

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 3, 2014

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: Q-10315-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Farmville/ Develop a new 10-station dialysis facility in Farmville by relocating 7 dialysis stations from Fresenius Medical Care Dialysis Services East Carolina University and 3 dialysis stations from Greenville Dialysis Center/ Pitt County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Farmville proposes to develop a new 10-station dialysis facility in Farmville (Pitt County) by relocating seven dialysis stations from Fresenius Medical Care Dialysis Services Eastern Carolina University (FMC ECU) and three dialysis stations from Greenville Dialysis Center, both of which are located in Pitt County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant is proposing to relocate dialysis stations within Pitt County; therefore, the county and facility need methodologies in the 2014 State Medical Facilities Plan (2014 SMFP) are not applicable to this review.

Policies

Policy GEN-3: Basic Principles in the 2014 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

However, *Policy ESRD-2: Relocation of Dialysis Stations* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* in the 2014 SMFP are applicable to this review.

Policy ESRD-2: Relocation of Dialysis Stations states,

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

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 10-station dialysis facility, FMC Farmville, in Pitt County, by relocating seven existing dialysis stations from FMC ECU and three existing dialysis stations from Greenville Dialysis Center. Since both facilities are located in Pitt County, there is no change in dialysis station inventory in Pitt County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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, the Certificate of Need Section 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 applicant proposes to develop FMC Farmville, a new 10-station dialysis facility in Pitt County, for a total capital cost of \$1,624,001. In Section XI.6, pages 91-92, the applicant describes its plans to assure improved energy efficiency and water conservation. The applicant states that the building will meet the requirements for energy conservation. The applicant also states that the FMC Facility Design and Maintenance Department continually evaluates the design plans for energy efficiency and water conservation, and provides examples of its use of energy-efficient efforts. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The application is consistent with Policy ESRD-2 and Policy GEN-4. Therefore, the application is conforming to this criterion.

- (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

BMA currently operates three dialysis facilities in Pitt County. In this application, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Farmville proposes to establish a new 10-station dialysis facility in Farmville, Pitt County, by relocating seven existing dialysis stations from FMC ECU in Pitt County, and three existing dialysis stations from Greenville Dialysis Center, also in Pitt County. In Section II.1, pages 14-15, the applicant states there are 33 current Pitt County BMA patients who have expressed their willingness to consider transferring to the new facility. Of those 33 patients, the applicant projects that 33 current BMA dialysis patients, 24 of whom are residents of Pitt County, will transfer to the new facility in Farmville. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section IV.1, page 55, the applicant identifies the population of in-center and home dialysis patients served, as of June 30, 2014, at FMC ECU and Greenville Dialysis Center, as shown in the tables below:

FMC ECU

Patient's County of Residence	In-Center Patients	Home Patients
Pitt	130	10
Beaufort	6	2
Craven	1	1
Edgecombe	2	3
Granville	1	0
Greene	0	2
Lenoir	0	1
Martin	4	3
Northampton	1	0
Washington	1	0
Wayne	0	1
Wilson	1	2
Other	4	0
Total	151	25

Greenville Dialysis Center

Patient's County of Residence	In-Center Patients	Home Patients
Pitt	118	24
Beaufort	4	0
Bertie	0	1
Chowan	0	1
Craven	1	1
Edgecombe	3	0
Greene	3	2
Guilford	1	0
Halifax	1	0
Hertford	0	2
Hoke	1	0
Hyde	0	1
Lenoir	1	3
Martin	7	2
Northampton	0	1
Perquimans	0	1
Wayne	1	1
Wilson	0	1
Other	2	0
Total	143	41

In Section III.3, page 37, the applicant states that it received letters of support from 33 in-center dialysis patients indicating that they either live in Farmville or that they would be willing to consider transferring their care to FMC Farmville since the location would be

more convenient. However, two of the 33 letters of support are from home dialysis patients, not in-center patients. Therefore, corrected data is show in brackets. On page 38, the applicant projects that FMC Farmville will serve 34 [32] patients by the end of the first year of operation. In Section III.7, page 44, and in letters of support provided in Exhibit 22, the applicant identifies the county of residence for each of the patients who provided a letter of support. For FMC ECU, five in-center patients would come from Pitt County, one from Edgecombe, and one from Wilson for a total of seven in-center patients. For Greenville Dialysis Center, 18 in-center patients would come from Pitt County, three from Edgecombe, two from Greene, and one from Wilson for a total of 24 in-center patients. Two letters of support were received from patients at Greenville Dialysis Center who are home-trained patients, one from Wilson County and one from Pitt County. In Section III.7, page 44, the applicant provides a table showing the projected patient origin of the in-center patients to be served at FMC Farmville for the first two years of operation following completion of the project, as shown below:

County	Operating Year 1 CY 2016	Operating Year 2 CY 2017	County Patients as a Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Pitt	25.6 [24.6]	27.2 [26.2]	74.0% [75.5%]	75.2% [76.6%]
Edgecombe	4.0	4.0	11.6% [12.3%]	11.0% [11.7%]
Greene	2.0	2.0	5.8% [6.1%]	5.5% [5.9%]
Wayne	2.0 [1.0]	2.0 [1.0]	5.8% [3.1%]	5.5% [2.9%]
Wilson	1.0	1.0	2.9% [3.1%]	2.8% [2.9%]
Total	34.6 [32.6]	36.2 [34.2]	100.0%	100.0%

Note: Percentages may not foot due to rounding. Corrections made by Project Analyst are in brackets.

