

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: May 18, 2012
PROJECT ANALYST: Bernetta Thorne-Williams
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-8808-12/ Bio-Medical Applications of North Carolina, Inc d/b/a BMA Fuquay-Varina/ Add two dialysis stations for a total of 19 certified stations upon completion of this project and Project I.D # M-8596-10/ Wake 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 BMA Fuquay-Varina, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), purposes to add two dialysis stations for a total of 19 certified dialysis stations upon completion of this project and Project I.D # M-8596-10 [relocate 10 stations (3 stations from BMA Cary, 5 stations from BMA Fuquay-Varina, and 2 stations from BMA Dunn) to create a new dialysis facility, FMC Angier]. In this application, the applicant also proposes to develop a home dialysis program for Peritoneal Dialysis. 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 seven dialysis stations in Wake County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA Fuquay-Varina in the January 2012 SDR is 3.45

patients per station. This utilization rate was calculated based on 76 in-center dialysis patients and 22 certified dialysis stations. (76 patients / 22 stations = 3.4545 patients per station).

Application of the facility need methodology indicates an additional station is needed for this facility, as illustrated in the following table.

| | | |
|--|---|-----------|
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 6/30/11 | | 86.4% |
| Certified Stations | | 22 |
| Pending Stations | | 0 |
| Total Existing and Pending Stations | | 22 |
| In-Center Patients as of 6/30/11 (SDR2) | | 76 |
| In-Center Patients as of 12/31/10 (SDR1) | | 75 |
| Difference (SDR2 - SDR1) | | 1 |
| Step | Description | |
| (i) | Multiply the difference by 2 for the projected net in-center change | 2 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/11 | 0.0267 |
| (ii) | Divide the result of Step (i) by 12 | 0.0022 |
| (iii) | Multiply the result of Step (ii) by the number of months from the most recent month reported in the Jan 2012 SDR (6/30/11) until the end of calendar year 2011 (6 months) | 0.0133 |
| (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 | 77.0133 |
| (v) | Divide the result of Step (iv) by 3.2 patients per station | 24.0667 |
| | and subtract the number of certified and pending stations as recorded in SDR2 [22] to determine the number of stations needed | 2 |

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two 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.

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, pages 22-23, 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, pages 29-30, the applicant states:

“BMA Fuquay-Varina 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, page 24, 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 83.7% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. Another 2.4% of patients are covered by VA. Thus, 86.1% 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 site dialysis stations in close proximity to the patient residence. BMA is an advocate of community based treatment delivery when such is possible and appropriate. BMA suggests that the patient population of BMA Fuquay-Varina will continue to increase at a rate equal to the Wake County Five Year Average Annual Change Rate as published in the January 2012 SDR.”

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

Maximize Healthcare Value

In Section II.3, page 24, the applicant states:

“BMA is not projecting a capital expenditure for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis station [sic] at 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 by VA. 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 BMA Fuquay-Varina, proposes to add two dialysis stations for a total of 19 certified stations and to develop a home training program for Peritoneal Dialysis, upon completion of this project and Project I.D # M-8596-10.

Population to be Served

In Section IV.1, page 39, the applicant identifies the population it served, as of December 31, 2011, as illustrated in the table below.

| County of Residence | # of Patients Dialyzing In-Center 12-31-11 |
|---------------------|--|
| Wake | 54 |
| Harnett | 21 |
| Johnston | 5 |
| Total | 80 |

In Section III.7, page 38, 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 | Home Patients | In-center Patients | Home Patients | Year 1 | Year 2 |

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| | | | | | | |
|--------------|------|-----|------|-----|--------|--------|
| | | | | | | |
| Wake | 60.6 | 6.4 | 64.1 | 6.7 | 87.0% | 87.63% |
| Harnett | 10.0 | 0.0 | 10.0 | 0.0 | 13.00% | 13.37% |
| Total | 70.6 | 6.4 | 74.0 | 6.7 | 100.0% | 100.0% |

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, pages 12-15, the applicant states:

“BMA is proposing to add two dialysis stations to BMA Fuquay-Varina resulting in 19 stations at BMA Fuquay-Varina. 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 60.8 patients rounded to 61 patients.

