

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 12, 2014  
PROJECT ANALYST: Bernetta Thorne-Williams  
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: L-10341-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Spring Hope/ Add two dialysis stations for a total of 15 certified stations upon project completion / Nash 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.

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Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC of Spring Hope, whose parent company is Fresenius Medical Care Holdings Inc., purposes to add two dialysis stations for a total of 15 certified dialysis stations upon project completion.

#### **Need Determination**

The 2014 State Medical Facilities Plan (2014 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 a surplus of 17 dialysis stations in Nash County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for FMC of Spring Hope in the July 2014 SDR is 4.0 patients per station. This utilization rate was calculated based on 40 in-center dialysis patients and 10 certified dialysis stations. (40 patients / 10 stations = 4.0 patients per station).

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Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		100.0%
Certified Stations		10
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>13</b>
In-Center Patients as of 12/31/13 (SDR2)		40
In-Center Patients as of 6/30/13 (SDR1)		33
Step	Description	
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.4242
(ii)	Divide the result of Step (i) by 12	0.0354
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.4242
(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	56.9697
(v)	Divide the result of Step (iv) by 3.2 patients per station	17.8030
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations 10] to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

Policy GEN-3: Basic Principles, page 38 of the 2014 SMFP, is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and*

*demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section II.1, pages 19-20, Section II.3, pages 26-29, Section V.7, page 41-42, 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 20-21, Section VI, pages 43-46 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 V.7, pages 41-42, 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 maximum 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 determination in the July 2014 SDR and Policy GEN-3. 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.

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The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Spring Hope, proposes to add two dialysis stations for a total of 15 certified stations at its facility located at 102 Dodd Street, in Spring Hope, upon project completion.

**Population to be Served**

In Section IV.1, page 36, the applicant identifies the population it served, as of June 30, 2014, as illustrated in the table below.

County of Residence	# of Patients Dialyzing In-Center
Nash	44
Franklin	1
Edgecombe	2
<b>Total</b>	<b>47</b>

In Section III.7, page 32, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

FMC of Spring Hope				
County	Operating Year 1 2016	Operating Year 2 2017	County In-center Patients as % of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Nash	46.0	46.8	93.9%	94.0%
Franklin	1.0	1.0	2.0%	2.0%
Edgecombe	2.0	2.0	4.1%	4.0%
<b>Total</b>	<b>49.0</b>	<b>49.8</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identified the population to be served.

**Analysis of Need**

In Section III.7, pages 32-33, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize FMC of Spring Hope, which is summarized as follows:

The majority of patients projected to utilize FMC of Spring Hope will be Nash County residents. The projections are based on the following assumptions:

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- BMA assumes the number of Nash County patients will increase at the Nash County Five Year Average Annual Change Rate of 1.8% as published in the July 2014 SDR.
- BMA does not assume that the number of patients from Franklin or Edgecombe County who are projected to use FMC of Spring Hope will increase.

The following table summarizes BMA’s methodology for projecting future in-center patient growth.

Nash County	In-Center Patients
BMA begins with Nash County patients dialyzing as of June 30, 2014.	44
BMA used ½ of the change rate to project the census forward for 6 months to December 21, 2014.	$[44 \times (.0018 / 12 \times 6)] + 44 = 44.4$
This population is projected forward for one year to December 31, 2015.	$(44.4 \times .0018) + 44.4 = 45.2$
Then the 3 patients from other counties are added in for the projected beginning census.	$45.2 + 3 = 48.2$
The Nash County patient population is projected forward for one year to December 31, 2016.	$(45.2 \times .0018) + 45.2 = 46.0$
The 3 patients from other counties are added in for the projected ending census for Operating Year 1 – December 2016.	$46.0 + 3 = 49.0$
The Nash County patient population is projected forward another 12 months to December 31, 2017.	$(46.0 \times .0018) + 46.0 = 46.8$
Then the 3 patients from other counties are added in for the projected ending census Operating Year 2 – December 31, 2017.	$46.8 + 3 = 49.8$ (which is rounded down to 49)

Based on the information above, FMC of Spring Hope is projected to serve 49 in-center patients at the end of operating year one for a utilization rate of 80.0% or 3.27 patients per station. This meets the requirement in 10A NCAC 14C .2203(b) that at the end of the first operating year the facility shall serve at least 32 patients or 3.2 patients per station.

**Access**

In Section VI.1, pages 43-47, the applicant describes how underserved persons will have access to services provided by FMC of Spring Hope. On page 43, the applicant states:

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or other traditionally underserved persons.”*

The 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 identified the population to be served, demonstrated the need the population has for the project and the demonstrated extent to which all residents of the area, in particular 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.