The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant proposes to relocate 10 certified dialysis stations from two existing BMA facilities located in Pitt County to develop a new facility in Farmville. The applicant projects the stations will be utilized at 85.0% [80.0%] of capacity by the end of the first year of operation, with 34 [32] patients dialyzing on 10 in-center dialysis stations [34 [32]/10 = 3.40 [3.20]; 3.40 [3.20]/4 = 85.0% [80.0%].

In Section III.3, pages 37, the applicant states,

“The intent of this application is to bring In-center dialysis care closer to the patients of western Pitt County and other patients dialyzing in BMA facilities, residing closer to Farmville than to Greenville, NC. Thus, this application should be viewed within the context of geographic accessibility.

Exhibit 22 of this application includes letters of support from 33 In-center dialysis patients who have indicated that they either live in Farmville, or that dialysis at a facility in Farmville would be a more convenient setting than the patient’s current dialysis facility.”

Projected Utilization

In Section III.7, pages 43-51, the applicant provides its assumptions and methodology used to project utilization at FMC Farmville. The applicant states,

- “1. BMA has plotted the residence location of patients dialyzing at BMA facilities in the region. BMA has determined that there are a significant number of In-center dialysis patients residing in Farmville and the area near Farmville, who are currently travelling 10 or more miles for dialysis care and treatment. In-center dialysis patients must travel to the facility three times per week for their care. BMA has included letters of support from 33 In-center dialysis patients.
2. Development of a dialysis facility in Farmville will significantly reduce travel time and expense for a large number of dialysis patients who reside in, or near Farmville.
3. BMA has polled the patients of the area (this is limited to the patients currently serviced in BMA facilities) to determine their interest in transferring their care to a BMA facility in Farmville. A significant number of patients have signed letters of support for the project.”

The applicant provides a patient zip code chart on page 44, indicating where the 33 patients who signed letters of support reside and where they currently receive their care, illustrated as follows:

Dialysis Facility/ County		Patient Residence by Zip Code Area*									
		27828	27829	27830	27834	27852	27864	27893	28538	28554	Total
Greenville Dialysis Center	Pitt	15	1		3						19
	Edgecombe		1			1	1				3
	Greene								1	1	2
	Wayne			1				1[0]			2[1]
	[Wilson]							[1]			[1]
FMC ECU	Pitt	3			2						5
	Edgecombe						1				1
	Wilson							1			1

*Note: Corrections made by Project Analyst are in brackets and are derived from patients’ letters of support in Exhibit 22. Includes home-trained patients.

The applicant further states its assumptions and methodology to project utilization at FMC Farmville, on pages 45-51, as follows:

- “4. Based upon the above, BMA projects that upon completion of this project, 33 [sic] In-center dialysis patients will transfer their care to the new FMC Farmville dialysis facility.*
- 5. BMA readily acknowledges that it is proposing to relocate the majority of stations from FMC ECU and the minority of patients from ECU. BMA is proposing that 70% of the stations originate at FMC ECU while only 21.2% of the patients proposed to be served are transferring from ECU.”*

The applicant reports, on pages 46-47, that FMC ECU has had a “*more erratic*” census from June 2008 to December 2013, and more growth, than Greenville Dialysis Center, beginning with 124 in-center patients on June 30, 2008 to 151 in-center patients on December 1, 2013. By contrast, Greenville Dialysis Center had 141 in-center patients, then 146 in-center patients, for the same time period. In addition, the applicant states, on pages 47-48, that FMC ECU has had 22.9% more admissions than discharges, from January 2013 through June 2014, compared to only 4.1% for Greenville Dialysis Center.

The applicant states, and demonstrates through the application of the ESRD facility need methodology, on pages 49-50, that the need for additional dialysis stations in Pitt County, as indicated in the July 2014 SDR, will be addressed, in part, by applying for one additional dialysis station at FMC Care of Ayden and 10 additional stations at FMC ECU during the October 1, 2014 CON application review cycle.

The applicant states, on page 51,

- “6. Given the need for stations in the County, coupled with the rapidly changing patient population of FMC ECU, BMA feels that it is more prudent to develop the new facility by relocation of stations that can be quickly replaced. Thus, BMA has proposed that the majority of stations should come from FMC ECU*
- 7. BMA assumes that the patient population of the facility will increase at the Pitt County Five Year Average Annual Change Rate as published in the July 2014 SDR. That rate is 6.5%.*
- 8. This project is scheduled to be completed December 31, 2015; ...*
Operating Year 1 is the period January 1 – December 31, 2016.
Operating Year 2 is the period January 1 – December 31, 2017.
- 9. BMA does expect that the patient population projected to transfer to the facility and residing within Pitt County will increase at a rate of 6.5%, commensurate with the Pitt County Five Year Average Annual Change Rate as published in the July 2014 SDR.*
- 10. BMA will not project any increase in the patient population for those patients residing in counties other than Pitt (Edgecombe, Greene, Wayne, and Wilson).*

However, based upon the patient letters of support for this project, BMA does project these patients to receive dialysis at the FMC Farmville facility once the project is completed. BMA will not project increases in these patients, but does add them to the projected population of Pitt County patients at appropriate points in time.

