

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 28, 2015

Findings Date: August 28, 2015

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: L-11011-15

Facility: Fresenius Medical Care Tarboro

FID #: 150155

County: Edgecombe

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

Project: Develop a new 10-station dialysis facility by relocating six dialysis stations from BMA East Rocky Mount and four dialysis stations from Greenville Dialysis Center

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 Fresenius Medical Care Tarboro (FMC Tarboro), whose parent company is Fresenius Medical Care Holdings, Inc., proposes to relocate six existing certified dialysis stations from BMA East Rocky Mount and four existing certified dialysis stations from Greenville Dialysis Center to develop FMC Tarboro in Tarboro (Edgecombe County) for a total of ten certified dialysis stations at FMC Tarboro upon project completion.

Need Determination

The applicant does not propose to develop new dialysis stations. Therefore, neither the county or facility need methodologies in the 2015 State Medical Facilities Plan (SMFP) are applicable to this review.

Policies

Policy ESRD-2: Relocation of Dialysis Stations is applicable to this review. Policy ESRD-2 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:

- (A) 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*
- (B) 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 relocate a total of ten existing dialysis stations, six from Edgecombe County and four from Pitt County, to establish a new facility, FMC Tarboro in Edgecombe County. Consequently, this would result in a change in the dialysis station inventory in Edgecombe County. However, the proposed relocation would not result in a surplus of stations in Edgecombe County because the January 2015 North Carolina Semiannual Dialysis Report (SDR) reported a deficit of four dialysis stations in Edgecombe County. Additionally, the relocation of the four stations from Pitt County would change the dialysis station inventory in Pitt County. According to the January 2015 SDR, Pitt County has a surplus of nine stations. Therefore, the relocation of four dialysis stations from Pitt County to Edgecombe County would not result in a deficit of dialysis stations in Pitt County. The application is consistent with Policy ESRD-2.

Conclusion

In summary, the application is consistent with Policy ESRD-2. 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

The applicant proposes to relocate six existing certified dialysis stations from BMA East Rocky Mount (Edgecombe County) and four existing certified dialysis stations from Greenville Dialysis Center (Pitt County) to develop FMC Tarboro. The proposed facility would have a total of ten certified dialysis stations upon project completion. The proposed primary and secondary sites being considered for FMC Tarboro are located on 77+ acres of land located at 123 Hospital Lane in Tarboro. The applicant does not propose to develop new dialysis stations, however, the dialysis station inventory in Edgecombe County

would increase by four stations (relocated from Pitt), thereby eliminating the four station deficit shown in Table B in the January 2015 SDR for Edgecombe County. There is a 9 station surplus in Pitt County in Table B in the January 2015 SDR.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located. With the exception of 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, in this application, the service area is Edgecombe County. Dialysis facilities may serve residents of counties not included in their service area.

In Section III.7, page 51, the applicant projects the number of in-center patients to be served in the first two years of operation following project completion, as illustrated in the following table:

FMC Tarboro				
COUNTY	Operating Year 1 2017	Operating Year 2 2018	County In-Center Patients as % of Total	
	In-Center	In-Center	Year 1	Year 2
Edgecombe	30.7	31.5	91.1%	91.3%
Halifax	2	2	5.9%	5.8%
Martin	1	1	3.0%	2.9%
Total	33.7	34.5	100.0%	100.0%

On pages 50-61, the applicant provides the assumptions and methodology used to project patient origin, See the discussion under Analysis of Need below.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section III.7, pages 50-61, the applicant provides the assumptions and methodology used to project the number of in-center dialysis patients expected to utilize the FMC Tarboro facility, which are summarized below.

- The majority of patients projected to utilize FMC Tarboro will be Edgecombe County residents. See the table above.
- The applicant received letters from 39 patients expressing an interest in utilizing the proposed facility. Thirty-seven are already on dialysis. The letters of support from patients currently receiving dialysis serves state:

“I understand from my nephrology physician that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to develop a new dialysis

facility in Tarboro ...

The proposed new BMA dialysis facility in Tarboro will be convenient for me and close to my home. Development close to the hospital and other medical offices would allow me to schedule multiple doctor visits for a day when I have dialysis, and reduce the number of visits to the hospital area....

I would be willing to consider transferring to the BMA facility in Tarboro.”

The letters of support from patients with stage 5 CKD state:

“When I do need dialysis, I would like to utilize the new BMA facility in Tarboro for my dialysis treatment. The proposed new BMA dialysis facility in Tarboro will be convenient for me and close to my home.

I would be willing to consider getting my dialysis at the new BMA Facility in Tarboro.”

- On page 51, the applicant provides a table illustrating where the 39 patients are currently receiving services, as shown in the following table.