Assumptions:

BMA assumes that the Wake County patient population of BMA Fuquay-Varina will increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate as published in the January 2012 SDR. That rate is: 5.9%.

In the CON application to develop FMC Angier, Project ID # M-8596-10, BMA projected that 11 Harnett County residents and one Johnston County resident would transfer from BMA Fuquay-Varina to the FMC Angier facility. BMA continues to expect these 12 patients to transfer.

In addition to the above noted transfers, BMA projects that all of the Johnston County residents will have transferred to either FMC Stallings Station in Clayton or to FMC Angier (upon its opening). Both FMC Stallings Station and FMC Angier are actually closer to the residence location of Johnston County patients than the BMA Fuquay-Varina facility. Thus future projections of patients to be served at BMA Fuquay-Varina will not include the Johnston County patients. This should not be read to say that BMA will not accept patients from Johnston County. Rather, the intent here is plainly consistent with multiple BMA CONO [sic] applications. BMA believes that patients desire to dialyze in a convenient location closer to their residence location. Thus, BMA can suggest that patients from Johnston County would continue to dialyze at BMA Fuquay-Varina when other, more convenient choices are available.

At this time the FMC Angier project has been delayed. As a consequence, BMA will project completion of the FMC Angier project as of December 31, 2012. BMA

projections of future patient population for BMA Fuquay-Varina will reflect 12 transfers at the date BMA has projected that [sic]

BMA will not project any change in the patient population from other counties. However, BMA does assume that with the exception of patients previously noted as expected transfers to FMC Angier, that patients residing in Harnett and Johnston Counties but dialyzing at BMA Fuquay-Varina will continue to dialyze at the facility as a function of patient choice.

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

| <i>Wake County</i> | <i>In-Center</i> |
|--|--------------------------------|
| <i>BMA begins with Wake County patients utilizing the BMA Fuquay-Varina dialysis facility as of December 31, 2011.</i> | <i>54 Wake County patients</i> |
| <i>BMA projects growth of this patient population using the Wake County</i> | |

| | |
|---|------------------------------------|
| <i>Five Year Average Annual Change Rate for one year to December 31, 2012.</i> | $(54 \times 0.059) + 54 = 57.2$ |
| <i>BMA adds the remaining patients from Harnett County who are projected to continue at BMA Fuquay-Varina.</i> | $57.2 + 10 = 67.2$ |
| <i>BMA projects the patient population from Wake County to increase at 5.9%. This is the projected Wake County patient population for December 31, 2013. ...</i> | $(57.2 \times .059) + 57.2 = 60.6$ |
| <i>BMA adds the remaining patients from Harnett County who are projected to continue at BMA Fuquay-Varina. This is the projected census for the end of Operating Year 1.</i> | $60.6 + 10 = 70.6$ |
| <i>BMA projects the patient population from Wake County forward 12 months at 5.9%. This is the projected Wake County patient population for December 31, 2013. [sic] This is the end of Operating Year 1. [sic]</i> | $(60.6 \times .059) + 60.6 = 64.1$ |
| <i>BMA adds the remaining patients from Harnett County who are projected to continue at BMA Fuquay-Varina. This is the projected census for the end of Operating Year 2.</i> | $64.1 + 10 = 74.1$ |

...

In addition to the In-Center patient projections, BMA has noted that BMA Fuquay-Varina also seeks to develop a home dialysis program for Peritoneal Dialysis. BMA has received requests from both patients and nephrology physicians with privileges at BMA Fuquay-Varina to develop a PD program.

... The facility has space for a home program and there is interest. Thus, BMA will develop a home PD program at BMA Fuquay-Varina.

...

