, the applicant discusses the needs of the population to be served by the proposed relocated facility, stating that the existing lease is expiring, the building has outlived its useful life, the space is cramped, and there is no room to expand the home therapies program. The applicant also states that necessary renovations would be invasive and

severely impact patient access to care. Therefore, the applicant adequately demonstrates the need the proposed population has for the proposed facility relocation project.

Access

In Section L.1(a), page 47, the applicant states:

“It is BMA 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.”

In Section L.1(b), page 48, the applicant projects that 85% of its in-center and total patients will be covered by some combination of Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed increase in stations, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services,
- use of established methodologies and assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services,
- documentation from patients willing to transfer their care to the facility due to the facility location being closer to their homes or more convenient to access,
- projected utilization using the county AACR, and
- projected payor mix of in-center patients, based on the facility’s historical payor mix, averaging above 85% reimbursement by Medicare or Medicaid.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

The applicant proposes to replace and relocate the existing 25-station facility within the same county. In Section D, page 21, the applicant states:

“BMA is planning to relocate to a new building within 1/10th of a mile from the existing facility. The relocation will not have any effect on the population presently served by the facility.

...

The relocation will not have any effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed healthcare.”

In summary, the applicant adequately demonstrates 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.

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- documentation from patients willing to transfer their care to the facility due to the facility location being closer to their homes or more convenient to access,
- documentation of the close relative location of the replacement facility and demonstration that the same patient population will be served, and
- projected payor mix of in-center patients, based on the facility’s historical payor mix, averaging above 85% reimbursement by Medicare or Medicaid.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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.

NC

In Section E.1, page 22, the applicant states that BMA has no other alternative to this proposal. However, the applicant discusses expansion of the facility, renovation of the facility, and alternative sites for the relocation. The applicant states:

“The lease is expiring. The building has out lived its useful life. The space in the building is cramped. There is no room to expand the home therapies program. Remaining in the current space is not a viable option.”

Thus, after considering the above, the applicant concludes that its proposal to relocate the facility is the most effective alternative.

However, the application provides contradictory information. The staffing projection in Section H.1, page 33, appears to be for a project to add two stations at FMC Neuse River. Forms B and C in Section R are not consistent with each other. The floor plan provided by the applicant in support of the proposed renovations in Exhibit K-1 shows a total of 26 dialysis stations, not 25. The application does not clearly state how FMC Neuse River patients will access home hemodialysis services. These discrepancies call into question the availability of healthcare resources and manpower, the provision of necessary ancillary services, the validity of the proposed construction costs, and the financial feasibility of the project.

Furthermore, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. See the discussions regarding capital cost and financial feasibility found in Criterion (5), the discussion regarding staffing in Criterion (7), the discussion regarding the provision of ancillary services in Criterion (8), and the discussion regarding construction costs found in Criterion (12), which are incorporated herein by reference.

In summary, the applicant does not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the need.

The information in the application, including any exhibits, is not adequately supported for the following reasons:

- the application provides discrepancies in the project description, which raises questions regarding appropriate staffing and capital costs,
- the floor plan shows a total of 26 dialysis stations, not 25 as stated in the application, which raises question regarding capital costs, and

- the application fails to demonstrate that home hemodialysis will be accessible.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the application is not conforming to this criterion.

- (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.

NC

The applicant proposes to replace and relocate the 25-station FMC Neuse River facility within Granville County.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant provides the capital cost of the project as summarized in the following table:

**FMC Neuse River
 Project Capital Costs**

		Total Capital Costs
Construction Project Costs		
Construction Contract	\$1,548,928	
Sub-Total Construction Costs		\$1,548,929
Miscellaneous Project Costs		
Water Treatment Equipment	\$225,000	
Equipment/Furniture	\$269,924	
Architect & Engineering Fees	\$139,404	
Other: Contingency/Generator	\$84,417	
Sub-Total Miscellaneous Costs		\$718,744
Total Capital Cost		\$2,267,672

Totals may not sum due to rounding

In Sections F.10 and F.11, page 27, the applicant states that the project will not involve start-up and initial operating expenses.