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 34-35, the applicant discusses the alternatives considered, which include the following:

- Maintain the Status Quo – The applicant concluded that this was not the best option for the patients residing in Nash County because, according to the July 2014 SDR, the facility is operating at 100% utilization. The addition of the three previously approved dialysis stations (See Project I.D. # L-8796-12) for a total of 13 certified stations has reduced that

utilization rate to 90.39% but continued growth in the patient population without an increase of stations could force Nash County residents to travel to facilities located further away.

- Apply for Fewer Stations – The applicant concluded that based on the facility need methodology, the applicant could have applied for up to five additional stations; however, the applicant opted for the least costly approach of applying for two additional stations.
- Relocate Stations from BMA Rocky Mount – The applicant concluded, based on information in the July 2014 SDR concerning BMA owned and operated facilities in Nash County that this option was not its most effective alternative. [See tables on page 34 of the application that demonstrate why relocating stations from BMA Rocky Mount was not considered to be the most effective alternative].
- Develop the Facility as Proposed – The applicant concluded that the development of the project as proposed would be its least costly and most effective alternative.

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

In summary, the applicant adequately demonstrates that the FMC of Spring Hope 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 of Spring Hope 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 of Spring Hope shall develop no more than two additional stations for a total of no more than 15 certified stations upon completion of this project, which shall include any home hemodialysis training and isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Spring Hope shall install plumbing and electrical wiring through the walls for no more than a total of 15 dialysis stations, which shall include any home hemodialysis training and isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Spring Hope shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance 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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In Section VIII.1, page 52, the applicant states that the total capital cost of the project will be \$6,000 which includes \$1,000 for ancillary water equipment, \$2,000 for patient chairs and \$3,000 for patient televisions. On page 52, the applicant states the project will be funded by means of accumulated reserves. In Section IX, page 55, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated September 15, 2014 from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

*"This is to inform you that Fresenius Medical Holdings, Inc is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA is submitting a Certificate of Need Application to add two dialysis stations to its FMC Spring Hope facility in Nash County. The project calls for the following capital expenditures:*

<i>Capital Expenditure</i>	<i>\$6,000</i>
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*As Vice President, I am authorized and do hereby authorize the addition of two dialysis stations, for the capital cost identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$6,000 as may be needed for this project."*

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

In Section X.1, page 56, the applicant provides the allowable charge per treatment for each payor source for FMC of Spring Hope, as illustrated in the table below:



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Payor Source	Charge per Treatment
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
Medicare/Medicaid	\$239.02
VA	\$231.12
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.02
State Kidney Program	\$100.00
Other Self/Indigent	\$1,425.00

In Sections X.2-X.4, pages 58-63, the applicant reports projected revenues and expenses for FMC of Spring Hope, as illustrated in the table below:

<b>FMC of Spring Hope</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$1,966,956	\$1,948,886
Total Operating Costs	\$1,810,823	\$1,824,570
<b>Net Profit</b>	<b>\$156,133</b>	<b>\$124,316</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 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 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.

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Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Spring Hope proposes to add two

dialysis stations to the existing facility for a total of 15 stations upon completion of the proposed project. Based on the facility need methodology in the July 2014 SDR, the applicant adequately demonstrated the need for five additional stations, however, the applicant has opted to add only two addition stations based on the number of in-center patients it currently serves.

There are currently two existing and two approved ESRD facilities in Nash County. Both existing and one of the approved ESRD facilities are owned and operated by BMA. The second approved facility will be owned by DaVita. That approval is currently under appeal. The following table illustrates utilization of the two existing facilities.

**Utilization as of June 30, 2014**

<b>Name of Facility</b>	<b># of Certified Stations</b>	<b># of In-Center Patients</b>	<b>% of Utilization</b>	<b>Location</b>
FMC of Spring Hope	13	47	90.38%	Spring Hope
Rocky Mount Kidney Center	42	169	100.60%	Rocky Mount

The applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing or approved dialysis services 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.

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In Section VII, page 48, the applicant provides the current number of full-time equivalent (FTE) positions (8.75) and projects to hire 1.50 new FTEs. Those new positions include a RN (0.50) and a Technician (1.00). The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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 38, the applicant lists the providers of the necessary ancillary and support services. The information regarding coordination of services in Section V, pages 38-42 and referenced exhibits, is reasonable and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (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 44, the applicant reports that 95.43% of the patients who received treatments at FMC of Spring Hope had some or all of their services paid for by Medicare or Medicaid in the past year, as shown in the table below.