Name of Facility	# of Support Letters	Zip Code	City/ County
Dialysis Care of Edgecombe County	27	27819 (1) 27852 (1) 27864 (3) 27872 (1) 27801 (1) 27874 (1) 27866 (19)	Conetoe/Edgecombe Macclesfield/Edgecombe Pinetops/Edgecombe Roxobel/Bertie Rocky Mount/Edgecombe Scotland Neck/Halifax Tarboro/Edgecombe
BMA East Rocky Mount	3	27864 (3)	Pinetops/Edgecombe
FMC Halifax County	3	27843 (2) 27857 (1)	Hobgood/Halifax Oak City/Martin
BMA Rocky Mount	1	27886 (1)	Tarboro/Edgecombe
BMA Pitt (Greenville Dialysis)	2	27829 (1) 27841 (1)	Fountain/Pitt Hassell/Martin
FMC ECU	1	27864 (1)	Pinetops/Edgecombe
Stage 5 CKD (not on dialysis yet)	2	27886 (2)	Tarboro/Edgecombe
Total	39		

- The applicant assumes that the two chronic kidney disease (CKD) patients not yet receiving dialysis treatment will become dialysis patients and utilize FMC Tarboro.
- On page 43, the applicant states the proposed facility will enhance geographic accessibility for patients traveling to BMA Rocky Mount or the facilities in Halifax or Pitt counties. Additionally, on page 14, the applicant states that 27 Dialysis Care of Edgecombe County

patients are considering transferring to the proposed facility because of their current relationship with the nephrologists with Eastern Nephrology Associates (ENA). The proposed Medical Director is an ENA nephrologist.

- The applicant assumes the number of patients living in Edgecombe County will grow at half the Five Year Average Annual Change Rate (AACR) of 4.8% as published in Table B of the January 2015 SDR. Therefore, the applicant assumes a growth rate of 2.4%. See pages 58-59.
- On page 61, the applicant states in-center utilization projections begin with 30 in-center patients living in Edgecombe County. This number is increased by half the Edgecombe County 5-year AACR or 2.4%. Patients from the other counties are added to get the total at the end of each interval. The calculations are shown in the table below.

BMA begins with 30 Edgecombe County patients projected to transfer to the facility once it is open (December 31, 2016).	30 in-center patients
The result is projected forward by 12 months to December 31, 2017.	$(30 \times .024) + 30 = 30.7$
The 3 patients living in other counties are added. This is the projected census at the end of Operating Year One.	$30.7 + 3 = 33.7$
The result is projected forward for 12 months to December 31, 2018.	$(30.7 \times .024) + 30.7 = 31.5$
The 3 patients living in other counties are added. This is the projected census at the end of Operating Year Two.	$31.5 + 3 = 34.5$

The applicant projects to serve 33 in-center patients at FMC Tarboro by the end of Operating Year One or 3.3 patients per station [$33/10 = 3.3$] and 34 in-center patients by the end of Operating Year Two or 3.4 patients per station [$34/10 = 3.4$]. The projected utilization rate is 82.5% at the end of Operating Year One [$33/ (4 \times 10) = 82.5$] and 85% at the end of Operating Year Two [$34/ (4 \times 10) = 85$]. Thus projected utilization exceeds the 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected in-center utilization at FMC Tarboro is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to develop a new 10-station facility in Tarboro.

Access

In Section VI.1, pages 76-81, the applicant describes how underserved persons will have access to services provided by FMC Tarboro. On page 76, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ...

...

It is BMA [sic] 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.”

On page 80, the applicant projects that 88.79% of all patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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 six existing certified dialysis stations from BMA East Rocky Mount and four existing certified dialysis stations from Greenville Dialysis to FMC Tarboro. In Section III.3(c), pages 45-49, the applicant discusses how the needs of dialysis patients at BMA East Rocky Mount and Greenville Dialysis will continue to be met after the relocation of those stations to the proposed FMC Tarboro facility. Each facility is discussed separately below.

BMA East Rocky Mount

The January 2015 SDR reports the facility had 117 in-center patients dialyzing on 30 dialysis stations for a utilization rate of 97.5% as of June 30, 2014. Utilization is projected using the AACR for Edgecombe County as published in the January 2015 SDR (4.8%). BMA projects the patient population forward from December 31, 2014 to December 31, 2016, the projected completion date for the proposed project, as illustrated in the table below.

