

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 16, 2015

PROJECT ANALYST: Jane Rhoe-Jones  
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: Q-10328-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Ayden / Add one dialysis station to existing facility for a total of 16 stations upon project completion / 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. d/b/a FMC Ayden is currently certified for 15 in-center dialysis stations. In this application, the applicant proposes to add one dialysis station to the existing facility for a total of 16 in-center dialysis stations upon completion of this project. FMC Ayden is located at 3793 Lee Street in Ayden.

#### **Need Determination**

The applicant proposes to add one additional dialysis station. The facility need methodology in the 2014 State Medical Facilities Plan (2014 SMFP) is applicable to this review. The SMFP provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for any additional dialysis stations in Pitt County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%.

The July 2014 SDR reports that as of January 31, 2013, there were 15 certified dialysis stations at FMC Ayden and 56 in-center patients, which is a 93% utilization rate or 3.7 patients per station [56 patients / 15 certified stations = 3.73; 3.73 / 4 = 0.9333]. In this application, FMC Ayden is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.7 patients per station, or 93%, as calculated above.

See the following table, which illustrates the facility need methodology:

<b>FMC AYDEN --- OCTOBER 1 REVIEW---JULY 2014 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		93.3%
Certified Stations		15
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>15</b>
In-Center Patients as of 12/31/13 (SDR2)		56
In-Center Patients as of 6/30/13 (SDR1)		52
Step	Description	
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.1538
(ii)	Divide the result of Step (i) by 12	0.0128
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.1538
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	64.6154
(v)	Divide the result of Step (iv) by 3.2 patients per station	20.1923
	and subtract the number of certified and pending stations as recorded in SDR2 [15 stations] to determine the number of stations needed	5

*Step (C) of the facility need methodology (2014 SMFP, page 364) states, “The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations.”* As shown in the table above, based on the facility need methodology for dialysis stations, the FMC Ayden facility has a need for five additional stations. The applicant proposes to add one new station and therefore, the application is consistent with the facility need methodology for dialysis stations. Thus, at the completion of this project, FMC Ayden will be certified for 16 in-center dialysis stations.

**Policies**

There is one policy in the 2014 SMFP that is applicable to this review: Policy GEN-3. Policy GEN-3 states:

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

#### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section I.13, pages 4-9, Section II.1, pages 19-20, Section II.3, pages 26-29, Section V.7, page 41, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section II.1, pages 20-22, Section III, page 33, Section V.7, pages 40-41, Section VI, pages 42-46, Section VII, pages 48-49, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section II.1, pages 21-22, Section III.9, pages 33-34, Section V.7, pages 40-41, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximize value for resources expended in meeting the need identified in the 2014 SMFP. Therefore, the application is consistent with *Policy GEN-3*.

#### Conclusion

The application is consistent with the facility need methodology for additional dialysis stations and applicable policies in the 2014 SMFP. 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Ayden proposes to add one in-center dialysis station to the existing facility pursuant to the facility need determination for a facility total of 16 stations upon completion of this project. The July 2014 SDR reports that as of January 31, 2013 there were 15 certified dialysis stations at FMC Ayden and 56 in-center patients, which is an 93% utilization rate or 3.7 patients per station [56 patients / 15 certified stations = 3.70; 3.70 / 4 = 0.9333]. In Pitt County there are three dialysis facilities (FMC Ayden, FMC Dialysis Services East Carolina University and Greenville Dialysis Center). BMA owns each of the three facilities.