The following table demonstrates the growth of the BMA Fuquay-Varina PD patient population.

| | |
|---|---|
| <p><i>BMA begins with 6 patients projected to transfer their care to BMA Fuquay-Varina after certification of the program. BMA will project this certification to be effective December 31, 2012.</i></p> | <p style="text-align: center;"><i>6 PD patients</i></p> |
| <p><i>This patient population is projected forward for 12 months at the Wake County Five Year Average Annual Change Rate. This is the end of Operating Year 1.</i></p> | <p style="text-align: center;">$(6 \times .059) + 6 = 6.4$</p> |
| <p><i>The PD population is projected forward for 12 months to December 31, 2014. This is the end of Operating Year 2.</i></p> | <p style="text-align: center;">$(6.4 \times .059) + 6.4 = 6.7$</p> |

The applicant projects to serve 70 in-center patients or 3.7 patients per station ($70/19=3.7$) by the end of Year 1 and 74 in-center patients or 3.9 patients per station ($74/19=3.9$) by the end of Year 2 for the proposed 19 station facility. This exceeds 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. The applicant also adequately demonstrates the need for the proposed home training for peritoneal dialysis.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for two additional stations following completion of Project I.D # M-8596-10 and this 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.

CA

In Section III.9, page 38, the applicant states, “*There are no suitable alternatives to this project.*” The applicant adequately demonstrated the need for two additional stations based on the continued growth of Wake 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 BMA Fuquay-Varina shall materially comply with all representations made in the certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fuquay-Varina shall develop no more than two additional stations for a total of no more than 19 stations, which shall include any home hemodialysis training or isolation stations, upon completion of Project ID # M-8596-10 and this project.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fuquay-Varina 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 56, the applicant projects no capital cost for the proposed project. In Section IX, page 59, the applicant further 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 two dialysis stations to the BMA Fuquay-Varina dialysis facility in Wake County for a total of 19 stations upon completion of this project

and CON Project ID # M-8596-10, relocation of five stations to FMC Angier. This project does not require any capital expenditures on behalf of BMA.

As Vice President, I am authorized and do hereby authorize the addition of two stations to BMA Fuquay-Varina.”

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, if required, 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.

| | Project Year 1 | Project Year 2 |
|--------------------|----------------|----------------|
| Net Revenue | \$3,448,109 | \$3,651,238 |
| Operating Expenses | \$3,112,885 | \$3,320,746 |
| Profit | \$335,224 | \$330,492 |

Source: Application pages 61 and 65

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 two dialysis stations to the existing facility for a total of 19 stations upon completion of Project ID # M-8596-10 and the proposed project. The applicant adequately demonstrated the need for two additional stations based on the number of in-center patients it proposes to serve. As of December 31, 2011, the 22 station facility was operating at 91% capacity ($80/22 = 3.6$; $3.6/4 = 91\%$). Pursuant to the certificate of need issued for Project I.D. # M-8596-10, five stations and 12 in-center patients are expected to transfer to FMC Angier. Assuming 68 patients ($80 - 12 = 68$) and 17 stations ($22 - 5 = 17$), the facility would be operating at 100% of capacity ($68/17$

= 4; $4/4 = 100\%$). The target occupancy rate is 80%. To operate at 80%, the facility needs 21 stations if it is serving only 68 in-center patients. Upon completion of this project, the facility will have only 19 stations serving 70 patients (end of year 1) which is an occupancy rate of 92% ($70/19 = 3.7$; $3.7/4 = 92\%$).