11. BMA has projected the patient population of the facility based upon the 32 [sic] In-center patients transferring their care to the facility upon completion of the project. “

Based on the applicant’s assumption that the Pitt County in-center patients projected to transfer to the proposed facility will increase at the Pitt County AACR of 6.5% annually, the 23 patients expected to transfer would increase to 24 from January 1, 2015 – December 31, 2015 $\{(23 \times 0.065) + 23 = 24.49\}$. December 31, 2015 is projected to be the date of completion of the proposed project. The applicant states, on page 51, it will round down to the nearest whole number. Therefore, 24 patients from Pitt County would be projected to transfer to FMC Farmville upon completion of the project. The following table projects utilization for FMC Farmville based on the methodology and assumptions provided by the applicant in Section III.7, page 51:

BMA begins with 23 Pitt County in-center dialysis patients as of January 1, 2015 who have indicated a willingness to transfer.	23 in-center patients
23 in-center patients from Pitt County are projected to increase to 24 by the date of completion of the project, December 31, 2015 by applying the Pitt County Five Year Average Annual Change Rate (AACR) of 6.5%.	$(23 \times 0.065) + 23 = 24$
The census of in-center patients from Pitt County is projected forward 12 months to December 31, 2016, the end of Operating Year One, by applying the Pitt County Five Year AACR of 6.5%.	$(24 \times 0.065) + 24 = 25.6$
Eight in-center patients are added who live outside of Pitt County and who indicated a willingness to transfer. This is the projected census for the end of the Operating Year One.	$25.6 + 8 = 33.6$ in-center patients
The census for Pitt County patients only is projected forward 12 months to the end of Operating Year Two, December 31, 2017, using Pitt County’s Five Year AACR of 6.5%.	$(25.6 \times 0.065) + 25.6 = 27.3$
The eight patients who live outside of Pitt County and who indicated a willingness to transfer are added, resulting in the projected census for the end of Operating Year Two.	$27.3 + 8 = 35.3$ in-center patients

In Section III.7, page 51, the applicant provides a table projecting utilization at FMC Farmville, as follows:

BMA begins with 24 Pitt County in-center dialysis patients projected to transfer upon completion of the project, December 31, 2015.	24 in-center patients
The census of in-center patients from Pitt County is projected forward 12 months to December 31, 2016, the end of Operating Year One, by applying the Pitt County Five Year Average Annual Change Rate (AACR) of 6.5%.	$(24 \times 0.065) + 24 = 25.6$
Eight in-center patients are added who live outside of Pitt County and who indicated a willingness to transfer. This is the projected census for the end of the Operating Year One.	$25.6 + 8 = 33.6$ in-center patients
The census for Pitt County patients only is projected forward 12 months to the end of Operating Year Two, December 31, 2017, using Pitt County's Five Year AACR of 6.5%.	$(25.6 \times 0.065) + 25.6 = 27.2$ [27.3]
The eight patients who live outside of Pitt County and who indicated a willingness to transfer are added, resulting in the projected census for the end of Operating Year Two.	27.2 [27.3] + 8 = 36.2 [35.3] in-center patients

Note: Corrections made by the Project Analyst are in brackets.

Therefore, the projected utilization for FMC Farmville, calculated by the Project Analyst and by the applicant, is 33 patients in Operating Year One, and 35 patients in Operating Year Two. The applicant states, on page 51, *“For purposes of utilization and revenue calculations, BMA will round down to the whole patient.”* The Project Analyst reviewed the patient letters of support in Exhibit 22, determining that only 23 in-center patients were from Pitt County. One additional patient from Pitt County was a home dialysis patient and therefore could not be included in the calculations for projected utilization of in-center patients.

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires the applicants to *“... 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....”* In this application, the applicant adequately demonstrates that FMC Farmville will serve a total of 33 in-center patients on 10 dialysis stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5% of capacity. Therefore, the applicant demonstrates that the proposed Pitt County facility would meet the minimum performance standard requirements in the Rule.

Access to Services

In Section VI.1, page 63, the applicant states,

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ...It is BMA policy to provide all services to patients regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population projected to be served has for the proposed FMC Farmville facility, and demonstrates that all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, 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 relocate seven existing certified dialysis stations from its FMC ECU facility and three existing dialysis stations from its Greenville Dialysis Center facility, both in Pitt County, to develop a new, 10-station dialysis facility, FMC Farmville.

In Section III.3, pages 38-41, the applicant discusses how the needs of dialysis patients at FMC ECU and Greenville Dialysis Center will continue to be met after the transfer of stations to the proposed FMC Farmville dialysis facility.