**Population to be Served**

In Section III.7, pages 31-32 of the application, the applicant projects the following patient origin for FMC Ayden, which is based on the current patient population:

<b>FMC AYDEN PROJECTED PATIENT ORIGIN</b>				
<b>County</b>	<b>County Patients as % of Total</b>			
	<b>Operating Year 1</b>	<b>Operating Year 1</b>	<b>Operating Year 1</b>	<b>Operating Year 1</b>
Pitt	62.1	66.1	91.2%	91.7%
Craven	3	3	4.4%	4.2
Greene	1	1	1.5%	1.4%
Lenoir	2	2	2.9%	2.8%
<b>TOTAL</b>	<b>68.1</b>	<b>72.1</b>	<b>100%</b>	<b>100%</b>

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section III.1, page 30, the applicant states the application is filed pursuant to the Facility Need Methodology (2014 SMFP). In Section II.1, pages 13-14, and Section III.7, page 32, the applicant provides the following assumptions and methodology it used to project the need for one additional station at FMC Ayden:

1. “BMA assumes that the dialysis patient population residing in Pitt County and dialyzing at FMC Ayden will increase at a rate commensurate with the Pitt County Five Year Average Annual Change Rate, 6.5% as published in the July 2014 SDR.
2. BMA assumes that the three patients residing in Craven, Green and Lenoir Counties, and dialyzing at FMC Ayden are dialyzing at FMC Ayden as a function of patient choice. BMA will not demonstrate any increase in this segment of the patient population but does project these patients to continue to dialyze at FMC Ayden. These patients will be added to projected patient population for FMC Ayden at appropriate points in time.”

On pages 14 and 32, the applicant provides a table, reproduced below, to illustrate the projected in-center patient population of FMC Ayden:

<b>FMC AYDEN IN-CENTER PATIENT PROJECTIONS</b>	
<i>BMA begins with the Pitt County patient population dialyzing at the facility as of June 30, 2014.</i>	<i>53 in-center patients</i>
<i>BMA uses one-half of the Pitt County Average Annual Change Rate of 6.5% to project the census forward for 6 months to December 31, 2014.</i>	<i>[53 x (.065/12x6)] + 53 = 54.7</i>
<i>BMA projects this patient population forward for 1 year to December 31, 2015.</i>	<i>(54.7 x .065) + 54.7 = 58.3</i>
<i>BMA adds the 6 patients reside [sic] in other counties. This is the projected beginning census.</i>	<i>58.3 + 6 = 64.3</i>
<i>BMA projects the Pitt County patient population forward for 1 year to December 31, 2016.</i>	<i>(58.3 x .065) + 58.3 = 62.1</i>
<i>BMA adds the 6 patients reside [sic] in other counties. This is the projected ending census for Operating Year 1, December 31, 2016.</i>	<i>62.1 + 6 = 68.1</i>
<i>BMA projects the Pitt County patient population forward for 12 months to December 31, 2017.</i>	<i>(62.1 x .065) + 62.1 = 66.1</i>
<i>BMA adds the 6 patients reside [sic] in other counties. This is the projected ending census for Operating Year 2, December 31, 2017.</i>	<i>66.1 + 6 = 72.1</i>

In Operating Year One, the applicant projects to serve 68 in-center patients on 16 dialysis stations, which is 4.3 patients per station, or 107.5% of capacity [68 / 16 = 4.25; 4.3 / 4 = 1.07]. In Operating Year Two, the applicant projects to serve 72 in-center patients on 16 stations, which is 4.5 patients per station, or 112.5% of capacity [72 / 16 = 4.5; 4.5 / 4 = 1.13]. Thus, assuming only two shifts per day, it is projected that FMC Ayden will exceed 100% capacity in the first operating year. However, in Section VII.10, page 49, the applicant states that the facility will operate a third shift on Monday, Wednesday and Friday beginning in the first operating year to accommodate the projected utilization. At the end of the first operating year the applicant projects to serve at least 3.2 patients per station per day as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding historical and projected growth of dialysis patients at FMC Ayden.

### Access

In Section VI.1, pages 42-46, the applicant describes how underserved persons will have access to services provided by FMC Ayden. On page 42, the applicant states:

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

The applicant projects 90.3% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and the extent to which all residents of the area, in particular underserved groups are likely to have access to the services provided. 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.