However, the line drawings for the proposed facility, as provided in Exhibit K-5, clearly depict a facility with 26 dialysis stations. This calls into question the proposed construction costs of the project.

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated September 15, 2017 from the Senior Vice President & Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project and committing cash reserves for the capital expenditure in the amount of \$2,267,672. Exhibit F-2 contains the Fresenius Medical Care, Inc. and Subsidiaries Consolidated Financial Statements, as of December 31, 2016. The Consolidated Balance Sheets, page 2, shows cash and cash equivalents of \$357,899,000, total assets of \$20,135,661,000 and net assets (total assets less total liabilities) of \$10,533,297,000. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1	Operating Year 2
Total In-Center Treatments*	12,448	13,041
Total Gross Revenues (Charges)	\$ 51,829,815	\$ 54,194,699
Total Net Revenue	\$ 10,486,901	\$ 10,965,908
Total Operating Expenses (Costs)	\$ 3,561,223	\$ 3,670,762
Net Income	\$ 6,925,678	\$ 7,295,146

*Based on Assumptions from page 71 and Form B, page 67.

However, there appears to be a total disconnect between revenues provided on Form B and revenues provided on Form C, pages 70 and 73.

Form B, page 66, jumps from serving 74 in-center patients and four PD patients with \$3,559,877 in net revenue for CY2016 to serving 76 in-center patients and four PD patients with \$9,410,146 in net revenue for CY2017, an increase of almost \$6 million, as illustrated below.

	CY2016	CY2017
Total Gross Revenue	\$ 47,201,968	\$ 46,513,811
Deductions from Gross Revenue	\$ 43,642,091	\$ 37,103,666
Total Net Revenue	\$ 3,559,877	\$ 9,410,146
Difference in Total Net Revenue		\$ 5,852,569

Form C, pages 69-70 and 72-73, though not properly identified, appear to reflect net revenue for in-center and peritoneal treatments, respectively, for CY2016, the interim, and the first two project years. The assumptions provided on pages 71 and 74 of the application support that conclusion.

Form C, page 69, shows \$3,559,877 in net revenue for CY2016, which appears to support the figure in the table above; however, that figure (\$3,559,877) does not incorporate the PD net revenue of \$246,734, as shown for CY2016 on Form C, page 72.

A comparison of the net revenue from Form B and the combined net revenues for in-center and PD services from Form C, pages 70 and 73 for the first two project years, is provided below.

	Operating Year 1	Operating Year 2
Total Net Revenue Form B	\$ 10,486,901	\$ 10,965,908
Net Revenue Form C, page 70	\$ 3,757,324	\$ 3,936,316
Net Revenue Form C, page 73	\$ 246,734	\$ 246,734
Total Net Revenue Forms C	\$ 4,004,058	\$ 4,183,050
Difference in Net Revenue Form C to Form B	(\$ 6,482,843)	(\$ 6,782,858)

In a discussion with the applicant to clarify the discrepancy in net revenue, the applicant states that Form C, pages 69-70 and 72-73 provide the correct projected net revenues and that the revenues provided on Form B were entered incorrectly.

Using the net revenues, as provided on Form C, pages 70 and 73, net income would be calculated as in the following table:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$ 4,004,058	\$ 4,183,050
Total Operating Expenses (Costs)	\$ 3,561,223	\$ 3,670,762
Net Income	\$ 442,835	\$ 512,288

Form B, page 67 shows net income of \$6,925,679 for OY1 and \$7,295,146, for OY2, differences of \$6,482,844 and \$6,782,858, respectively, from the net income shown in the table above. Differences of greater than \$6 million are noteworthy. Though the applicant stated that the figures in Form C were correct, the Project Analyst was unable to verify other figures related to gross revenue, deductions from gross, and operating expenses. The staffing costs cannot be relied upon as provided in Section H. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See Section R of the application for the assumptions used regarding costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and operating needs of the project. However, the applicant fails to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. The discussions regarding costs and charges found in Criterion (5) and

staffing found in Criterion (7) are incorporated herein by reference. See Section R of the application for the assumptions used regarding costs and charges.