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 52, the applicant provides the current number of full-time equivalent positions and projects that an additional 0.75 FTEs will be added to BMA Fuquay-Varina following completion of Project ID # M-8596-10 and the proposed project, as illustrated in the table below.

| Position | Current # of FTEs | Projected # of New FTEs | Total # of FTEs |
|---------------------|--------------------------------|--------------------------------|------------------------|
| RN | 2.50 | 0.00 | 2.50 |
| Tech | 6.00 | 0.75 | 6.75 |
| Clinical Manager | 1.00 | 0.00 | 1.00 |
| Medical Director | Contract Position – Not an FTE | | |
| Admissions | 0.20 | 0.00 | 0.20 |
| Dietitian | 0.55 | 0.00 | 0.55 |
| Social Worker | 0.35 | 0.00 | 0.35 |
| Home Training Nurse | 1.00 | 0.00 | 1.00 |
| Chief Tech | 0.33 | 0.00 | 0.33 |

| | | | |
|----------------|--------------|-------------|--------------|
| Equipment Tech | 0.40 | 0.00 | 0.40 |
| In-Service | 0.33 | 0.00 | 0.33 |
| Clerical | 1.00 | 0.00 | 1.00 |
| Total | 13.66 | 0.75 | 14.41 |

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 41, the applicant lists the providers of the necessary ancillary and support services. The information regarding coordination of services in Section V.1, page 41, 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.
- (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 11, 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) |
|-----------|--|---|---|
| Wake | 10% | 2.9% | 18.4% |
| Statewide | 17% | 2.4% | 19.7% |

Data for BMA Fuquay-Varina 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 BMA Fuquay-Varina.

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 47, the applicant states, "*BMA has a long history of providing dialysis services to the underserved populations of North Carolina.*" Further, on page 47, 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. The patient population of the BMA Fuquay-Varina is comprised of the following:

| <i>Facility</i> | <i>Medicaid/</i> | <i>Elderly</i> | <i>Medicare</i> | <i>Women</i> | <i>Racial</i> |
|-----------------|------------------|----------------|-----------------|--------------|---------------|
|-----------------|------------------|----------------|-----------------|--------------|---------------|

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| | | | | | |
|--------------------------|-------------------|--------------|-------|-------|-------------------|
| | <i>Low Income</i> | <i>(65+)</i> | | | <i>Minorities</i> |
| <i>BMA Fuquay-Varina</i> | 28.8% | 47.5% | 62.5% | 50.0% | 58.8% |

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 79.5% [sic] of facility treatment reimbursement is from Medicare.

It is clear that BMA Fuquay-Varina 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), page 48, the applicant indicates that 83.7 percent of patients at BMA Fuquay-Varina 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 | 13.8% |
| Medicare | 80.1% |
| Medicaid | 3.6% |
| VA | 2.4% |
| Other: Self/Indigent | 0.1% |
| 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 49, 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 51, 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 48, the applicant states it does not anticipate a “*significant change*” in the payor mix resulting from this proposal, as illustrated in the table below.

Projected Payor Source

| Payor Source | In-Center | Home |
|----------------------|---------------|---------------|
| Commercial Insurance | 13.8% | 0.0% |
| Medicare | 80.1% | 100.0% |
| Medicaid | 3.6% | 0.0% |
| VA | 2.4% | 0.0% |
| Other: Self/Indigent | 0.1% | 0.0% |
| Total | 100.0% | 100.0% |

As shown in the table above, the applicant projects that 83.7% of all in-center patients and 100% of its home training patients would 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 50, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Fuquay-Varina 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 Department Head of Nursing for Wake Tech Community College from the Director of Operations for Fresenius Medical Care offering BMA Fuquay-Varina 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, page 46, 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 & (type of) services in & County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to add two dialysis stations for a total of 19 certified dialysis stations, following completion of Project I.D. # M-8596-10 and 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, page 47, the applicant provides the following table to demonstrate that the medically underserved population will have access to its serves, 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>BMA Fuquay-Varina</i> | 28.8% | 47.5% | 62.5% | 50.0% | 58.8% |

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 79.5% [sic] 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 BMA Fuquay-Varina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Fuquay-Varina 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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) Utilization rates;

-C- In Section II.1, page 10, and Section III.7, page 34, the applicant provides the utilization rate as reported in the January 2012 SDR of 86.36% with 3.45 patients per station.

