

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: June 1, 2012
PROJECT ANALYST: Bernetta Thorne-Williams
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: L-8796-12/ Bio-Medical Applications of North Carolina, Inc d/b/a Fresenius Medical Care of Spring Hope/ Add three dialysis stations for a total of 13 certified stations upon completion of this project / 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 Fresenius Medical Care of Spring Hope, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), purposes to add three dialysis stations for a total of 13 certified dialysis stations upon project completion. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of six 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 Spring Hope in the January 2012 SDR is 3.2 patients per station. This utilization rate was calculated based on 32 in-center dialysis patients and 10 certified dialysis stations. (32 patients / 10 stations = 3.2 patients per station).

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

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Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		80.0%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 6/30/11 (SDR2)		32
In-Center Patients as of 12/31/10 (SDR1)		25
Difference (SDR2 - SDR1)		7
Step	Description	Result
(i)	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 6/30/11	0.5600
(ii)	Divide the result of step (i) by 12	0.0467
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January [year] SDR (6/30/11) until the end of calendar year 2011 (6 months)	0.2800
(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	40.9600
(v)	Divide the result of step (iv) by 3.2 patients per station	12.8000
	and subtract the number of certified and pending stations as recorded in SDR2 [10 stations] to determine the number of stations needed	3

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 40, of the 2012 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

In Section II.1, page 23, the applicant states:

“BMA is a high quality health care provider. ... In addition, BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

In Section II.3, page 30, the applicant states:

“FMC Spring Hope will have a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method of review is patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation. Other audits include Patient Satisfaction Surveys and chart audits. CQI membership includes the Medical Director, Area Manager, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing the improvement opportunities.”

See Exhibit 13 for copies of the CQI process.

The applicant adequately demonstrates that the proposal will promote quality and safety.

Promote Equitable Access

In Section II.3, pages 24-25, the applicant states:

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 88% of the In-Center dialysis

treatments will be covered by Medicare or Medicaid. Thus, 88% of the In-Center revenue is derived from government payors.

...

BMA is also keenly sensitive to the second element of “equitable access” – time and distance barriers. BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence. The ESRD patient population of Nash County continues to increase. At this time, there are two operational dialysis facilities in Nash County: FMC Spring Hope and BMA Rocky Mount. ... Spring Hope and Rocky Mount are on opposing sides of the County.

The ESRD patient population of the county continues to increase; BMA is filing a CON application to add three stations in order to appropriately meet the need of the population. By adding stations at FMC Spring Hope, BMA is attending to the needs of the patients of the county, within the county. This “within the county” effort ensures that patients do not have to leave their home county for dialysis.”

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section II.3, pages 25-26, the applicant states:

“BMA is projecting a capital expenditure of \$12,475 to be associated with this project. BMA is not seeking State or Federal monies to add these four [sic] stations to the facility; BMA is not seeking charitable contributions. Rather, BMA through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government pay sources. For example, within this application, BMA projects that 88% of the treatments are covered by Medicare and Medicaid. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, BMA must work diligently to control costs of delivery for dialysis, BMA does.”

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. See criterion (3) and (13) for additional discussion. The application is consistent with the facility need determination in the January 2012 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 Fresenius Medical Care of Spring Hope, proposes to add three dialysis stations for a total of 13 certified upon project completion.

Population to be Served

In Section IV.1, page 38, the applicant identifies the population it served, as of June 30, 2011, as illustrated in the table below.

County of Residence	# of Patients Dialyzing In-Center
Nash	30
Franklin	2
Total	32

In Section III.7, page 35, 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.

County	Year 1 Jan 1 to Dec 31, 2013	Year 2 Jan 1 to Dec 31, 2014	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Nash	40.5	42.3	95.3%	95.5%
Franklin	2.0	2.0	4.7%	4.5%
Total	42.5	44.3	100.0%	100.0%

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, pages 34-36, the applicant states:

“BMA is proposing to add three dialysis stations to FMC Spring Hope resulting in 13 stations at FMC Spring Hope. In order to meet the Review Criteria for Need, BMA must demonstrate that the facility will serve 3.2 patients per stations at the end of the first operating year. This is 41.6 patients rounded to 41 patients.