NA

- (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 33-34, the applicant describes the alternatives it considered prior to the submission of this application, which include:

- 1) Maintain the status quo: The applicant states that there is a thirteen-station deficit in Pitt County. Therefore, this alternative is not an option because failure to apply; although for one station, would not abate the station deficit in Pitt County.
- 2) Apply for more than one station at FMC Ayden: The applicant states that this alternative is not reasonable as the facility lacks physical capacity.
- 3) Relocate stations from its other facilities in Pitt County: The applicant states that this alternative is not feasible due to the high utilization of its other facilities in Pitt County.

On page 34, the applicant states, “*BMA has chosen the most effective and least costly alternative for meeting the needs of the patients projected to receive treatment at the FMC Ayden facility.*”

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 Ayden 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 Ayden 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 Ayden shall develop and operate no more than one additional station for a total of no more than 16 certified in-center dialysis stations upon completion of this project, including any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Ayden shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station for a total of no more than 16 dialysis stations upon completion of this project, including any home hemodialysis training or isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Ayden shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

In Section VIII.1, pages 50-51, the applicant projects the capital cost for the project will be \$5,000, which includes \$2,500 for RO water treatment equipment and \$2,500 for other equipment and furniture. In Section IX, page 56, the applicant projects no working capital needs (start-up and initial operating expenses) associated with the proposed project, since FMC Ayden is currently operational.

In Section VIII.2, pages 51-52, the applicant states the capital costs of the project will be funded with accumulated reserves. Exhibit 24 includes a September 15, 2014 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

*“BMA is submitting a Certificate of Need Application to add one dialysis station to its FMC Ayden facility in Pitt County. The project calls for the following capital expenditure:*

*Capital Expense                      \$5,000*

*As Vice President, I am authorized and do hereby authorize the addition of one dialysis station, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$5,000 as may be needed for this project.”*

In Exhibit 4, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc., the applicant’s parent, for the fiscal year ended December 31, 2013. As of December 31, 2013, FMC had \$275,719,000 in cash and cash equivalents, \$16,597,314 in total assets and \$8,075,490,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 55, the applicant provides the allowable charges per treatment for each payment source as follows:

<b>FMC AYDEN ALLOWABLE CHARGES</b>	
<b>Payor</b>	<b>Charge per Treatment</b>
Medicare	\$239.00
Medicaid	\$140.23
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
VA	\$231.12
State Kidney Program	\$100.00
Commercial Insurance	\$1,425.00
Private Pay	\$1,425.00

The applicant states that the commercial charge listed does not reflect the actual reimbursement. On pages 55-56, the applicant states that Medicare’s ‘bundling’ reimbursement program which provides one basic fee per dialysis treatment, is “approximately \$240 per treatment.” This fee ‘bundles,’ or includes all ancillary services which were previously billed separately.

The applicant projects revenues in Section X.2, page 57, and operating expenses in Section X.4, page 62, for FMC Ayden as follows:

<b>FMC AYDEN</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$3,210,585	\$3,335,880
Total Operating Costs	\$2,663,882	\$2,769,684
<b>Net Profit</b>	<b>\$ 546,703</b>	<b>\$ 566,196</b>

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.3, page 58, for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the 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.

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Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Ayden proposes to add one station to the existing facility for a total of 16 stations upon completion of the proposed project. The July 2014 SDR reports that the following three ESRD facilities are currently located in Pitt County.