FMC ECU

The following table identifies the county of residence for the in-center patients at FMC ECU as of June 30, 2014:

County	In-center Census
Pitt	130
Beaufort	6
Craven	1
Edgecombe	2
Granville	1
Martin	4
Northampton	1
Washington	1
Wilson	1
Other States	4
Total	151

The applicant states, on page 38, that it will “*demonstrate growth of the patient population at [sic] from Pitt County only. BMA assumes that patients residing in other counties, but dialyzing at FMC ECU are there by choice.*”

The applicant projects utilization at FMC ECU based on a starting census of 130 Pitt County in-center dialysis patients, and uses the Pitt County Five Year Average Annual Change Rate (AACR) of 6.5% as published in the July 2014 SDR, to project growth, as follows:

BMA begins with the 130 in-center patient population residing in Pitt County as of June 30, 2014. The facility has 38 stations.	130 in-center patients/ 38 stations
BMA projects this population forward for 6 months to December 31, 2014 using the Pitt County Five Year AACR of 6.5%.	$[130 \times (0.065/12 \times 6)] + 130 = 134.2$
This population is projected forward 12 months to December 31, 2015, the projected certification date for the project, using the Pitt County Five Year AACR of 6.5%.	$(134.2 \times .065) + 134.2 = 142.9$
The 21 patients residing in other counties who are receiving care at FMC ECU are added.	$142.9 + 21 = 163.9$
BMA subtracts the 7 patients projected to transfer to FMC Farmville upon completion of the project.	$163.9 - 7 = 156.9$, rounded up to 157 patients
BMA relocates 7 dialysis stations to FMC Farmville	$38 \text{ stations} - 7 = 31 \text{ stations}$
Five patients are dialyzing on a third shift, therefore they are subtracted out when calculating projected utilization.	$157 \text{ patients} - 5 = 152; 152/31 = 4.9 \text{ patients per station}$

To summarize, the applicant projects that FMC ECU will operate at 123% of capacity, with 152 in-center patients dialyzing on 31 stations as of December 31, 2015, which is the projected certification date of the FMC Farmville facility ($152/31 = 4.9$; $4.9/4 = 123\%$). The applicant states, on page 39, that it intends to continue to offer a third shift and that the seven stations to be relocated to FMC Farmville will be replaced through a CON application filed during the October 1, 2014 CON application review cycle. The applicant submitted its application for 10 in-center stations at FMC ECU, with three of

those stations to be dedicated to home dialysis training and support, on September 15, 2014 (CON Project I.D. #Q-10334-14).

Therefore, the applicant demonstrates that the needs of the population presently served at FMC ECU will continue to be adequately met following the proposed relocation of seven dialysis stations from FMC ECU to FMC Farmville and that access for medically underserved groups will not be negatively impacted.

Greenville Dialysis Center

In Section III.3, pages 40-41, the applicant discusses the impact of the proposed transfer of stations from Greenville Dialysis Center to FMC Farmville. The applicant provides a table indicating the county of residence for the in-center patients at Greenville Dialysis Center as of June 30, 2014, illustrated as follows:

County	In-center Census
Pitt	118
Beaufort	4
Craven	1
Edgecombe	3
Greene	3
Guilford	1
Halifax	1
Hoke	1
Lenoir	1
Martin	7
Wayne	1
Other States	2
Total	143

The applicant states, on page 40, that it will “*demonstrate growth of the patient population at [sic] from Pitt County only. BMA assumes that patients residing in other counties, but dialyzing at FMC ECU are there by choice.*”

The applicant projects utilization at Greenville Dialysis Center based on a starting census of 118 Pitt County in-center dialysis patients, and uses the Pitt County Five Year Average Annual Change Rate (AACR) of 6.5% as published in the July 2014 SDR, to project growth, as follows:

BMA begins with the 118 in-center patient population residing in Pitt County as of June 30, 2014. The facility has 48 stations.	118 in-center patients/ 48 stations
BMA projects this population forward for 6 months to December 31, 2014 using the Pitt County Five Year AACR of 6.5%.	$\{118 \times (0.065/12 \times 6)\} + 118$ $= 121.8$
This population is projected forward 12 months to December 31, 2015, the projected certification date for the project, using the Pitt County Five Year AACR of 6.5%.	$(121.8 \times .065) + 121.8 =$ 129.8 [129.7]
The 25 in-center patients residing in other counties who are receiving care at Greenville Dialysis Center are added.	129.8 [129.7] + 25 = 154.8 [154.7]
BMA subtracts the 26 [24] in-center patients projected to transfer to FMC Farmville upon completion of the project on December 31, 2015.	154.8 [154.7] – 26 [24] = 126.8 [130.7], rounded up to 127 [131] patients
BMA relocates 3 dialysis stations to FMC Farmville.	48 stations – 3 = 45 stations
BMA projects utilization.	127 [131] patients/45 stations $= 2.87$ [2.91] patients per station

*Corrections to the data are provided by the Project Analyst in brackets.

To summarize, the applicant projects that Greenville Dialysis Center will operate at 71.8% [72.8%] of capacity, with 129 [131] in-center patients dialyzing on 45 stations as of December 31, 2015, the projected certification date of the FMC Farmville facility (129 [131]/45 = 2.87 [2.91]; 2.87 [2.91]/4 = 71.8% [72.8%]). The applicant states, on page 41,

“The projected utilization will allow the facility to continue to accept referrals, and potentially serve as an overflow facility for patients in the immediate Greenville area. As noted earlier in this application, the two facilities are in close proximity.”

The applicant demonstrates that the needs of the population presently served at Greenville Dialysis Center will continue to be adequately met following the proposed relocation of three dialysis stations from Greenville Dialysis Center to FMC Farmville and that access for medically underserved groups will not be negatively impacted.