(2) Mortality rates;

-C- In Section II.1, page 10 and Section IV.2, page 39, the applicant provides the mortality rates illustrated below.

| BMA Fuquay-Varina | Beginning In-Center and Home Patients | Ending In-Center and Home Patients | Average | Deaths | % Gross Mortality |
|-------------------|---------------------------------------|------------------------------------|---------|--------|-------------------|
| 2008 | 16 | 20 | 18 | 1 | 5.6% |
| 2009 | 20 | 28 | 24 | 5 | 20.8% |
| 2010 | 28 | 38 | 33 | 9 | 27.3% |

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

-C- In Section II.1, page 10, the applicant states, “*BMA Fuquay-Varina has recently applied to add home training for peritoneal dialysis. At the present time and until the facility is certified for home training, patients desiring to perform home dialysis are referred to the BMA Raleigh Facility.*” See Exhibit 20 for a copy of the home training agreement with BMA Raleigh Facility.

(4) The number of transplants performed or referred;

- C- In Section II.1, page 10, the applicant provides the number of transplants performed and referred by BMA Fuquay-Varina, as illustrated in the following table.

| BMA Fuquay- Varina | Transplants Referred | | Transplants Performed | |
|--------------------------|----------------------|------|-----------------------|------|
| | 2010 | 2011 | 2010 | 2011 |
| | 24 | 46 | 3 | 1 |

- (5) The number of patients currently on the transplant waiting list;
- C- In Section II.1, page 10 and Section IV.5, page 39, the applicant states, “*BMA Fuquay-Varina has eight patients on the transplant waiting list.*”
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section II.1, page 11 and Section IV.6, page 39, the applicant states in 2011 that there were 134 hospital admissions of which 50 were dialysis related and 84 that were non-dialysis related.
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.
- C- In Section II.1, page 11 and Section IV.7, page 40, the applicant states in 2010 and 2011 that there were no patients at the facility with an infectious disease.

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

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

-NA- BMA Fuquay-Varina is an existing facility.

- (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- BMA Fuquay-Varina is an existing facility.

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

-NA- BMA Fuquay-Varina is an existing facility.

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

-C- See Exhibit 12 for a copy of BMA Fuquay-Varina's Emergency/Disaster Manual which has policies and procedures for back-up electrical service in the event of a power outage.

(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- BMA Fuquay-Varina is an existing facility.

(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

-C- In Section II.1, page 12, the applicant states, "*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at BMA Fuquay-Varina.*"

(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 34-38, and Criterion (3).

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

-NA- BMA Fuquay-Varina is an existing facility.

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

-C- In Section II.1, 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.”*

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(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- BMA Fuquay-Varina does not propose to establish a new End Stage Renal Disease facility.

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

-C- See Section II.1, pages 17-20, and Section III.7, pages 35-37, for the assumptions used by the applicant in determining its utilization for the BMA Fuquay-Varina would be 3.7 patients per station per week as of the end of the first operating year of the additional stations ($70/19 = 3.7$).

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

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 17-20, and Section III.7, pages 35 -37.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

- (1) diagnostic and evaluation services;

- C- In Section II.1, page 20, the applicant states, “*Patients will be referred to WakeMed Cary for diagnostic and evaluation services.*” See Exhibit 16 for a copy of the hospital agreement with WakeMed Hospital.

- (2) maintenance dialysis;

- C- The applicant states in Section II.1, page 20, “*The facility will provide in-center dialysis.*”

- (3) accessible self-care training;

- C- In Section II.1, page 20 the applicant states, “*Patients desiring self care training for in-center hemo-dialysis will be trained at BMA Fuquay-Varina; patients desiring self care training for home dialysis will be referred to the BMA Raleigh home training department for on site training and follow-up care.*” Exhibit 20 contains a copy of the home training center program agreement.