<b>Facility</b>	<b>Owned/ Operated by</b>	<b># of Certified Stations</b>	<b>% Utilization</b>	<b>Address</b>	<b>Distance to Proposed Facility<sup>1</sup></b>
FMC Ayden	FMC	15	93.33%	3793 Lee St. Ayden	Applicant
FMC Dialysis Services ECU	FMC	38	99.34%	2355 W. Arlington Blvd. Greenville	12.2 miles
Greenville Dialysis Center	FMC	48	76.04%	510 Paladin Dr. Greenville	13.8 miles

Source: July 2014 SDR. <sup>1</sup><http://www.mapquest.com>

FMC owns each of the three facilities in Pitt County. The three facilities are located within 20 miles of each other. As reported in the July 2014 SDR, FMC Ayden operated with 15 certified stations and had a utilization rate of 93.3% as of December 31, 2013; FMC Dialysis Services-ECU operated with 38 stations and had a utilization rate of 99.34%; and Greenville Dialysis Center operated with a utilization rate of 76%. According to Table B in the July 2014 SDR, there is a 13-station deficit in Pitt County.

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<sup>1</sup><http://www.mapquest.com>

The applicant adequately demonstrates that one additional station is needed for the patients expected to utilize FMC Ayden. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Consequently, the applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities 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.

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In Section VII.1, page 47, the applicant provides staffing for FMC Ayden, as illustrated in the following table:

<b>FMC AYDEN</b>			
<b>FULL-TIME EQUIVALENT (FTE) POSITIONS</b>			
	<b>CURRENT</b>	<b>ADD</b>	<b>TOTAL</b>
RN	2.00	.75	2.75
Tech	7.00	2.00	9.00
Clinical Manager	1.00	-	1.00
FMC Director of Operations	.15	-	.15
Dietician	.80	-	.80
Social Worker	.80	-	.80
Chief Tech	.25	-	.25
Equip Tech	.75	-	.75
In-Service	.25	-	.25
Clerical	.75	-	.75
<b>Total FTEs</b>	<b>13.75</b>	<b>2.75</b>	<b>16.50</b>

The applicant projects a total of 16.50 FTE positions upon project completion. In Section VII.4, page 48, the applicant states it anticipates no difficulty recruiting additional staff for the facility. In Section V.4(c), page 39, the applicant states the current Medical Director for FMC Ayden is John Reed, MD. In Exhibit 21, the applicant provides a September 3, 2014 letter of support from Dr. Reed which also indicates his willingness to continue to serve as Medical Director of the facility. Additionally, in Section VII.10, page 54, the applicant states FMC Ayden will operate three shifts; two shifts, six days a week from 7:00 a.m. to 5:00 p.m., and the third shift three days a week from 5:00 p.m. to 10:00 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.

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In Section V.1, page 37, the applicant identifies the providers of the necessary ancillary and support services for FMC Ayden. The applicant provides further detail of the ancillary and support services in Section V, pages 38-40. In Exhibits 15, 19, 21, 25 and 26, the applicant provides documentation to support the statements regarding the provision of necessary ancillary and support services. 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.

NA

(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;

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In Section VI.1(b), page 43, the applicant reports that 90.3% of the patients who received treatments at FMC Ayden had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payor mix for this existing facility:

<b>FMC AYDEN JUNE 2014 PAYOR MIX</b>	
<b>PAYOR</b>	<b>PERCENTAGE</b>
Medicare	83.96%
Medicaid	4.48%
Commercial Insurance	7.95%
VA	1.73%
Medicare/Commercial	1.88%
<b>Total</b>	<b>100.0%</b>

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, Craven, Greene and Lenoir counties and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Pitt County	16.3%	6.7%	21.3%
Craven County	15.1%	6.5%	19.6%
Greene County	21.1%	7.6%	24.6%
Lenoir County	24.6%	11.0%	21.1%
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 1/1/2013 – 12/21/2013, page 99*).<sup>2</sup>

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, handicapped, minorities or women utilizing health services.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ....”*<sup>3</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American. (p.216) 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. 216). 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 Medicare coverage, compared to just 53 percent of those with a transplant.”* (p. 216)

<sup>2</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

<sup>3</sup>[www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
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%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

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:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
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	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>4</sup>

FMC Ayden demonstrates that it currently provides adequate access to medically underserved populations. 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;

<sup>4</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

C

In Section VI.1(f), page 44, 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. ... .”*

In Section VI.6(a), page 45, the applicant states there have been no civil rights access complaints filed against any North Carolina BMA facilities in the last five years. 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 43, the applicant provides the projected payor mix for the proposed services at FMC Ayden, as shown below in the table. The applicant projects no change from the current payor mix.