Assumptions:

- 1. FMC Spring Hope is currently operating at 80% capacity with a census of 32 patients dialyzing on 10 certified dialysis stations. BMA does not project to operate a third dialysis shift at FMC Spring hope due to a lack of patient interest.*
- 2. BMA assumes that the patient population of FMC Spring Hope will increase at a rate commensurate with the Nash County Five Year Average Annual Change Rate as published in the January 2012 SDR. That rate is: 4.5%*
- 3. FMC Spring Hope qualifies for additional stations using the Facility Need Methodology.*
- 4. BMA projects that this three station expansion will be completed and certified by December 31, 2012. Operating Year 1 is the period from January 1, 2013 through December 31, 2013. Operating Year 2 is the period from January 1, 2014 through December 31, 2014.*

...

Projections of future patient populations of FMC Spring Hope are derivative of the current patient population. The patient population of FMC Spring Hope is then expected to increase at a rate commensurate with the Nash County Five Year Average Annual Change Rate as published in the January 2012 SDR. That rate is 4.5%

BMA will project that six patients from BMA Rocky Mount will transfer their care to FMC Spring Hope after the project is completed. All of these patients are residents of Nash County and reside closer to FMC Spring Hope than BMA Rocky Mount.

BMA notes that there are two patients from Franklin County dialyzing at FMC Sprint Hope. BMA will project these patients to continue dialysis at FMC Spring Hope as a function of choice. No growth is forecast for this portion of the patient population. These two patients are added to the projected census at appropriate points in the calculations.

The following table demonstrates the calculations used to arrive at the projected census for Operating Years One and Two.

<i>Nash County</i>	<i>In-Center</i>
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<i>BMA begins with Nash County patients utilizing the FMC Spring Hope dialysis facility as of June 30, 2011.</i>	<i>30 Nash County patients</i>
<i>BMA projects growth of this patient population using the Nash County Five Year Average Annual Change Rate for one year to June 30, 2012.</i>	$(30 \times 0.045) + 30 = 31.4$
<i>BMA projects this patient population forward for six months to June 30, 2013 [sic]. This is the projected certification date for this project.</i>	$(31.4 \times 0.045) + 31.4 = 32.8$
<i>BMA adds the two Franklin County patients and six patients transferring from BMA Rocky Mount.</i>	$32.8 + 2 + 6 + 40.5$
<i>BMA projects the patient population from Nash County forward for 12 months at 4.5%. This is the projected Nash County patient population for June 30, 2014.</i>	$(38.8 \times 0.045) + 38.8 = 40.5$
<i>BMA adds the two patients from Franklin County. This is the end of Operating Year 1.]</i>	$40.5 + 2 = 42.5$
<i>BMA projects the patient population from Nash County forward for 12 months at 4.5%. This is the projected Nash County patient population for June 30, 2015.</i>	$(40.5 \times 0.045) + 40.5 = 42.3$
<i>BMA adds the two patients from Franklin County. This is the end of Operating Year 2.</i>	$42.3 + 2 = 44.3$

...

BMA projected utilization calculation [sic] are a function of the projected year end census rounded down to the whole number. Utilization at FMC Spring Hope is expected to be:

Operating Year 1

*42 patients dialyzing on 13 stations = 3.23 patients per station
 $42 / (4 \times 13) = 0.808$ or 80.8%*

Operating Year 2

*44 patients dialyzing on 13 stations = 3.38 patients per station
 $44 / (4 \times 13) = 0.846$ or 84.6%*

In step four of the applicant’s assumptions, the applicant states, “BMA projects that this three station expansion will be completed and certified by December 31, 2012. Operating Year 1 is the period from January 1, 2013 through December 31, 2013. Operating Year 2 is the period from January 1, 2014 through December 31, 2014.” However, in the table above, the applicant states June 30, 2013 as the certification date, June 30, 2014 as the end of operating Year 1 and June 30, 2015 as the end of operating Year 2. Additionally, on page 14, in the table with projected calculations of patient census, the applicant states, “BMA projects growth of this patient population using the Nash County Five Year Average Annual Change Rate for one year to June 30, 2012. BMA projects this patient population forward for six months [emphasis added] to June 30, 2013. This is the projected certification date for this project.” BMA’s projected growth for six months from June 30, 2012 would be December 21, 2012 and not June 30, 2012. Furthermore, the growth rate for six months would be 0.225 and not .045 (1 yr), as reported by the applicant. Therefore, in-center patients receiving dialysis services at FMC Spring hope would change slightly, as illustrated in the table below:

Nash County	In-Center
Beginning census for FMC Spring Hope	30 Nash County patients
Projected growth patient population using the Nash County Five Year Average Annual Change Rate for one year to June 30, 2012.	$(30 \times .045) + 30 = 31.4$
Patient population forward for <u>six months</u> [emphasis added] to	

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December 31, 2012. This is the projected certification date for this project.	$(31.4 \times 0.225) + 31.4 = 32.1$
Add the two Franklin County patients and six patients transferring from BMA Rocky Mount. This is the beginning census December 31, 2012.	$32.1 + 2 + 6 + 40.1$
Projected patient population from Nash County forward for 12 months at 4.5%. This is the projected Nash County patient population for December 31, 2013.	$(38.1 \times 0.045) + 38.1 = 39.8$
Add the two patients from Franklin County. This is the end of Operating Year 1. [December 31, 2013].	$39.8 + 2 = 41.8$
Projected patient population from Nash County forward for 12 months at 4.5%. This is the projected Nash County patient population for December 31, 2014.	$(39.8 \times 0.045) + 39.8 = 41.5$
Add the two patients from Franklin County. This is the end of Operating Year 2. [December 31, 2014].	$41.5 + 2 = 43.5$

FMC Spring Hopes projects its patient population forward by six months (December 31, 2012) which is 40.1 patients. The applicant could reasonably project to serve 41.8 ($39.8 + 2 = 41.8$) patients, rounded to the nearest whole number, would be 42 in-center patients or 3.2 patients per station ($42/13 = 3.23$) by the end of Operating Year 1 (2013) and 41.5 ($41.5 + 2 = 43.5$), rounded to the nearest whole number, would be 44 in-center patients or 3.3 patients per station ($44/13 = 3.38$) by the end of Operating Year 2 (2014) for the proposed 13 station facility. Year 1 meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

In summary, although the applicant failed to clearly define its projected operating year timeframe, the applicant adequately identified the population to be served and demonstrated the need the population has for three additional stations following completion of the proposed project. 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, page 37, the applicant states several alternatives were considered including not proposing to expand the facility and applying for fewer stations. The applicant adequately demonstrated the need for three additional stations based on the continued growth of Nash County and the facility's projected utilization. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrated that the proposal is its least costly or most effective alternative. Consequently, 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 Fresenius Medical Care 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 Fresenius Medical Care of Spring Hope shall develop no more than three additional stations for a total of no more than 3 additional stations for a total of 13 certified stations, which shall include any home hemodialysis training or isolation stations upon completion of this project.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Spring Hope shall install plumbing and electrical wiring through the walls for no more than a total of 13 dialysis stations, including any home hemodialysis training or isolation stations.**
4. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Spring Hope shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
5. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care 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 53, the applicant projects \$12,475 in capital cost for the proposed project. In Section IX, page 57, 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 March 15, 2012 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 proposes to add three dialysis stations to the FMC Spring Hope dialysis facility for a total of 13 stations upon completion of this project. This project calls [sic] the following capital expenditures on behalf of BMA.

<i>Capital Expenditure</i>	<i>\$ 12,475</i>
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As Vice President, I am authorized and do hereby authorize the relocation [sic] addition of three stations for a total of 13 dialysis stations at FMC Spring Hope. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$12,475 as may be needed for this project."

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2009 and 2010. As of December 31, 2010, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$163,292,000 with \$12,017,618,000 in total assets and \$6,561,629,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the proposed project.