In summary, the applicant proposes to develop a new 10-station dialysis facility in Farmville, in Pitt County, by relocating existing stations from two BMA dialysis facilities in Pitt County. The applicant adequately demonstrates that the two facilities from which dialysis stations would be transferred would have sufficient capacity following the transfer of stations to the proposed Pitt County facility. Thus, the applicant adequately

demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. Therefore, 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.

CA

In Section III.9, pages 53-54, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicant states this alternative would not address the need for more dialysis stations in Pitt County. By applying to relocate seven stations from FMC ECU and three from Greenville Dialysis Center, the applicant states it can then apply for 10 dialysis stations at FMC ECU during the October 2014 CON application review cycle based on facility need. (CON Project I.D. #Q-10334-14.) Only one station can be added to BMA's FMC Care of Ayden and cannot be "*economically expanded*", as stated on page 49. This addition of one station was applied for during the October 1, 2014 CON application review cycle. (CON Project I.D. #Q-10328-14.) Moreover, no stations can be added to Greenville Dialysis Center due to physical building constraints and not being able to qualify for more stations based on facility need.
- 2) Create a Larger FMC Farmville Facility – the applicant states that this alternative was not an option since it received only 33 letters from patients willing to consider transferring their care to FMC Farmville. No more than 10 stations could be justified.
- 3) Develop a New Dialysis Facility in another area of Pitt County – the applicant states that this alternative was not chosen since the largest number of patients not currently being served by a more local dialysis facility reside in Farmville.
- 4) Relocate more Stations from Greenville Dialysis Center – the applicant states that this alternative would not address the growing deficit of dialysis stations in Pitt County. Greenville Dialysis Center is "*at physical plant capacity*" and currently does not qualify for more stations based on facility need.

After considering the above alternatives, the applicant states that the alternative represented in the application, to develop a new facility in Farmville, is the most effective alternative.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Farmville shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Dialysis Services Eastern Carolina University shall relocate no more than 7 dialysis stations to FMC Farmville, which shall include any isolation or home hemodialysis stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Greenville Dialysis Center shall relocate no more than 3 dialysis stations to FMC Farmville, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Farmville shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 7 dialysis stations at FMC Dialysis Services Eastern Carolina University for a total of no more than 31 dialysis stations at FMC Dialysis Services Eastern Carolina University.**
 - 6. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 3 dialysis stations at Greenville Dialysis Center for a total of no more than 45 dialysis stations at Greenville Dialysis Center.**
 - 7. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Farmville shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII.1, page 72, the applicant states that the total capital cost will be \$1,624,001, including \$1,031,928 in construction costs, \$499,318 in miscellaneous costs

including \$210,000 for water treatment equipment, \$131,771 for equipment and furniture, \$92,874 in architect and engineering fees, and \$64,673 in other miscellaneous costs. In addition, the capital cost includes \$92,755 in contingency. In Section VIII.2, page 73, and in Exhibit 24, the applicant indicates that Fresenius Medical Care Holdings, Inc., parent company of BMA, will finance the project with accumulated reserves. In Section IX.1, page 76, the applicant states there will be \$89,897 in start-up expenses and states, on page 77, that there will be \$944,625 in initial operating expenses, for a total working capital requirement of \$1,034,522. In Exhibit 24, the applicant provides an August 15, 2014 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

“BMA proposes to develop a new 10 station dialysis facility by transferring existing and certified dialysis stations from FMC Dialysis Services East Carolina and Greenville Dialysis Center (also known as BMA Pitt County). The project calls for the following capital expenditures on behalf of BMA.

Capital Expenditure \$ 1,624,001

As Vice President, I am authorized and do hereby authorize the development of this 13 [sic] station dialysis facility, Fresenius Medical Care Farmville, for capital costs of \$1,624,001. Further, I am authorized and do hereby authorize ad commit all necessary cash and cash reserves for the capital expenditure, start up and working capital which may be needed for this project.”

In Exhibit 4, the applicant provides a copy of the most recent audited financial reports for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2013 and 2012. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 78, the applicant provides its allowable charges per treatment for each payment source, as illustrated below:

FMC Farmville

Source of Payment	In-Center Charge Per Treatment
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$137.29
VA	\$146.79
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
Other: Self/Indigent	\$1,425.00

The applicant provides the following explanations for the costs and charges on page 78,

“BMA includes Blue Cross / Blue Shield within its commercial insurance category. ...Medicare Advantage programs are included within the Medicare/Commercial category.

...

BMA also notes that Medicare began the “Bundling” reimbursement program in 2010. The Bundling program provides one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As a consequence of this, the basic rate for Medicare reimbursement has been approximately \$240 per treatment. Medicare will provide additional reimbursement for some co-morbid conditions. BMA has reflected a Medicare rate of \$239 in the above table.”

The applicant projects revenues in Section X.2, page 80, and operating expenses in Section X.4, page 84, summarized in the table below:

FMC Farmville	Operating Year 1 CY 2016	Operating Year 2 CY 2017
Total Net Revenue	\$1,549,262	\$1,609,415
Total Operating Expenses	\$1,466,267	\$1,518,809
Net Profit	\$82,995	\$90,607

In Section X.3, page 81, the applicant states it is using an average number of in-center patients for the first operating year equal to 33.78 patients. The applicant further states, *“BMA rounded down and multiplied 33 by 156 annual treatments to project the number of treatments for Operating Year 1. This figure is then reduced by the allowance for missed treatments, again 6.5%.”* In a similar manner, the applicant states it uses an

average of 35.39 patients for operating year two, rounds down to 35, and multiplies by 156 annual treatments to provide the number of treatments. Likewise, this number is reduced by 6.5% for missed treatments.