<b>FMC OF SPRING HOPE PAYOR MIX AS OF JUNE 30, 2014</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	81.40%
Medicaid	1.04%
Medicare/Commercial	12.99%
Commercial	4.56%
<b>Total</b>	<b>100.00%</b>

Additionally, on page 43, the applicant reports that FMC of Spring Hope patient population consists of 41.1% elderly (65+), 46.0% women and 67.9% racial minorities.

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 Durham County 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>
Nash County	20%	8.6%	19.7%
Statewide	17%	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>1</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, minorities, women or handicapped persons 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>2</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.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”* (p. 216).

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

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<sup>1</sup><http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<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>3</sup>

FMC of Spring Hope 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

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

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

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In Section VI.1(f), page 45, the applicant states:

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

In Section VI.6(a), page 46, the applicant states there have been no patient civil rights access complaints filed within 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

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In Section VI.1(c), page 44, the applicant states it does not anticipate a significant change in the payor mix, as illustrated in the table below.

Source of Payment	As a % of Total
Commercial Insurance	4.56%
Medicare	81.40%
Medicaid	1.04%
Medicare/Commercial	12.99%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects 95.4% 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 services at FMC of Spring Hope. 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.

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In Section VI.5(a), page 46, 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 of Spring Hope will have an open policy, which means that Nephrologists may apply to admit patients at the facility. The attending physicians receive referrals from other physicians, Nephrologists or hospital emergency rooms.”*

Also see Exhibit 7, for FMC’s admission policy.

The applicant adequately demonstrated that it will offer a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

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In Section V.3, page 39, the applicant states that FMC of Spring Hope has requested to be included in the clinical rotation of nursing students attending Nash Community College. Exhibit 19 includes a letter dated September 15, 2014 from Fresenius Medical Care to the Nursing Instruction of Nash Community College offering the use of the facility as a clinical training site. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of



applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add two dialysis station for a total of 15 dialysis stations at FMC of Spring Hope upon project completion. There are currently two existing and two approved ESRD facilities in Nash County. Both the existing and one of the approved facilities are owned and operated by BMA. The second approved facility will be owned by DaVita. That approval is currently under appeal.

In Section V.7, page 41-42, 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. On page 41, the applicant states:

*“BMA does not expect this proposal to have effect [sic] on the competitive climate in Nash County. ... BMA also has an approved CON application to relocate stations from BMA Rocky Mount to develop FMC South Rocky Mount facility. In addition, DaVita Dialysis has been approved to develop a facility in Rocky Mount (that decision is the subject of an appeal). ...*

*BMA facilities are compelled to operate at a maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 95% of the in-center patients will be relying upon either Medicare or Medicaid. ...”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area would have a positive impact on quality and access to the proposed services. This determination is based on the following analysis:

- The applicant adequately demonstrates the need to add two additional dialysis stations 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 will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (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

The applicant currently provides dialysis services at FMC of Spring Hope. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC of Spring Hope 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**

*.2202(a)(1) Utilization rates;*

- C- See Section II.1, page 10, and Section IV.1, page 36, and Exhibit 2 (copy of the July 2014 SDR Tables A and B). As of December 31, 2013, the utilization rate for FMC of Spring Hope was 100%.

*.2202(a)(2) Mortality rates;*

- C- In Section II.1, page 10, and Section IV.2, page 36, the applicant reports the following facility mortality rates for the FMC of Spring Hope facility: 2011 – 17.5%; 2012 – 9.1%; and 2013 – 18.9%.

*.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 10, and Section IV.3, page 36, the applicant states, “*FMC of Spring Hope is not certified to offer home training. Patients who are candidates for home dialysis are referred to the BMA Rocky Mount facility.*”

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

- C- In Section II.1, page 10, and Section IV.4, page 36, the applicant reports 5 transplant patients were referred in 2012 and one transplant was performed and 4 transplant patients were referred in 2013 and zero transplants were performed.

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

- C- In Section II.1, page 10, and Section IV.5, page 36, the applicant reports two patients are currently on the transplant waiting list.

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

- C- In Section II.1, page 10, and Section IV.6, page 37, the applicant reported 140 patients were admitted to the hospital in 2013. Thirty-two of those admissions were dialysis related and 108 of those admissions were non-dialysis related.

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

-C- In Section II.1, page 11, and Section IV.7, page 37, the applicant reported that, as of June 30, 2014, there were no patients dialyzing at FMC of Spring Hope with an infectious disease (Hepatitis B or AIDS). Additionally, the applicant reports that none of the patients dialyzing at either Nash County facility converted to infectious disease status.

*(b) An applicant that proposes to develop a new facility, increase the number of 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.*

-NA- FMC of Spring Hope is an existing facility.

.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.*

-NA- FMC of Spring Hope is an existing facility.