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

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	Project Year 1	Project Year 2
Net Revenue	\$1,953,069	\$2,051,455
Operating Expenses	\$1,674,215	\$1,756,649
Profit	\$278,854	\$294,806

Source: Application pages 59 and 62

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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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The applicant proposes to add three dialysis stations to the existing facility for a total of 13 stations upon completion of the proposed project. Based on the facility need methodology in the January 2012 SDR, the applicant adequately demonstrated the need for three additional stations based on the number of in-center patients it proposes to serve, including six patients who plan on transferring from BMA Rocky Mount. See Exhibit 22 for patient letters of support expressing an interest in transferring from BMA Rocky Mount to FMC Spring Hope. As of June 30, 2011, the 10 station facility was operating at 80% capacity ($32/10 = 3.2$; $3.2/4 = 80\%$). Upon completion of this project, the facility will have 13 stations serving 42 patients (end of year 1) which is an occupancy rate of 80% ($42/13 = 3.2$; $3.2/4 = 80.7\%$).

The applicant adequately demonstrated that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, 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 50, the applicant provides the current number of full-time equivalent positions (6.5) and projects no new FTEs will be added for the proposed three station addition. 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 Application Section V.1, page 40, the applicant lists the providers of the necessary ancillary and support services. The information regarding coordination of services in Section V.1, page 40, of the application and referenced in exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

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.

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- (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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The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table was obtained on May 24, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008 (Estimate by Cecil G. Sheps Center)
Nash	20%	8.6%	19.7%
Statewide	17%	6.7%	19.7%

Data for FMC Spring Hope is not available on the DMA web site.

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 FMC Spring Hope.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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

In Section VI.1(a), page 45, the applicant states, “*BMA has a long history of providing dialysis services to the underserved populations of North Carolina.*” Further, on page 45, the applicant states:

“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. BMA projects the patient population of the FMC Spring Hope facility to be comprised of the following:

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC Spring Hope</i>	<i>53.1%</i>	<i>46.8%</i>	<i>81.3%</i>	<i>50.0%</i>	<i>81.3%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 81.3% of facility treatment reimbursement is from Medicare.

It is clear that FMC Spring Hope projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section VI.1(b), pages 45-46, the applicant indicates that 88 percent of patients at FMC Spring Hope have some or all of their services paid for by Medicare or Medicaid. The table below illustrates the historical payor mix for the facility.

Historical Payor Source

Payor Source	In-Center
Commercial Insurance	9.0%
Medicare	85.0%
Medicaid	3.0%
Other: Self/Indigent	3.0%
Total	100.0%

The applicant demonstrated that it 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;

C

In Section VI.1(f), page 47, 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 48, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”* The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.1(c), page 46, the applicant states it does not anticipate a change in the payor mix resulting from this proposal, as illustrated in the table below.

Projected Payor Source

Payor Source	In-Center
Commercial Insurance	9.0%
Medicare	85.0%
Medicaid	3.0%
Other: Self/Indigent	3.0%
Total	100.0%

As shown in the table above, the applicant projects that 88% of all in-center patients will have some or all of their services paid for by Medicare or Medicaid.

The applicant demonstrated that it will provide adequate access to elderly and medically underserved populations. 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 48, 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 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.”

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

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

C

See Exhibit 19 for a copy of a letter to the Nursing Instructor for Nash Community College from the Director of Operations for Fresenius Medical Care offering FMC Spring Hope as a clinical training site. The applicant adequately demonstrated that the

facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is 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

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 43-44, in which BMA discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to End-Stage Renal Disease services in Nash County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to add three dialysis stations for a total of 13 certified dialysis stations following completion of this project, the applicant also demonstrated that the proposed project is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

In Section VI.1(a), page 45, the applicant provides the following table to demonstrate that the medically underserved population will have access to its services, as illustrated below.

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC Spring Hope</i>	<i>53.1%</i>	<i>46.8%</i>	<i>81.3%</i>	<i>50.0%</i>	<i>81.3%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 81.3% of facility treatment reimbursement is from Medicare.

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 Spring Hope. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC 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.

.2202 INFORMATION REQUIRED OF APPLICANTS

.2202(a)(1) Utilization rates;

-C- See Sections II.1, page 10 and IV.1, page 38, and Exhibit 2 (copy of the July 2012 SDR).

.2202(a)(2) Mortality rates;

-C- In Sections II.1, page 10 and IV.2, page 38, the applicant reports the following facility mortality rates for the FMC Spring Hope facility: 2009 – 26.1%; 2010 – 40.0%; and 2011 – 7.0%.