Therefore, revenues will exceed operating expenses in each of the first two operating years of the new facility. Operating costs and revenues are based on reasonable assumptions including projected utilization. See Section X.3, pages 81-86, of the application for the assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is 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 develop a new 10-station dialysis facility, FMC Farmville, in Farmville, Pitt County, by relocating seven existing dialysis stations from FMC ECU and three existing dialysis stations from Greenville Dialysis Center, both located in Pitt County. The July 2014 SDR indicates there are three dialysis facilities in Pitt County, as follows:

**Pitt County Dialysis Facility Data
December 31, 2013**

Facility	# of In-Center Patients	# of Certified Stations	% Utilization
FMC Dialysis Center East Carolina University (FMC ECU)	151	38	99.34%
Greenville Dialysis Center	146	48	76.04%
FMC Care of Ayden	56	15	93.33%

As illustrated in the table above, there are currently three dialysis facilities in Pitt County. FMC ECU is located approximately 12 miles from the proposed FMC Farmville dialysis facility, Greenville Dialysis Center is approximately 13 miles, and FMC Care of Ayden is approximately 19.5 miles. In Exhibit 22, the applicant provides letters from 33 dialysis patients currently receiving care at BMA dialysis facilities who reside in Farmville or who have indicated that the proposed FMC Farmville facility would be more convenient for them. In Section III.3, page 37, the applicant provides information on where these patients

live in relation to the proposed FMC Farmville facility. The proposed facility is located in zip code area 27828. Eighteen patients live in the 27828 zip code area in Farmville. An additional 13 patients live seven miles or less from Farmville. The applicant provides the zip codes of the 33 patients on page 37, summarized as follows:

Zip Code	Number of Patient Letters
27828	18
27829	2
27830	1
27834	5
27852	1
27864	2
27893	2
28538	1
28554	1
Total	33

BMA is not adding dialysis stations in Pitt County, rather it is transferring stations from two existing facilities, FMC ECU and Greenville Dialysis Center. As shown in the Pitt County Dialysis Facility Data table above, FMC ECU was operating at over 99% of capacity as of December 31, 2013.

In Section III.7, page 51, the applicant demonstrates that FMC Farmville will serve a total of 34 [32] in-center patients on 10 stations at the end of the first operating year, which is 3.4 [3.2] patients per station per week, or a utilization rate of 85.0% [80.0%] ($34 [32]/10 = 3.40 [3.2]$; $3.40 [3.2]/4 = 85.0\% [80.0\%]$). Also, the applicant's projected utilization rates are based entirely on patients currently served at BMA dialysis facilities in Pitt County who have expressed their willingness to consider transferring to the proposed Farmville facility because it will be more convenient for them.

Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Pitt County. Therefore, 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.

C

In Section VII.1, page 69, the applicant projects the number of FTE positions following completion of the proposed project, as illustrated in the table below.

Position	Projected # of FTEs
RN	1.50

Technician	4.50
Clinical Manager	1.00
Medical Director*	
Administration – FMC Director of Operations	0.15
Dietitian	0.33
Social Worker	0.33
Chief Technician	0.10
Equipment Technician	0.33
In-Service	0.15
Clerical	0.75
Total	9.14

*The Medical Director is a contract position, not an FTE of the facility.

In Section V.4, page 61, the applicant states that the Medical Director for FMC Farmville will be Dr. Kristel McLawhorn. In Exhibit 21, the applicant provides a letter dated August 4, 2014 signed by Dr. McLawhorn of Eastern Nephrology Associates confirming her commitment to serve as Medical Director. In Section VII.4, page 70, the applicant states they anticipate no difficulty in hiring the necessary staff for the FMC Farmville dialysis facility, and describe the experience they have and methods they use in recruiting and hiring staff necessary to operate their dialysis facilities. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is 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.

C

In Section V.1, page 58, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicant discusses coordination with the existing health care system on pages 60-62. Exhibits 21 and 25 contain documents which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section V.1 and Exhibits 21 and 25 is reasonable and credible and supports a finding of conformity with 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

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

NA

- (11) Repealed effective July 1, 1987.

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

C

In Section XI.6, page 93 of the application, the applicant indicates that it will construct a 6,628 square feet facility and, in Section XI.6, page 90, states that each dialysis station will be an average of 226 square feet. In Section VIII.1, pages 72-73, the applicant lists its project costs, including \$1,031,928 for construction and \$592,073 in miscellaneous costs including water treatment equipment, furniture, and architect/engineering fees, for a total project cost of \$1,624,001. On pages 91-92, the applicant describes its plans for energy-efficiency, including water conservation. Applicable energy saving features and water conservation methods include plans for the following:

- HVAC system operating efficiency “*will equal industry standards for high seasonal efficiency.*”
- Efficient exit signs, external insulation wrap for hot water heaters, water flow restrictors at sink faucets, and other measures will be used for energy 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 use less amperage.