<b>FMC AYDEN PROJECTED PAYOR MIX</b>	
<b>PAYOR</b>	<b>PERCENTAGE</b>
Medicare	83.96%
Medicaid	4.48%
Commercial Insurance	7.95%
VA	1.73%
Medicare/Commercial	1.88%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects 90.3% of all patients will have their care paid for by Medicare and Medicaid.

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(a), page 45, 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 Ayden will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”*

The applicant adequately demonstrates that FMC Ayden will continue to 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 39, the applicant states that Exhibit 19 contains an agreement between FMC Ayden and Pitt Community College for student nurse clinical rotations at FMC Ayden.

The information provided in Section V.3 is reasonable and credible for an existing 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 add one dialysis station for a total of 16 certified dialysis stations at FMC Ayden upon completion of the project. According to the July 2014 SDR there are currently three ESRD facilities located in Pitt County and a deficit of 13 dialysis stations in

the county. Of those existing ESRD facilities, all operated above 75% utilization (FMC Ayden at 93.3%, FMC Dialysis Services – ECU at 99.3% and Greenville Dialysis Center at 76%). The applicant projects that 90% of all patients who receive services at FMC Ayden will have their care paid for by Medicare and Medicaid.

In Section V.7, pages 40-41, the applicant discusses how any enhanced competition in the service area will the promote cost effectiveness of, quality of and access to the proposed services. The applicant states in part:

*“BMA does not expect this proposal to have effect on the competitive climate in Pitt County. According to the July 2014 SDR there are currently three dialysis facilities operating within Pitt County; all are operated by BMA. ...”*

See also Sections II (pages 19-29), III (pages 33-34), V (pages 37-41), VI (pages 42-46), VII (pages 48-49) and referenced exhibits, 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 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 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 continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20), respectively, are incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13), respectively, are incorporated herein by reference.

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 currently provides dialysis services at FMC Ayden. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Ayden has

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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

#### **10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant provides the utilization rate of 93.3% or 3.7 patients per station ( $56 / 15 = 3.7$ ) as reported in Table A of the July 2014 SDR.

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant provides the mortality rates as 5.7%, 11.2% and 7.2% for 2011, 2012 and 2013, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-NA- In Section II.3, page 11, the applicant states, “*FMC Ayden is not certified to offer home training. Patients who are candidates for home dialysis are referred to Greenville Dialysis Center.*”

(4) *The number of transplants performed or referred;*

- C- In Section II.1, page 11, the applicant states FMC Ayden referred 15 patients for a transplant in 2012 and 19 in 2013. One transplant was performed in 2012 and two in 2013.
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section II.1, page 11, the applicant states, “*FMC Ayden has 18 patients on the transplant waiting list.*”
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section II.1, page 11, the applicant states that there were 105 hospital admissions in 2013, 39 were dialysis related and 66 were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section II.1, page 12, the applicant states that there were no patients at the facility in 2012 or 2013 with an infectious disease; nor were there any conversions to infectious status during the last calendar year.

*(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:*

- (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.*
- NA- FMC Ayden is an existing facility. However, the applicant provides a copy of the hospital affiliation agreement with Pitt County Memorial Hospital in Exhibit 25.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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.*

-NA- FMC Ayden is an existing facility. However, the applicant provides a copy of a transplantation agreement with Pitt County Memorial Hospital in Exhibit 26.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- FMC Ayden is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- In Exhibit 12 the applicant provides a copy of the *Emergency Management and Disaster Planning* policy, which provides procedures for back-up electrical service in the event of a power outage for FMC Ayden.