BMA begins with 77 Edgecombe County in-center patients as of December 31, 2014.	77 in-center patients
The Edgecombe County patients are projected forward six months to June 30, 2015.	$[77 \times (.048 / 12 \times 6)] + 77 = 78.8$
BMA subtracts the 14 patients expected to transfer to FMC Rocky Mount.	$78.8 - 14 = 64.8$
The results are projected forward six months to December 31, 2015.	$(64.8 \times .048) + 64.8 = 66.4$
The results are projected forward one year to December 31, 2016 – the proposed certification date for this project.	$(66.4 \times .048) + 66.4 = 69.6$
BMA subtracts the 4 patients projected to transfer to FMC Tarboro.	$69.6 - 4 = 65.5$
BMA adds 25 Nash County patients and the six patients from Halifax, Pitt and Wilson counties.	$65.5 + 25 + 6 = 96.6$

As shown in the table above, the applicant projects that BMA East Rocky Mount will serve 96 in-center dialysis patients as of December 31, 2016 on 24 stations, which is four patients per station ($96/24=4$) or 100% utilization once FMC Tarboro is operational. On pages 46-47, the applicant states that it anticipates filing a certificate of need application in September 2015 based on the facility need methodology to add dialysis stations.

Greenville Dialysis

The January 2015 SDR reports the facility had 143 in-center patients dialyzing on 48 dialysis stations for a utilization rate of 74.48% as of June 6, 2014. On page 47, the applicant states that, as of December 31, 2014, Greenville Dialysis had 145 in-center dialysis patients. The applicant used the AACR (6.5%) for Pitt County published in the January 2015 SDR to project utilization.

BMA projects the patient population forward from December 31, 2014 to December 31, 2016, the projected completion date for the proposed project, as illustrated in the table below.

BMA begins with 127 Pitt County in-center patients as of December 31, 2014.	127 in-center patients
The Pitt County patients are projected forward one year to December 31, 2015.	$(127 \times .065) + 127 = 135.3$
BMA subtracts the 19 Pitt County patients and 3 patients from Green and Wayne counties who are projected to transfer to FMC Farmville.	$135.3 - 19 = 116.3 - 3 = 113.3$
The results are projected forward one year to December 31, 2016 the projected certification date for the proposed project.	$(113.3 \times .065) + 113.3 = 120.66$
15 patients from other counties are added.	$120.66 + 15 = 135.66$
BMA subtracts 1 patient from Edgecombe County, 1 patient from Martin County and 1 patient from Pitt County projected to transfer to the new facility.	$135.66 - 3 = 132.66$

One page 48, the applicant states in step 2, that BMA would subtract 19 patients from Pitt County and 3 patients from Wayne and Green counties. However, the applicant did not subtract the 3 patients from Green and Wayne counties in the table in the application. The table above shows those 3 patients being subtracted. Thus, based on the applicant’s assumptions on page 48, Greenville Dialysis is expected to serve 133 in-center patients.

Greenville Dialysis currently has 48 dialysis stations. In the FMC Farmville application (Project I.D. # Q-10315-14), BMA proposed to relocate three dialysis stations to FMC Farmville and in the current application, BMA proposes to relocate four dialysis stations to FMC Tarboro. Thus, Greenville Dialysis is projected to have 41 ($48-7= 41$) stations as of December 31, 2016.

As shown in the table above, Greenville Dialysis is projected to serve 133 patients on 41 stations, which is 3.2 patients per station per week ($133/41=3.243$) once the FMC Farmville and FMC Tarboro projects are complete.

Access

The applicant states medically underserved populations will continue to have access to services provided by BMA. See Section VI.1, pages 76-81.

Conclusion

The applicant demonstrates that the needs of the population presently served at BMA East Rocky Mount and Greenville Dialysis will be adequately met following the relocation of six stations from BMA East Rocky Mount and four stations from Greenville Dialysis to FMC Tarboro. Consequently, the application is conforming with 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.

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In Section III.9, pages 62-63, the applicant discusses the alternatives considered which are described below.

- Maintaining the Status Quo – The applicant concluded that this alternative would not resolve the deficit of dialysis stations in Edgecombe County as reported in the January 2015 SDR.
- Relocation of More Stations – The applicant concluded that relocating more stations to create a larger facility was not the most effective alternative since the applicant concluded that 10-stations was appropriate given the level of interest expressed by the potential patients.
- Relocate Stations to Another Area of the County – BMA considered relocating stations to another area other than Tarboro within Edgecombe County. However, the applicant concluded that Tarboro is situated approximately in the center of Edgecombe County and has the second largest patient population within the county; Tarboro would be accessible to the whole county.
- Develop the Facility as Proposed – The applicant concluded that the development of the project, as proposed, would eliminate the deficit of stations in Edgecombe County and reduce the surplus of stations in Pitt County.

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 the FMC Tarboro proposal is the least costly or most effective alternative to meet the identified 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 Tarboro 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 Tarboro shall develop and operate no more than ten dialysis stations at FMC Tarboro which shall include any home hemodialysis or isolation stations.**
- 3. Bio-Medical Application of North Carolina, Inc. d/b/a FMC Tarboro shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any home hemodialysis or isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify six stations at BMA East Rocky Mount for a total of no more than twenty-four certified dialysis stations at BMA East Rocky Mount upon project completion.**
- 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four stations at Greenville Dialysis for a total of no more than forty-one certified dialysis**

stations at Greenville Dialysis upon completion of Project I.D. # Q-10315-14 and this project.

7. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tarboro shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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.

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Availability of Funds

In Section VIII.1, page 86, the applicant states that the total capital cost of the project will be \$1,673,480 which includes \$1,056,730 for construction, \$230,000 for water treatment equipment, \$120,731 for equipment/furniture, \$95,106 for architect/engineering fees, \$65,240 for other (unspecified), and \$105,673 for contingencies.

In Section IX.2 page 91, the applicant projects that the initial operating expenses associated with the proposed project will be \$1,022,008. In Section IX.1(b), page 90, the applicant states the estimated start-up expenses are \$90,512. Therefore, the projected total working capital (start-up and initial operating expenses) associated with the proposed project is projected to be \$1,112,519.

In Section VIII.3, page 87, the applicant states that the project will be funded with the accumulated reserves of Fresenius Medical Care Holdings, Inc. the parent company of Bio-Medical Applications of North Carolina, Inc. Exhibit 24 contains a letter dated March 16, 2015 from the Vice President of Fresenius Medical Care Holdings, Inc. (FMC), which states:

“As Vice-President, I am authorized and do hereby authorize the development of this new Fresenius Medical Care Tarboro, and relocation of dialysis stations from BMA East Rocky Mount and Greenville Dialysis Center for capital costs as identified Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of 1,673,480 as may be needed for this project. I am also authorized, and authorize any additional funds as may be necessary for the start-up costs in the new location.”

In Exhibit 4, the applicant provides the audited financial statements for FMC for the years ending December 31, 2012 and December 31, 2013. As of December 31, 2013, FMC and Subsidiaries had \$276 million in cash and cash equivalents, \$16.6 billion in total assets and \$7.7 billion in net assets (total assets less total liabilities).

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

In Section X.1, page 92, the applicant provides the allowable charges, per treatment, for each payment source, as illustrated in the table below:

Payor Source	Charge per Treatment
Private	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.02
Medicaid	\$140.23
Medicare/Medicaid	\$239.02
Medicare/Commercial	\$239.02
State Kidney Program	\$100.00
VA	\$231.12
Other.; Self/Indigent	\$1,425.00

The applicant projects revenues in Section X.2, page 93 and operating expenses in Section X.4, page 98, of the application, as illustrated in the table below:

FMC Tarboro		
	Operating Year 1 2017	Operating Year 2 2018
Total Net Revenue	\$1,637,339	\$1,693,377
Total Operating Costs	\$1,582,724	\$1,627,214
Net Profit	\$54,615	\$66,163

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X of the application for the applicant’s assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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 relocate six existing certified dialysis stations from BMA East Rocky Mount in Edgecombe County and four existing certified dialysis stations from Greenville Dialysis in Pitt

County to establish a new ten-station dialysis facility at 123 Hospital Lane in Tarboro in Edgecombe County.

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located. With the exception of 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, in this application, the service area is Edgecombe County. Dialysis facilities may serve residents of counties not included in their service area.

The January 2015 SDR reports there are two dialysis facilities located in Edgecombe County, as shown in the table below.

Name of Facility	Owner	# of Existing and Approved Stations	Utilization Rate*	Address	Distance to Proposed Facility ¹
BMA East Rocky Mount	Bio-Medical Applications of NC, Inc.	30	97.50%	230 S. Fairview Road - Rocky Mount	14.1 miles
Dialysis Care of Edgecombe County	DaVita Healthcare Partners, Inc.	35	88.46%	3206 Western Blvd - Tarboro	0.8 miles

Source: January 2015 SDR

*The utilization rate is based on the number of existing certified stations and in-center patients as of December 31, 2014.

As reported in the January 2015 SDR, Edgecombe County has a deficit of four ESRD stations. Relocating four ESRD stations from Greenville Dialysis would eliminate the deficit of stations in Edgecombe County. Additionally, the January 2015 SDR reported a surplus of nine stations in Pitt County. Relocating four stations from Pitt County to Edgecombe County would reduce the surplus of stations in Pitt County.

In Section V.7, pages 71-75, the applicant states:

“[T]he first and most obvious change to the competitive environment with Edgecombe County would be a third operational dialysis facility.

Within the application BMA has provided letters of support from patients currently dialyzing at the Dialysis Care of Edgecombe County facility. The physicians of Eastern Nephrology Associates ... communicated with the patients and informed them of the ... new facility where a physician associated with Eastern Nephrology Associates would be the Medical Director. ...