Costs and charges are described by the applicant in Section X of the application, pages 78-86. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is 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 VI.1, page 63, the applicant states,

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the FMC Farmville facility will be comprised of the following:

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC Farmville</i>	<i>8.4%</i>	<i>24.1%</i>	<i>84.0%</i>	<i>56.5%</i>	<i>67.7%</i>

...It is clear that BMA provides service to historically underserved populations. 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.”

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the

percentage of uninsured people for each county. The following table illustrates those percentages for Pitt County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Pitt County	16.3%	6.7%	21.3%
Statewide	16.5%	6.7%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2013 – 12/31/2013*, page 99).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis...”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which shows that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native Americans (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary

¹ <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%20%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216)

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.3%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

³ <http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

*Source: 2013 USRDS Annual Data Report, page 332.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is therefore 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 applicants;

C

In Section VI.1, page 66, 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 applicants 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 VI.6, page 67, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

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 VI.1, page 65, the applicant states,

“Projections of future in-center reimbursement are presented as weighted blend of the FMC ECU and Greenville Dialysis facility historical In-center performance.”

**FMC Farmville
Projected Patient Payor Mix**

Payor Source	In-Center Dialysis
Commercial Insurance	5.5%
Medicare	76.6%
Medicaid	5.2%
VA	4.6%
Medicare/Commercial	7.7%
Other: Self/Indigent	0.3%
Total	100.0%

As shown in the table above, the applicant projects that 81.8% of in-center patients will be Medicare or Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, 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 VI.5, page 67, 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 Farmville 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 it will provide a range of means by which a person can access services. Therefore, 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 V.3, page 60, the applicant states, “*All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment.*” Exhibit 19 contains a letter from the Administrative Assistant for Fresenius Medical Care to the Dean of The College of Nursing, East Carolina University, dated August 1, 2014, offering FMC Farmville as a site for clinical rotation of nursing students. The information provided in Section V.3 and Exhibit 19 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Farmville (Pitt County) by transferring existing stations from two BMA facilities in Pitt County. According to the July 2014 SDR, there are three dialysis facilities in Pitt County and all are operated by BMA, listed as follows:

Pitt County Dialysis Centers		
Facility	Location	Utilization
FMC Dialysis Center East Carolina University	Greenville	99.34%
Greenville Dialysis Center	Greenville	76.04%
FMC Care of Ayden	Ayden	93.33%

In Section V.7, page 62, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA does not expect this proposal to have effect on the competitive climate in Pitt County.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that 81.8% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility is no different.

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives."

See also Sections II, III, V, VI and VII 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 credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Pitt County. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need to relocate 10 dialysis stations within Pitt County, and that it is a cost-effective alternative to meet that need;
- The applicant adequately demonstrates it will continue to provide quality services; and
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations.

Therefore, the application is 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

The applicant proposes to relocate stations from two Pitt County facilities, FMC ECU and Greenville Dialysis Center, to a new facility in Pitt County, FMC Farmville.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC ECU and Greenville Dialysis Center have operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. 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, which are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

.2202(a)(1) Utilization rates;

- C- In Section II.1, page 11, and Exhibit 5 (copy of the July 2014 SDR, Tables A and B), the applicant provides the utilization rates for FMC ECU and Greenville Dialysis Center.

.2202(a)(2) Mortality rates;

- C- In Section II.1, page 11, the applicant reports 2011, 2012 and 2013 facility mortality rates for FMC ECU and Greenville Dialysis Center.

.2202(a)(3) The number of patients that are home-trained and the number of patients on home dialysis;

- C- In Section II.1, page 11, the applicant states that FMC ECU has 25 home trained patients and Greenville Dialysis Center has 41 home trained patients as of June 30, 2014.

.2202(a)(4) The number of transplants performed or referred;

- C- In Section II.1, page 12, the applicant reports that FMC ECU referred 124 patients for transplant evaluation in 2013, and 9 patients received transplants in 2013.

Greenville Dialysis Center referred 30 patients for transplant evaluation in 2013, and 11 patients received a transplant in 2013.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

-C- In Section II.1, page 12, the applicant states that FMC ECU has 24 patients on the transplant waiting list, and that Greenville Dialysis Center has 39 patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section II.1, page 12, for FMC ECU, the applicant reports a total of 405 hospital admissions in 2013; 61.7% were non-dialysis related and 38.3% were dialysis-related. For Greenville Dialysis Center, the applicant reports a total of 413 hospital admissions in 2013; 71.7% were non-dialysis related and 28.3% were dialysis-related.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section II.1, page 12, the applicant reports that neither FMC ECU nor Greenville Dialysis Center have any current patients with Hepatitis B, and neither facility had any Hepatitis B conversions in 2013.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).*

-C- Exhibit 25 contains a copy of a letter, dated August 13, 2014, and signed by the President of Vidant Medical Center, which states the hospital's intention to enter into an agreement with FMC Farmville to provide a range of services to patients receiving dialysis care at the facility. A listing of services to be provided by Vidant Medical Center is included in the letter.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

(A) *timeframe for initial assessment and evaluation of patients for transplantation,*