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

-C- In Sections II.1, page 10 and IV.3, page 38, the applicant states, “*FMC Spring Hope does not have a home training program. Patients desiring to perform home dialysis are referred to the BMA Rocky Mount facility.*”

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

-C- In Sections II.1, page 10 and IV.4, page 38, the applicant reports 3 transplants patients were referred in 2010 and zero transplants were performed and 11 transplants patients were referred in 2011 and zero transplants were performed.

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

-C- In Sections II.1, page 10 and IV.5, page 38, the applicant reports four 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 Sections II.1, page 11 and IV.6, page 38, the applicant reported in 2011 41 patients were admitted to the hospital, five of those admissions were dialysis related and 36 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- During 2010 and 2011 the applicant reported no conversions and no patients with infectious disease. The applicant further reported FMC Spring Hope currently has two patients with an infectious disease. See Sections II., page 11 and IV.7, page 39.

(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 Spring Hope is an existing facility.

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- .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 Spring Hope is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- FMC 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 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- In Section II.1, page 12, the applicant states, “BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA [sic] staffing consistently meets CMS and State guidelines for dialysis staffing. For safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC Spring Hope.
- .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 34-36, and Criterion (3).

- .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 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 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.”

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 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 not 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, pages 15-18, and Section III.7, pages 35-36, for the assumptions used by the applicant in determining its utilization for the FMC Spring Hope would be 3.2 patients per station per week as of the end of the first operating year of the additional stations ($42/13 = 3.2$).
- .2203(c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*
- C- In Sections II.1, pages 16-20 and III.7, pages 35-36, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

- .2204(1) *Diagnostic and evaluation services;*
- C- See Sections II.1, page 21 and V.1(e), page 40, and Exhibit 16.
- .2204(2) *Maintenance dialysis;*
- C- See Sections II.1, page 21 and V.1(c), page 40.

- .2204(3) *Accessible self-care training;*
-C- See Sections II.1, page 21 and V.1(d), page 40. Exhibit 20 contains a copy of FMC Spring Hope's home training agreement with BMA Rocky Mount.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
-C- See Sections II.1, page 21 and V.2(d), page 44, and Exhibit 20.
- .2204(5) *X-ray services;*
-C- See Sections II.1, page 21 and V.1(g), page 40. Exhibit 16 contains a copy of FMC's agreement with Nash General Hospital.
- .2204(6) *Laboratory services;*
-C- See Sections II.1, page 21 and V.1(h), page 40, and Exhibit 18.
- .2204(7) *Blood bank services;*
-C- See Sections II.1, page 21 and V.1(i), page 40. The applicant identifies Nash General Hospital as the provider of blood bank services. See Exhibit 16 for a copy of the agreement with Nash General Hospital.
- .2204(8) *Emergency care;*
-C- See Sections II.1, page 21 and V.1(b), page 40 and Exhibit 16.
- .2204(9) *Acute dialysis in an acute care setting;*
-C- See Sections II.1 page 21 and V.1(a), page 40, and Exhibit 16.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
-C- In Sections II.1, page 21 and V.1(p), page 40, the applicant states, "*Patients will be referred to Raleigh Access Center, Hardee's Heart Center or Triangle Interventional Center. The surgeons of these locations will coordinate with the patient and schedule vascular surgery.*"
- .2204(11) *Transplantation services;*
-C- See Sections II.1, page 22 and V.1(f), page 40. Exhibit 17 contains a copy of a transplant agreement between FMC Spring Hope and UNC Hospital.
- .2204(12) *Vocational rehabilitation counseling and services;*
-C- See Section II.1, page 22 and V.1(o), page 40. The applicant states Vocational Rehabilitation of Nash County will provide vocational rehabilitation counseling and services.
- .2204(13) *Transportation*
-C- See Sections II.1, page 22 and V.1(q), page 40. The applicant identifies Tar River Transit 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 50, the applicant provides the proposed staffing. The applicant states on page 51 that the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.

.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- See Sections II.1, page 22 and VII.5, page 51, and Exhibits 14 and 15.