The information in the application, including any exhibits, is not reasonable or adequately supported for the following reasons:

- the application provides discrepancies in the project description, which raises questions regarding appropriate staffing and capital costs,
- the floor plan shows a total of 26 dialysis stations, not 25 as stated in the application, which raises question regarding capital costs,
- revenues and expenses, as provided of Forms B and C, are not clearly stated and do not correspond to one another, and
- the assumptions regarding the preparation of the pro forma financial statements, including costs and charges, cannot be relied upon.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is not conforming to this criterion.

- (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 the existing FMC Neuse River facility to a new site in Granville County.

On page 373, the 2017 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 consists of Granville County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are two operational dialysis facilities in Granville County, as follows:

Granville County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
FMC Dialysis Services Neuse River	25	75.00%	3.0000
FMC Dialysis Services of Oxford	23	83.70%	3.3478

Source: July 2017 SDR, Table B.

Fresenius related entities own and operate both of the two existing dialysis facilities in Granville County.

According to Table D in the July 2017 SDR, there is no deficit or surplus of stations in Granville County.

The applicant is proposing to relocate the existing facility to a new location in Granville County in close proximity to the current location. The applicant does not propose to establish a new facility or add new stations. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 12-15 of the application. The growth projections are based on a projected 5.8% annual increase in the number of in-center dialysis patients (Granville County residents only) at the FMC Neuse River facility, based on the July 2017 SDR published Granville County AACR. At the end of Operating Year One, the applicant projects 85.9 in-center patients, rounded down to 85 patients will be dialyzing on 25 stations for a projected utilization rate of 3.4 patients per station per week (85 in-center patients / 25 stations = 3.4) which is 85% of capacity. The discussion regarding need and projected utilization in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the need to relocate the existing facility within Granville County.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Granville County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services, and
- the applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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.

NC

In Section H.1, page 33, the applicant provides the projected staffing for FMC Neuse River in OY2 by full-time equivalent (FTE) positions, as shown in the table below:

FMC Neuse River Proposed FTE Positions and Salaries OY2			
Position	Total FTE Positions	OY2 Projected Annual Salary per FTE	OY2 Total Projected Salary
Registered Nurse	4.00	\$77,021	\$308,084
Home Training Nurse	1.00	\$72,021	\$72,021
Patient Care Technician	8.00	\$37,387	\$299,096
Dietitian	1.00	\$71,800	\$71,800
Social Worker	1.00	\$62,459	\$62,459
Clinical Manager	1.00	\$100,876	\$100,876
Administrator	0.15	\$105,348	\$15,802
In-Service	0.15	\$77,255	\$11,588
Clerical	1.00	\$42,116	\$42,116
Chief Tech	0.15	\$67,774	\$10,166
Equipment Tech	0.50	\$40,969	\$20,485
Total FTEs	17.95		

Notes: The Medical Director is an independent contractor, not an employee.

In Exhibit I.5, the applicant provides a letter from Tomasz Gawecki, MD, dated August 16, 2017, indicating support for the project and a willingness to continue to serve as Medical Director of the facility. In Section H.3, page 34, the applicant states it does not anticipate any difficulties in filling staff positions as it will use aggressive recruiting and advertising efforts, coupled with a range of benefits and competitive salaries to attract qualified staff.

In Section H.1, page 33, the applicant states, “*This is an application to add two dialysis stations at FMC Neuse River.*”, which is contradictory to the applicant’s description in Section A.6, page 3, where the applicant states the project is to “*Relocate the entire dialysis facility.*” The statement made by the applicant on page 33 appears to be in error; however, the discrepancy brings into question the validity of the proposed staffing expense provided on the same page. Therefore, the applicant does not adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

The information in the application, including any exhibits, is not based on reasonable and adequately supported assumptions regarding:

- the project description and the number of dialysis stations proposed, and
- the adequacy of the proposed staffing.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the application is not conforming to this criterion.

- (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.

NC

In Section I.1, page 37, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting will be provided by Duke Regional Hospital; blood bank services, diagnostic/evaluation, and X-ray will be referred to Granville Medical Center or Duke Regional Hospital. Exhibit I-3 includes a transfer agreement between the applicant and Durham Regional Hospital (Duke Regional Hospital). Exhibit I-4 contains a transplant services agreement from Duke University Medical Center. Exhibit I-2 contains an agreement for lab services between Spectra and FMC. In Section C.1, page 12, the applicant states:

“The facility is not planning to offer home hemodialysis training and support, but will offer peritoneal training and support.”