[T]he second and obvious effect upon competition is that some patients currently receiving care at [Dialysis Care of Edgecombe County] have indicated a preference to transfer their care to [FMC Tarboro] upon completion and certification of the project.

¹ <http://www.mapquest.com>

BMA has evaluated the possible effects of patients transferring from DC Edgecombe facility to the new FMC Tarboro.

- a. BMA has included 27 letters from patients for [sic] DC Edgecombe.*
- b. BMA ... projected 33 patients to transfer their care to the new facility. ... BMA considered that the three patients from Halifax and Martin Counties are currently dialyzing in a BMA facility. BMA ... assumed that eight of the patients transferring to the new facility are currently dialyzing at a BMA facility.*
- c. BMA assumes that 22 patients transferring their care to the new facility are currently dialyzing at the DC Edgecombe facility.*
- d. BMA ... calculated the probable utilization of the DC Edgecombe facility as of December 31, 2016, the projected certification date of this project.*
- e. [T]he January 2015 indicates ... the DC Edgecombe facility is certified for 25 dialysis stations with nine stations pending certification*
- f. The DC Edgecombe facility filed a CON application, ... Project ID # L-8745-11, seeking approval to add 10 stations ... for a total of 35 stations. That application ... approved. ... At the time of the SDR publication, only one of the 10 stations approved has been certified.*
- g. The SDR indicates the DC Edgecombe in-center census was 92 patients on June 30, 2014.*
- h. BMA will demonstrate growth of the Edgecombe County patient population using the published Five Year Average Annual Change Rate of 4.8%*
- i. [N]o growth is applied to the patients residing in other counties ... [See the table on page 73.]*
- j. BMA projects the utilization at DC Edgecombe County to be 82 patients dialyzing on 26 stations ... This calculates to 3.154 patients per station, or 78.85%.*
- k. Utilization will exceed 80% by December 31, 2017. [See the table on page 73.]*

The applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities or facilities. 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 83, the applicant provides projected staffing for FMC Tarboro upon project completion, as illustrated in the following table:

FMC Tarboro	
Full-Time Equivalent (FTE) Positions	
RN	1.50
Tech	4.50
Clinical Manager	1.00
Admin. (FMC Dir. Ops)	0.15
Dietician	0.50
Social Worker	0.50
Chief Tech	0.10
Equip. Tech	0.50
In-Service Coordinator	0.15
Clerical	1.00
Total FTEs	9.90

The applicant projects a total of 9.90 FTE positions upon project completion. On pages 84-86, the applicant discusses BMA's recruitment policy and states that they do not anticipate difficulty in recruiting and retaining qualified staff because of their aggressive recruiting practice and their competitive salary structure. In Section V.4(c), page 70, the applicant identifies the Medical Director for FMC Tarboro as Dr. Scott Kendrick. In Exhibit 21 the applicant provides a letter from Dr. Kendrick indicating his willingness to serve as Medical Director of the facility. Additionally, in Section VII.10, page 85, the applicant states FMC Tarboro will operate two shifts, six days a week from 7:00 a.m. to 5:00 p.m.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed dialysis 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 67, the applicant lists the proposed providers of the necessary ancillary and support services. Exhibits 20, 21, 25 and 26 contain documentation of service agreements and coordination with the existing health care system. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

- (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, pages 100-103, the applicant discusses the primary and secondary sites being considered for the proposed FMC Tarboro. The applicant states that BMA plans to lease space for the proposed new facility. The primary and secondary sites being considered are located on a tract of land at 123 Hospital Lane in Tarboro. The 77+ acres will be subdivided into sites that will be suitable for the proposed facility.

See Exhibits 30 and 31 for documentation on the availability of both sites for leasing. Also, see those Exhibits for documentation on the availability of water, sewer, and electric services for the proposed sites. Maps for the proposed sites can also be found in Exhibits 30 and 31. The applicant further states on pages 100-103, that both sites are located near medical offices and Vidant Health - Edgecombe.

In Section XI.6, page 104, the applicant states that the facility will be 7,307 square feet. The applicant projects the construction cost will be \$1,056,730 and architect and engineering fees will be \$95,106, which is a total of \$1,151,836. Thus, the cost per square foot is projected to be \$157.63 ($\$1,151,836/7,307 = \157.63). See Section VIII.1, page 87 and Section XI.6(h), page 106. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 106:

FMC Tarboro	
Facility Area	Estimated Total Sq. Ft.
Ancillary Areas:	
Administration/Offices/Receptions/Elevator & Lobby	562
Public Lobby	465
Mechanical Equipment	124
Housekeeping	37
General Storage/	817
Staff Lounge	200
RO	573
Other: bathrooms, circulation	1,694
Sub-Total Support	4,472
Treatment Areas:	
Nurses Station - Included in Dialysis Station Area	
Dialysis Stations	2,672
Isolation Room(s)	163
Sub-Total Treatment	2,835
Total Square Feet	7,307