(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.*

-NA- FMC Ayden is an existing facility.

(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- In Section II.1, page 13, the applicant states, “*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water*

*supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC Ayden.”*

(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, pages 13-14, and Section III.7, page 32, the applicant provides the methodology and assumptions to project patient origin. The patient origin is presented in the following table:

<b>FMC AYDEN PROJECTED PATIENT ORIGIN</b>				
<b>County</b>	<b>County Patients as % of Total</b>			
	<b>Operating Year 1</b>	<b>Operating Year 1</b>	<b>Operating Year 1</b>	<b>Operating Year 1</b>
Pitt	62.1	66.1	91.2%	91.7%
Craven	3	3	4.4	4.2
Greene	1	1	1.5%	1.4%
Lenoir	2	2	2.9%	2.8%
<b>TOTAL</b>	<b>68.1</b>	<b>72.1</b>	<b>100%</b>	<b>100%</b>

The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC Ayden is an existing facility.

(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 rate for such services.*

-C- In Section II.1(9), page 15, 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.”

*(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- FMC Ayden is an existing facility.

*(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- FMC Ayden projects utilization of 4.25 patients per station per week as of the end of the first operating year. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 13-14, and Section III.7, pages 30 and 32. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

#### **10A NCAC 14C .2204 SCOPE OF SERVICES**

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

*(1) diagnostic and evaluation services;*

-C- In Section II.1, page 16, the applicant states, “*Patients requiring diagnostic and evaluation services will be referred to Vidant Health Systems in Greenville or, Physicians East Medical Services.*”

*(2) maintenance dialysis;*

-C- In Section II.1, page 16, the applicant states, “*The facility will provide in-center dialysis.*”

*(3) accessible self-care training;*

- C- In Section II.1, page 17, the applicant states, “*Patients who are candidates for self-care are referred to the facility home training department.*”
  - (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.1, page 17, the applicant states, “*Patients who are candidates for home dialysis will be referred to the Greenville Dialysis home training department. ...*”
  - (5) *x-ray services;*
- C- In Section II.1, page 17, the applicant states, “*Patients ... will be referred to Vidant Health Systems Greenville or Physicians East Medical Services.*”
  - (6) *laboratory services;*
- C- In Section II.1, page 17, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 15 for the laboratory services agreement with Spectra Laboratories.
  - (7) *blood bank services;*
- C- In Section II.1, page 17, the applicant states, “*Patients in need of blood transfusion will be referred to Vidant Health Systems in Greenville.*”
  - (8) *emergency care;*
- C- In Section II.1, page 17, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*”
  - (9) *acute dialysis in an acute care setting;*
- C- In Section II.1, page 17, the applicant states, “*Patients requiring admission to hospital [sic] will be referred to Vidant Health Systems in Greenville.*”
  - (10) *vascular surgery for dialysis treatment patients;*
- C- In Section II.1, page 17, the applicant states, “*Patients will be referred to Eastern Nephrology Associates-Vascular Center, or Greenville Surgical Specialty, LLC.*”
  - (11) *transplantation services;*

-C- In Section II.1, page 17, the applicant states, “*FMC Ayden has a transplant agreement with Vidant Health System.*” See Exhibit 26 for a copy of the transplantation agreement with Vidant Health Systems.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section II.1, page 18, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the [sic] East Carolina Vocational Rehabilitation.*”

(13) *transportation.*

-C- In Section II.1, page 18, the applicant states, “*Transportation services are provided by Pitt Area Transit System (PATs), Door-to-Door, Jackie McNear (offers both private and social services transportation), Care First, and Med One.*”

#### **10A NCAC 14C .2205 STAFFING AND STAFF TRAINING**

*(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 II, page 18, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 48, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

*(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 18, and Section VII.5, page 48, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten-week training program, and that staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 9 contains an outline of the training program and Exhibit 10 contains the outline of the continuing education programs.