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- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- FMC of Spring Hope is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 12 contains a copy of backup procedures in the event of a power outage.
- .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.*
- NA- FMC of Spring Hope is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section VII.2, page 49 and Section XI.6, pages 67-70. In Section XI.6(g), page 69, the applicant states, “*BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and 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 31-33, for all assumptions, including the methodology by which patient origin is projected. The applicant provides projected patient origin which is based on the historical experience of FMC of Spring Hope, as shown in the table below.

<b>FMC of Spring Hope</b>						
<b>County</b>	<b>Operating Year 1 2016</b>		<b>Operating Year 2 2017</b>		<b>County In-center Patients as % of Total</b>	
	<b>In-center Patients</b>		<b>In-center Patients</b>		<b>Year 1</b>	<b>Year 2</b>
Nash	46.0		46.8		93.9%	94.0%
Franklin	1.0		1.0		2.0%	2.0%
Edgecombe	2.0		2.0		4.1%	4.0%
<b>Total</b>	49.0		49.8		100.0%	100.0%

.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.*

-NA- FMC of Spring Hope is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section II.1, page 14, 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.*

-NA- FMC of Spring Hope is an existing facility.

.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.*

-C- See Section II.1, page 15, and Section III.7, pages 31-33, for the assumptions used by the applicant in determining its utilization for the FMC of Spring Hope facility. The applicant projects to serve 49 in-center patients as of the end of the first operating year of the additional stations, which is 3.27 patients per station per week ( $49/15 = 3.27$ ). The discussion regarding projected utilization found in Criterion (13) is incorporated herein by reference.

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

-C- In Sections II.1, pages 12-13 and III.7, pages 31-33, the applicant provides the assumptions and methodology used to project utilization. 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 38, the applicant states that diagnostic and evaluation services will be provided by Boice-Willis Clinic, or Nash UNC Healthcare Hospital. Exhibit 25 contains a copy of an agreement with Nash UNC Healthcare Hospital.

.2204(2) *Maintenance dialysis;*

-C- In Section V.1(c), page 38, the applicant states that maintenance dialysis will be provided at FMC of Spring Hope.

.2204(3) *Accessible self-care training;*

- C- In Section V.1(d), page 38, the applicant states that accessible self-care training will be provided at BMA Rocky Mount. Exhibit 20 contains a copy of FMC of Spring Hope's home training agreement with BMA Rocky Mount.

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

- C- In Section V.1(d), page 38, the applicant states that an accessible follow-up program for support of peritoneal patients dialyzing at home will be provided by BMA Rocky Mount.

.2204(5) *X-ray services;*

- C- In Section V.1(g), page 38, the applicant states that X-ray services will be provided by Boice-Willis Clinic.

.2204(6) *Laboratory services;*

- C- In Section V.1(h), page 38, the applicant states that laboratory services will be provided by SPECTRA. See Exhibit 15 for a copy of the service agreement.

.2204(7) *Blood bank services;*

- C- In Section V.1(i), page 38, the applicant identifies Nash UNC Healthcare Hospital as the provider of blood bank services. See Exhibit 25 for a copy of the agreement with Nash General Hospital.

.2204(8) *Emergency care;*

- C- In Section V.1(b), page 38, the applicant states that all staff are trained to respond to emergency situations. Patients will then be transported to Nash UNC Healthcare Hospital. See Exhibit 25 for a copy of the service agreement.

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



- C- In Section V.1(a), page 38, the applicant states that acute dialysis in an acute care setting will be provided by Nash UNC Healthcare Hospital. See Exhibit 25 for a copy of the hospital service agreement.

*.2204(10) Vascular surgery for dialysis treatment patients;*

- C- In Section V.1(p), page 38, the applicant states vascular surgery will be provided by, Hardee's Heart Center, Triangle Interventional Vascular Access Center and Raleigh Access Center.

*.2204(11) Transplantation services;*

- C- In Section V.1(f), page 38, the applicant states that transplantation services will be provided by UNC Hospital, Duke University Medical Center, or Vidant. Exhibit 26 contains copies of transplant agreements between FMC of Spring Hope and the three hospitals listed above.

*.2204(12) Vocational rehabilitation counseling and services;*

- C- In Section V.1(o), page 38, the applicant states Vocational Rehabilitation of Nash County will provide vocational rehabilitation counseling and services.

*.2204(13) Transportation*

- C- In Section V.1(q), page 38, the applicant identifies Tar River Transit and private transportation service as the provider of transportation services.

**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.1, page 48, the applicant provides the proposed staffing. The applicant states on page 49 that the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion of staffing found in Criterion (7) 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 VI.5, page 49, the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 9 contains the training outline. and Exhibit 10 contains the outline for the continuing education program.