The energy savings features incorporated into the plans are described in Section XI.6(d), page 104.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed dialysis services. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. 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(b), page 77, the applicant reports that 88.8% of the patients who received treatments at BMA East Rocky Mount and 87.8% of patients who received treatments at Greenville Dialysis had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payment source for these two existing facilities:

2014 BMA EAST ROCKY MOUNT PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Commercial Insurance	5.53%
Medicare	79.58%
Medicaid	5.89%
Medicare/Commercial	3.32%
VA	4.53%
Other: Self/ Indigent	1.15%
Total	100.0%

2014 GREENVILLE DIALYSIS PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Commercial Insurance	6.00%
Medicare	78.16%
Medicaid	3.06%
Medicare/Commercial	6.62%
VA	5.69%
Other: Self/ Indigent	0.46%
Total	100.0%

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 Edgecombe and Pitt counties 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) *
Edgecombe	31%	13.5%	21.3%
Pitt	16%	6.7%	21.3%
Statewide	17%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).²

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

² <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.³

The applicant demonstrates that medically underserved populations currently have adequate access to services available at BMA East Rocky Mount and Greenville Dialysis. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(f), page 81, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community services under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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(a), page 82, the applicant states there have been no civil rights access complaints filed within the last five years against any BMA’s North Carolina facilities. Therefore, 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(c), page 80, the applicant provides the projected payor mix for in-center patients for the proposed FMC Tarboro facility, as shown in the table below.

FMC TARBORO PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Commercial Insurance	5.53%
Medicare	79.58%
Medicaid	5.89%
Medicare/Commercial	3.32%
VA	4.53%
Other: Self / Indigent	1.15%
Total	100.0%

As shown in the table above, the applicant projects 88.8% of all patients will have their care paid for by Medicare or Medicaid. The projected percentages are the same as the historical payor mix for BMA East Rocky Mount which is located in the same county as the proposed facility.

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services at FMC Tarboro. 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(a), page 81, the applicant states the means by which a person will have access to the proposed services offered at FMC Tarboro includes referrals from physicians, nephrologists and the emergency department. The applicant further states on page 81, that FMC Tarboro will

have an open door policy which means any nephrologist may apply to admit patients to the facility.

The applicant adequately demonstrates that FMC Tarboro will offer a range of means by which a person can access its 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 69, the applicant states that FMC Tarboro will be offered as a training site for nursing students. Exhibit 19 includes a letter dated March 15, 2015 from FMC to the Dean of Edgecombe Community College offering the use of FMC Tarboro as a clinical training site. The information provided in Section V.3 is reasonable and credible for a new facility 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 relocate six existing certified dialysis stations from BMA East Rocky Mount in Edgecombe County and four existing certified dialysis stations from Greenville Dialysis in Pitt County to establish a new ten-station dialysis facility at 123 Hospital Lane in Tarboro in Edgecombe County.

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located. With the exception of 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, in this application, the service area is Edgecombe County. Dialysis facilities may serve residents of counties not included in their service area.

The January 2015 SDR reports there are two dialysis facilities located in Edgecombe County, as shown in the table below.

Name of Facility	Owner	# of Existing and Approved Stations	Utilization Rate*	Address	Distance to Proposed Facility ⁴
BMA East Rocky Mount	Bio-Medical Applications of NC, Inc.	30	97.50%	230 S. Fairview Road - Rocky Mount	14.1 miles
Dialysis Care of Edgecombe County	DaVita Healthcare Partners, Inc.	35	88.46%	3206 Western Blvd - Tarboro	0.8 miles

Source: January 2015 SDR

*The utilization rate is based on the number of existing certified stations and in-center patients as of December 31, 2014.

As reported in the January 2015 SDR, Edgecombe County has a deficit of four ESRD stations. Relocating four ESRD stations from Greenville Dialysis would eliminate the deficit of stations in Edgecombe County. Additionally, the January 2015 SDR reported a surplus of nine stations in Pitt County. Relocating four stations from Pitt County to Edgecombe County would reduce the surplus of stations in Pitt County.

In Section V.7, pages 71-75, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost effectiveness, quality and access to the proposed services. The applicant states in part:

“[T]he first and most obvious change to the competitive environment with Edgecombe County would be a third operational dialysis facility.

Within the application BMA has provided letters of support from patients currently dialyzing at the Dialysis Care of Edgecombe County facility. The physicians of Eastern Nephrology Associates ... communicated with the patients and informed them of the ... new facility where a physician associated with Eastern Nephrology Associates would be the Medical Director. ...

[T]he second and obvious effect upon competition is that some patients currently receiving care at [Dialysis Care of Edgecombe County] have indicated a preference to transfer their care to [FMC Tarboro] upon completion and certification of the project.