However, the table in Section I.1, page 37, contradicts the above statement, showing that home training for hemodialysis, peritoneal dialysis and follow-up will be provided at FMC Neuse River. Section L.7, page 51, and Section L.1(b), page 48, show FMC Neuse River does not currently offer home hemodialysis services and does not propose to offer home hemodialysis services. The Project Analyst was unable to find any other reference to the

provision of home hemodialysis services anywhere else in the application. Therefore, the applicant fails to demonstrate that home hemodialysis training will be made available to the patients at the proposed facility.

The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 38-39, stating that Fresenius has relationships with the medical community in the area, including area physicians and hospitals. On page 38, the applicant identifies Dr. Tomasz Gawecki as the Medical Director for the facility. A letter from Dr. Gawecki is included in Exhibit I-5. Dr. Gawecki's curriculum vitae is included in Exhibit I-6.

The applicant adequately demonstrates that the proposed service will be coordinated with the existing health care system, but fails to adequately demonstrate that the necessary ancillary and support services will be available.

The information in the application, including any exhibits, is not based on reasonable and adequately supported assumptions regarding the accessibility of home hemodialysis training.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the application is not 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.

NC

In Section K.2, page 43, the applicant states that the facility will have 4,269 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts a facility, with 23 dialysis stations on the main floor and one isolation dialysis station. The plan also shows a home hemodialysis room, as well as a peritoneal room. Both rooms have a dialysis station; therefore, the plan shows a total of 26 dialysis stations, as opposed to 25 stations.

In Section F.1, page 24, the applicant provides the proposed costs, including \$1,548,928 for construction, \$718,744 in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$2,267,672. In Section K.1, pages 41-42, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.
- HVAC system operating efficiency "will equal current industry standards for high seasonal efficiency." In addition, the system will be controlled via 7 day/24 hour set back time clock and maintained and serviced quarterly.

- Energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches and external insulation wrap for hot water heaters will be used for energy and water conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 24-25, and in Section R Proforma Financial Statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

However, the line drawings, as provided by the applicant depict a 26-station dialysis center, which calls into question whether or not the cost, design and means of construction represent the most reasonable alternative.

The information in the application, including any exhibits, is not based on reasonable and adequately supported assumptions regarding the:

- project description and the number of dialysis stations proposed, and
- the construction costs related to the development of the proposed 25-station facility.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the application is not conforming to this criterion.

- (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.7, page 51, the applicant reports that 85% of the patients who received treatments at FMC Neuse River had some or all of their services paid for by Medicare

or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the facility:

Payment Source	Patients by Percent of Total
Self Pay/Indigent/Charity	-0.03%
Medicare	69.00%
Medicaid	5.19%
Commercial Insurance	8.63%
Medicare/Commercial	10.74%
Miscellaneous (including VA)	647%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Granville	16%	47%	42%	16%	14%	11%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility's historical payor mix, and
- the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

In Section L.3(e), pages 49-50, the applicant states,

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 50, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

The applicant adequately demonstrates 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.

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility’s historical payor mix, and
- the existence of any civil rights access complaints against the existing facility.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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.1(b), page 48, the applicant provides the projected payor mix for the FMC Neuse River facility as shown in the table below:

Projected Payor Mix, OY2

Payment Source	Percent of Total Patients	Percent of In-Center Patients	Percent of PD Patients
Self Pay/Indigent/Charity	1.05%	0.32%	1.54%
Medicare	66.32%	65.81%	83.55%
Medicaid	6.32%	6.44%	0.00%
Commercial Insurance	7.37%	8.24%	6.06%
Medicare/Commercial	12.63%	12.26%	8.85%
Miscellaneous (including VA)	6.32%	6.94%	0.00%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding

As shown in the table above, the applicant projects that 85% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. The projected payor mix is comparable to the 2016 payor mix for FMC Neuse River, as shown in Criterion (13)(a). The applicant adequately demonstrates that medically underserved populations would have access to the proposed services.