(B) *composition of the assessment/evaluation team at the transplant center,*

(C) *method for periodic re-evaluation,*

- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- Exhibit 26 contains a copy of a letter, dated August 13, 2014, from the President of Vidant Medical Center agreeing to enter into a transplant agreement with FMC Farmville, providing all of the above stated criteria. In addition, Exhibit 26 contains a copy of a “*Transplant Center Evaluation Services Agreement*” between the applicant and Duke University Medical Center that includes the information required by this Rule.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Exhibits 30 and 31, the applicant provides a copy of a letter from the Town of Farmville Town Manager documenting the availability of water and power for the proposed primary and secondary sites, respectively.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 12 contains excerpts from Fresenius’ Clinical Services Integrated Policy and Procedure Manual Volume II which includes Guidelines for Use of Emergency Generators Policy.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section II.1, page 13, the applicant states that its primary site is a parcel located at 4302 South Main Street in Farmville. The applicant states it will “*diligently work with a property developer to secure the site.*” In Section XI.3, page 88, the applicant states that the secondary site is located on West Marlboro Road (US 264 Alternate). Exhibits 30 and 31 contain information from the owners of the two parcels that confirm the availability of the two sites.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- The applicant states, in Section I.1, page 13, that BMA, its parent company, “*will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations.*” See also Sections I.1, pages 7-8, VII.2, page 70, and Exhibits 12 and 13.

- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section II.1, page 14, the applicant provides projected patient origin for FMC Farmville and its assumptions and methodology for its projections.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- In Section II.1, page 22, the applicant states, “BMA reasonably expects that 100% of the patient population will reside within 30 miles of FMC Farmville.” On page 22, the applicant notes that all of Pitt County, Green County and “significant portions of Wayne, Wilson and Edgecombe Counties are within 30 miles of the facility.” In addition, in Section III.3, page 37, the applicant provides the locations of prospective patients of FMC Farmville and includes their respective distances to the facility. All are well within a 30-mile radius of the proposed facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II.1, page 23, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(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.*
- C- In Section II.1, pages 15-21, the applicant demonstrates that it will serve a total of 34 [32] in-center patients on 10 stations at the end of the first operating year, which is 3.4 [3.2] patients per station per week, or a utilization rate of 85.0% [80.0%]. Therefore, the applicant demonstrates that the proposed Pitt County facility would meet the minimum performance standard requirements in this rule.
- .2203(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.*
- N/A- The applicant is not 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. The

applicant is seeking to develop a new 10 station dialysis facility.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

- C- In Section II.1, pages 15-21, the applicant provides the assumptions and methodology used to project utilization of the facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) Diagnostic and evaluation services;

- C- The applicant states, in Section II, page 24, that diagnostic and evaluation services will be provided by Vidant Health Systems or Physicians East Medical Services.

.2204(2) Maintenance dialysis;

- C- The applicant states, in Section II, page 24, that the facility will provide maintenance dialysis.

.2204(3) Accessible self-care training;

- C- The applicant states, in Section II, page 24, that referrals will be provided to Greenville Dialysis' home training department for assessment of self-care and training. In addition, on page 24, the applicant states, "*The facility will provide space and nursing staff supervision for patients desiring to perform Self-Care.*"

.2204(4) Accessible follow-up program for support of patients dialyzing at home;

- C- The applicant states, in Section II, page 24, that patients are referred to Greenville Dialysis' home training department.

.2204(5) X-ray services;

- C- The applicant states, in Section II, page 24, that x-ray services will be provided by Vidant Health Systems or Physicians East Medical Services.

.2204(6) Laboratory services;

- C- Laboratory services will be provided on-site by the applicant through a contract with Spectra Labs, as stated by the applicant in Section II, page 24.

.2204(7) Blood bank services;

- C- The applicant states, in Section II, page 24, that blood bank services will be provided by Vidant Health Systems.

.2204(8) Emergency care;

- C- The applicant states, in Section II, page 24 that facility staff provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' is available for use at the facility. Patients in need of emergency care at a hospital are transported via emergency services.

- .2204(9) *Acute dialysis in an acute care setting;*
-C- The applicant states, in Section II, page 24, that acute dialysis in an acute care setting will be provided by Vidant Health Systems.
- .2204(10) *Vascular surgery for dialysis treatment patients*
-C- The applicant states, in Section II, page 25, that patients needing vascular surgery will be referred to Eastern Nephrology Associates-Vascular Center or Greenville Surgical Specialty, LLC.
- .2204(11) *Transplantation services;*
-C- Transplantation services will be provided by either Duke University Medical Center (UMC) or Vidant Health Systems, as stated in Section II, page 25. A copy of an agreement between FMC Farmville and Duke UMC for these services is provided in Exhibit 26. A letter of intent to provide these services by Vidant Health Systems is also included in Exhibit 26. See also Section V.1, page 58.
- .2204(12) *Vocational rehabilitation counseling and services; and*
-C- These services will be provided by East Carolina Vocational Rehabilitation, as stated in Section II, page 25.
- .2204(13) *Transportation*
-C- The applicant states, in Section II, page 25, that transportation services will be provided by Pitt Area Transit System (PATS), Door-to-Door, Jackie McNear, Care First, and Med One.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*
-C- In Section VII.1, page 69, the applicant provides a proposed staffing chart. In Section VII.2, page 70, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. See Criterion (7) for additional discussion on proposed staffing which is hereby incorporated by reference as if set forth fully herein.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
-C- In Section II.1, page 25, the applicant discusses the required training for staff and states that training is continually updated by the In-Service Instructor and Director of Nursing. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of continuing education programs.