BMA has evaluated the possible effects of patients transferring from DC Edgecombe facility to the new FMC Tarboro.

- a. BMA has included 27 letters from patients for [sic] DC Edgecombe.*
- b. BMA ... projected 33 patients to transfer their care to the new facility. ... BMA considered that the three patients from Halifax and Martin Counties are currently dialyzing in a BMA facility. BMA ... assumed that eight of the patients transferring to the new facility are currently dialyzing at a BMA facility.*

⁴ <http://www.mapquest.com>

- c. *BMA assumes that 22 patients transferring their care to the new facility are currently dialyzing at the DC Edgecombe facility.*
- d. *BMA ... calculated the probable utilization of the DC Edgecombe facility as of December 31, 2016, the projected certification date of this project.*
- e. *[T]he January 2015 indicates ... the DC Edgecombe facility is certified for 25 dialysis stations with nine stations pending certification*
- f. *The DC Edgecombe facility filed a CON application, ... Project ID # L-8745-11, seeking approval to add 10 stations ... for a total of 35 stations. That application ... approved. ... At the time of the SDR publication, only one of the 10 stations approved has been certified.*
- g. *The SDR indicates the DC Edgecombe in-center census was 92 patients on June 30, 2014.*
- h. *BMA will demonstrate growth of the Edgecombe County patient population using the published Five Year Average Annual Change Rate of 4.8%*
- i. *[N]o growth is applied to the patients residing in other counties ... [See the table on page 73.]*
- j. *BMA projects the utilization at DC Edgecombe County to be 82 patients dialyzing on 26 stations ... This calculates to 3.154 patients per station, or 78.85%.*
- k. *Utilization will exceed 80% by December 31, 2017. [See the table on page 73.]*

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 in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

In Section I.13 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. 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 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, as 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- See Section II.1, page 11, Section IV, page 65, and Exhibit 5 (copy of the January 2015 SDR, Tables A and B). As of June 30, 2014, the utilization rate for BMA East Rocky Mount was 97.5% and the utilization rate for Greenville Dialysis Center was 74.48%.

.2202(a)(2) Mortality rates;

-C- In Section II.1, page 11, and Section IV.2, page 65, the applicant states mortality rates for BMA East Rocky Mount were 21.1% in 2012, 15.7% in 2013, and 13.4% in 2014. The mortality rates for Greenville Dialysis for the same timeframe were 11.1%, 8.4% and 8.7%, respectively.

.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, and Section IV.3, page 65, the applicant states, “*BMA East Rocky Mount is not certified to provide home dialysis training and support. Patients ... are referred to BMA Rocky Mount.*” The applicant reports Greenville Dialysis had 57 home trained patients as of December 31, 2014.

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

-C- In Section II.1, page 12, and Section IV.4, page 65, the applicant states BMA East Rocky Mount referred one patient in 2013 and 12 patients in 2014 for transplant evaluation. One transplant was performed in 2013 with no transplants being performed in 2014. Greenville Dialysis referred 30 patients for transplant evaluation in 2013 and 40 in 2014. Of those, 13 transplants were performed in 2013 and 14 in 2014.

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

-C- In Section II.1, page 12, and Section IV.4, page 65, the applicant states there are currently 12 patients on the transplant waiting list at BMA East Rocky Mount and 16 patients on the transplant waiting list at Greenville Dialysis.

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

-C- In Section II.1, page 12, and Section IV.4, page 66, the applicant provides the hospital admissions rates, by admission diagnosis, as illustrated in the tables below.

BMA East Rocky Mount Hospital Admissions

Hospital Admissions 2014		Rate
Number dialysis related	75	25.25%
Number non-dialysis related	222	74.74%
Total Number Admissions	297	100.00%

Greenville Dialysis Hospital Admissions

Hospital Admissions 2014		Rate
Number dialysis related	46	8.2%
Number non-dialysis related	515	91.8%
Total Number Admissions	561	100.0%

.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, and Section IV.7, page 66, the applicant reported there were no patients dialyzing at BMA East Rocky Mount or Greenville Dialysis with an infectious disease (Hepatitis B or AIDS) in 2013 or 2014. Additionally, the applicant reports that none of the patients dialyzing at either facility converted to infectious disease status in either of those years.