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility's projected payor mix demonstrates adequate access for the medically underserved, and
- the facility's projected payor mix is consistent with the facility's historical payor mix.

The applicant adequately demonstrates that medically underserved populations would have access to the proposed services. This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency

Therefore, the applicant adequately demonstrates 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.4, page 50, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Neuse River will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that FMC Neuse River provides a range of means by which a person can access its services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- Nephrologists apply to receive medical staff privileges at the facility,
- any Nephrologist may apply to admit patients at the facility, and
- attending physicians receive referrals from other sources.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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.1, page 52, the applicant states that health related education programs are welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the Department Chair at Vance Granville Community College, dated September 14, 2017, inviting the school to include the facility in its clinical rotations for its nursing students.

The information provided in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding health professional training programs in the area.

The information in the application, including any exhibits, is reasonable and adequately supported because it shows the applicant offered the facility as a clinical training site for area health professional training programs.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

NC

The applicant proposes to relocate the existing FMC Neuse River facility to a new location in Granville County.

On page 373, the 2017 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 consists of Granville County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are two operational dialysis facilities in Granville County, as follows:

Granville County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
FMC Dialysis Services Neuse River	25	75.00%	3.0000
FMC Dialysis Services of Oxford	23	83.70%	3.3478

Source: July 2017 SDR, Table B.

Fresenius related entities own and operate both of the two existing dialysis facilities in Granville County.

According to Table D in the July 2017 SDR, there is no deficit or surplus of stations in Granville County.

The applicant is proposing to relocate the existing facility to a new location in Granville County. The applicant does not propose to establish a new facility or add new stations. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 12-15 of the application. The growth projections are based on a projected 5.8% annual increase in the number of in-center dialysis patients (Granville County residents only) at the FMC Neuse River facility, based on the July 2017 SDR Granville County AACR. At the end of Operating Year One, the applicant projects 85.9 in-center patients, rounded down to 85 patients will be dialyzing on 25 stations for a projected utilization rate of 3.4 patients per station per week (85 in-center patients / 25 stations = 3.4) which is 85% of capacity.

In Section N.1, page 53, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

“BMA does not expect this proposal to have effect on the competitive climate in Granville County. BMA does not project to serve dialysis patients currently being

served by another provider. The projected patient population for the FMC Neuse River facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Granville County five year average annual change rate of 5.80% as published within the July 2017 SDR.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 84% of the patients at FMC Neuse River will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 53, that its proposal will *“enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

See also Sections B, C, E, F, H, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on quality and access to the proposed dialysis services for the following reasons:

- the information provided in the application demonstrates the applicant will continue to provide adequate access to medically underserved populations, and
- the information provided in the application demonstrates will continue to provide quality services.

However, the applicant failed to demonstrate that the project, as proposed, is a cost-effective alternative. The information provided by the applicant does not support a conclusion that the project is cost-effective, as proposed, for the following reasons:

- the floor plan shows a total of 26 dialysis stations, not 25 as stated in the application, which raises question regarding capital costs,
- revenues and expenses, as provided of Forms B and C, are not clearly stated and do not correspond to one another, and
- adequacy of the proposed staffing was not demonstrated,
- accessibility of home hemodialysis training was not demonstrated, and
- the assumptions regarding the preparation of the pro forma financial statements, including costs and charges, cannot be relied upon.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the application is not conforming to this criterion.

(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

Bio-Medical Applications of North Carolina, Inc. owns and operates more than 100 facilities in North Carolina as of September 15, 2017. In Section O and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. The applicant states that two BMA facilities incurred immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. The applicant summarizes the deficiencies cited, the resolutions, and provides documentation in Exhibits O-3 and O-4, including correspondence from Licensure and the Centers for Medicare and Medicaid Services. On page 58, the applicant states that both facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant provides adequate and credible documentation of its current policies with regard to providing quality care, and
- the applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

NA

The applicant proposes to replace and relocate an existing 25-station dialysis facility within the same county. The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 are not applicable to this review because the applicant is not proposing to establish a new dialysis facility or increase the number of dialysis stations in an existing dialysis facility.