- (4) accessible follow-up program for support of patients dialyzing at home;

- C- In Section II.1, page 20, the applicant states, “*Patients desiring to dialyze at home will be referred to the BMA Raleigh home training department.*” See Exhibit 20 for a copy of the home training center program agreement.

- (5) x-ray services;

- C- In Section II.1, page 20, the applicant states that x-ray services will be provided at WakeMed Cary or WakeMed Raleigh. See Exhibit 16 for a copy of the hospital agreement with WakeMed Hospital.

- (6) laboratory services;

- C- In Section II.1, page 20, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.

- (7) blood bank services;
- C- In Section II.1, page 20, the applicant states, *“Patients in need of blood transfusion will be referred to Rex Hospital in Raleigh.”*
- (8) emergency care;
- C- In Section II.1, page 21, the applicant states, *“Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked “crash cart” is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.”* Exhibit 14 contains a copy of FMCNA Dialysis Services Training Manual. According to the manual’s table of contents, Emergency Solutions can be found on page 2 and the sample orientation schedule indicates that emergency equipment use is covered during week 1, day two of orientation.
- (9) acute dialysis in an acute care setting;
- C- Acute dialysis in an acute care setting will be provided at WakeMed Cary or WakeMed Raleigh. See Exhibit 16 for a copy of the hospital agreement with WakeMed Hospital
- (10) vascular surgery for dialysis treatment patients;
- C- In Section II.1, page 21, the applicant reports that patients in need of vascular surgery will be referred to the Capital Vascular Access Center, Triangle Interventions or to WakeMed.
- (11) transplantation services;
- C- In Section II.1, page 21, the applicant states, *“BMA Fuquay-Varina has a transplant agreement with the University of North Carolina Medical Center.”* However, the transplantation agreement contained in Exhibit 17 is between the applicant and Duke University Medical Center.
- (12) vocational rehabilitation counseling and services; and
- C- In Section II.1, page 21, the applicant states, *“Patients in need of vocational rehabilitation services will be referred to the [sic] Wake County Vocational Rehabilitation.”*
- (13) transportation.
- C- In Section II.1, page 21, the applicant states, *“Transportation services will be provided by TRACS, Tri-Star and Millennium transportation services.”*

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

-C- In Section VII.1, page 52, the applicant provides the following current and projected number of FTE for BMA Fuquay-Varina following completion of the proposed project, as illustrated in the table below:

| Position | Current # of FTEs | Projected # of New FTEs | Total # of FTEs |
|---------------------|--------------------------------|--------------------------------|------------------------|
| RN | 2.50 | 0.00 | 2.50 |
| Tech | 6.00 | 0.75 | 6.75 |
| Clinical Manager | 1.00 | 0.00 | 1.00 |
| Medical Director | Contract Position – Not an FTE | | |
| Admissions | 0.20 | 0.00 | 0.20 |
| Dietitian | 0.55 | 0.00 | 0.55 |
| Social Worker | 0.35 | 0.00 | 0.35 |
| Home Training Nurse | 1.00 | 0.00 | 1.00 |
| Chief Tech | 0.33 | 0.00 | 0.33 |
| Equipment Tech | 0.40 | 0.00 | 0.40 |
| In-Service | 0.33 | 0.00 | 0.33 |
| Clerical | 1.00 | 0.00 | 1.00 |
| Total | 13.66 | 0.75 | 14.41 |

The applicant adequately demonstrates that its proposed number of FTEs will meet the staffing requirements as stated in 42 C.F.R., Section 405.2100.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section II.1, page 21, the applicant states that BMA Fuquay-Varina will provide ongoing program training for nurses and technicians in dialysis techniques. See Section VII.5, page 53, of the application, for information concerning the training and continuing education programs currently in place at BMA Fuquay-Varina. Exhibit 14 contains copies of FMCNA Dialysis Services Training Manual which outlines its training program and see Exhibit 15 for examples of information presented as part of staff's mandatory in-service training.