(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.*
- C- See Exhibit 25 for a letter of intent from Vidant Health.
- .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- In Section V.1(f), page 67, the applicant indicates that transplantation services will be provided by Vidant Health. See Exhibit 26 which contains a letter of intent from Vidant Health.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Section XI.6(e), page 105, the applicant states that, “*FMC Tarboro will ensure the water used for dialysis purposes is analyzed periodically and treated as necessary to maintain continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques*”. In Section XI.6(f), page 105, the applicant further states that the facility will be served by standing power service. See Exhibit 12 for a copy of FMC’s Policy and Procedure Manual guidelines which include policies on, *Termination of Dialysis in an Emergency, Using Hand Crank During Power Failure and Back Up Generator Operational Checks*. See also Exhibit 13 for copies of the applicant’s policies, procedures and guidelines which include policies on, *Water Culture Policy and General Water Quality Policy*.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 12 for copies of the applicant’s policies, procedures and guidelines; which includes a section on power failure.

- .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- See Exhibits 30 and 31 for documentation from Eastern Trust Real Estate Company, LLC that the proposed primary and secondary sites are both located on 77+ acres identified as 123 Hospital Lane, Tarboro.
- .2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section VII.2, pages 83-85 and Section XI.6, pages 104-106. In Section XI.6(g), page 106, the applicant states, “*BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, and fire safety equipment, physical environment and other relevant health safety requirements.*”
- .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- See Section III.7, pages 58-61, for all assumptions, including the methodology by which patient origin is projected. The applicant provides projected patient origin based on letters of support from current patients at BMA and DVA Healthcare Renal Care, Inc. owned and operated facilities who have expressed an interest in considering transferring their care to the proposed FMC Tarboro facility. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- .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 III.8, page 61, the applicant states that 100% of its patients will reside within a 30 mile radius of the proposed FMC Tarboro 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, page 25, 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, page 26, the applicant states FMC Tarboro is projected to have 33 in-center patients by the end of Operating Year One, which is 3.3 patients [33/10 = 3.3] per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.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.

-NA- FMC Tarboro is a new dialysis facility.

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

-C- In Section III.7, pages 50-61, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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- In Section V.1(e), page 67, the applicant states that diagnostic and evaluation services will be provided by Vidant Health-Edgecombe.

.2204(2) Maintenance dialysis;

-C- In Section V.1(c), page 67, the applicant states that maintenance dialysis will be provided at on site at FMC Tarboro.

.2204(3) Accessible self-care training;

-C- In Section V.1(d), page 67, the applicant states that accessible self-care training will be provided by Greenville Dialysis or BMA Rocky Mount. The applicant states that FMC Tarboro will have agreements with both facilities to provide self-care training. See Exhibit 20 for a copy of a service agreement with BMA Greenville, BMA Rocky Mount and BMA South Rocky Mount to provide home training in home hemodialysis.

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

-C- In Section V.1, page 67, the applicant states that an accessible follow-up program for support of peritoneal patients dialyzing at home will be provided by Greenville Dialysis or BMA Rocky Mount.

.2204(5) X-ray services;

-C- In Section V.1(g), page 67, the applicant states that X-ray services will be provided by Vidant Health-Edgecombe.

.2204(6) Laboratory services;

-C- In Section V.1(h), page 67, the applicant states that routine, special and immunological laboratory services will be provided by Spectra Laboratories. See Exhibit 15 for a copy of the service agreement.

.2204(7) Blood bank services;

-C- In Section V.1(i), page 67, the applicant states that blood bank services will be provided by Vidant Health-Edgecombe.

.2204(8) Emergency care;

-C- In Section V.1(b), page 67, the applicant states emergency care will be provided by trained BMA staff and as needed ambulance transport to Vidant Health-Edgecombe.

.2204(9) Acute dialysis in an acute care setting;

-C- In Section V.1(a), page 67, the applicant states that acute dialysis in an acute care setting will be provided by Vidant Health.

.2204(10) Vascular surgery for dialysis treatment patients

- C- In Section V.1(p), page 67, the applicant states vascular surgery for dialysis patients will be provided by Fresenius Vascular Care Greenville, Greenville Surgical Specialty, LLC or Vidant Health.
- .2204(11) *Transplantation services;*
- C- In Section V.1(F), page 67, the applicant indicates that transplantation services will be provided by Vidant Health. See Exhibit 26 for a letter of intent from Vidant Health.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- In Section V.1(o), page 67, the applicant states that referrals will be made to NC Vocational Rehabilitation of Rocky Mount or East Carolina Vocational Rehabilitation for vocational rehabilitation counseling and services.
- .2204(13) *Transportation*
- C- In Section V.1(q), page 67, the applicant indicates that transplantation services will be provided by Tar River Transit, K&L Transport, Edgecombe and Nash Ambulance Services, or Eastern Medical Transport.

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.*
- C- In Section VII, page 83, the applicant provides the proposed staffing for Tarboro Dialysis. The applicant projects to employ 9.90 full time equivalent (FTE) positions, 4.5 of which are projected to be patient technicians. The applicant states on page 84 that the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The discussion of staffing found in Criterion (7) is incorporated herein by reference.
- .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 VII.5, page 84, the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 10 contains a copy of the training outline.