

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012

PROJECT ANALYST: Tanya S. Rupp

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: M-8805-12 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn / Add seven dialysis stations for a facility total of 31 stations upon completion of this project, Project ID #M-8596-10, and Project ID #M-8649-11 / Harnett County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn proposes to add seven in-center dialysis stations to the existing facility for a total of 31 stations upon completion of this project, Project ID #M-8596-10 [add one dialysis station to the existing facility], and Project ID #M-8649-11 [develop a 10-station facility by relocating 3 stations from BMA Cary, 5 stations from BMA Fuquay-Varina and 2 stations from BMA Dunn].

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 no need for an additional dialysis facility or stations in Harnett County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR is at least 3.2 patients per station, or 80%. In this application, BMA Dunn is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported in the January 2012 SDR is 3.92 patients per station, or 98%. This utilization rate was calculated based on 98 in-center dialysis patients and 25 certified dialysis stations as of June 30, 2011 (98

patients / 25 stations = 3.92 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		98.0%
Certified Stations		25
Pending Stations		1
Total Existing and Pending Stations		26
In-Center Patients as of 6/30/11 (SDR2)		98
In-Center Patients as of 12/31/10(SDR1)		87
Difference (SDR2 - SDR1)		11
Step	Description	Result
(i)	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.2529
(ii)	Divide the result of step (i) by 12	0.0211
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2012 SDR (6/30/11) until the end of calendar year 2011(6 months)	0.1264
(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	110.3908
(v)	Divide the result of step (iv) by 3.2 patients per station	34.4971
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	8

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.*” As shown in the table above, based on the facility need methodology for dialysis stations, the BMA Dunn facility has a need for eight stations. The applicant proposes to add only seven new stations and, therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2012 SMFP is also applicable to this review. Policy GEN-3 states:

“A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities

Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II, page 21, 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.”

On page 22, the applicant provides more detailed information about UltraCare. The applicant states,

“All of the nearly 40,000 FMCNA employees share the company’s UltraCare commitment of delivering excellent care to patients through innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service. UltraCare is delivered by highly trained staff and demonstrated through dedication, leadership and compassion, by every team member, every day.

There are six underlying elements of UltraCare:

*Clinical Leadership . Continuous Quality Improvement . Superior Customer Service
Team Approach to Care . Innovative Technology . Patient-Centered Care*

Every year since its launch in 2004, FMCNA staff participates in various supplementary training courses designed to incorporate these underlying elements into their work lives. In addition to professional certifications and regular training in their respective responsibilities, all employees engaged in patient care must achieve annual re-certification related to their UltraCare training. New employees participate in specialized Destination UltraCare training to ensure the mission is pervasive throughout our corporate culture.”

In addition, in Exhibit 13, the applicant provides a copy of Fresenius Medical Care’s Quality Improvement policies and procedures. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Harnett County.

Promote Equitable Access

In Section II, pages 22 - 23, 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 91.6% of the In-Center dialysis treatments will be covered by Medicare or Medicaid....

...

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. At this time, Harnett County has two operational dialysis facilities, and one new facility has been approved through the CON process, FMC Angier.”

In addition, in Section VI.1, page 47, the applicant states that in FY 2011, 79.7% of BMA North Carolina dialysis patients had some or all of their treatments paid for by Medicare. The applicant states,

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

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

In Section XI, page 69, the applicant states,

“Methods, [sic] which BMA of North Carolina dialysis facilities utilize to maintain efficient energy operations and, therefore, contain utility costs, are as follows:

HVAC System

- 1. The operating efficiency will current industry standards for high Energy Efficient Rating [sic].*
- 2. Systems are controlled via 7 day, 24 hour set back time clock,*
- 3. Systems are maintained and serviced quarterly along with air filter replacement.*

ENERGY CONSERVATION MEASURES

- 1. Energy efficient exit signs,*
- 2. Water flow restrictors at sink faucets,*
- 3. Water conserving flush toilets,*

4. *Optical sensor water switches*
5. *External insulation wrap for hot water heaters*

WATER TREATMENT EQUIPMENT

1. *A percentage of the concentrate water is re-circulated into supply feed water, therefore, [sic] lowering the quantity of water discharged in the drain,*
2. *Water treatment equipment electric motors are three phase, which run cooler and draw less amperage.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

SMFP Policy GEN-4, regarding Energy Efficiency and Sustainability for Health Service Facilities is not applicable in this review because the projected capital cost of the project is less than \$2 million.

In summary, the application is consistent with Policy GEN-3, and the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn proposes to add seven in-center dialysis stations to the existing facility for a total of 31 stations upon completion of this project, Project ID #M-8596-10 [add one dialysis station to the existing facility], and Project ID #M-8649-11 [develop a 10-station facility by relocating 3 stations from BMA Cary, 5 stations from BMA Fuquay-Varina and 2 stations from BMA Dunn].

Population to be Served

In Section III.7, page 36 of the application, the applicant projects the following payor mix:

COUNTY	OPERATING YEAR 1 2013		OPERATING YEAR 2 2014		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2

	PATIENTS	PATIENTS	PATIENTS	PATIENTS		
Harnett	89.6	7.7	99.3	10.7	82.9%	84.6%
Johnston	5	3	5	3	6.8%	6.2%
Sampson	5	1	5	1	5.1%	4.6%
Cumberland	5	1	5	1	5.1%	4.6%
TOTAL	104.6	12.7	114.3	15.7	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section II, pages 12 – 13, and in Section III.7, pages 33 - 35, the applicant provides the assumptions and methodology it used to project its need for seven additional dialysis stations at the BMA Dunn facility. Specifically, on page 34, the applicant states,

“In CON Project ID # M-8596-10, BMA has proposed to transfer two dialysis stations to the recently approved FMC Angier facility when that facility is completed. BMA projected that five Harnett County dialysis patients from BMA Dunn would transfer to FMC Angier. Within this application, BMA will continue to project that five patients will transfer.

FMC Angier is expected to be completed in late 2012. In order to offer conservative estimates of patient population to be served, BMA will project certification the project [sic] for December 31, 2012. Thus, Operating Year 1 is January 1, 2013 through December 31, 2013; Operating Year 2 is January 1, 2014 through December 31, 2014.”

Based on the paragraph above, it appears as though the applicant is referring to the FMC Angier facility. However, in the CON application for FMC Angier (Project ID #M-8596-10), the projected certification date for the facility is June 30, 2012. In addition, in Section 12 of this application, the timetable provided by the applicant projects a certification date for the addition of seven stations at BMA Dunn of December 31, 2012. Furthermore, in Section III, on page 33, the applicant indicates that Operating Year 1 is CY 2013, and Operating Year 2 is CY 2014, which is consistent with the information above. Therefore, the analyst concludes that the paragraph above refers to the BMA Dunn facility.

On page 34, the applicant continues:

BMA assumes that the patient population of BMA Dunn will be comprised of patients from Harnett, Cumberland, Johnston and Sampson Counties. BMA assumes that the patients from Cumberland, Johnston and Sampson Counties will continue to dialyze at BMA Dunn as a result of patient choice. Within this application, BMA projects the Harnett County ESRD patient population to continue to grow commensurate with the Harnett County Five Year Average Annual Change Rate as published in the January 2012 SDR; that rate is 13.1%.”

On page 35, the applicant provides a table that illustrates projected growth for the BMA Dunn facility, as shown below:

BMA DUNN	IN-CENTER PATIENTS	HOME PATIENTS
BMA begins with Harnett County patients dialyzing as of 12/31/11	91	6
Increase one year according to the Harnett County Five Year Average Annual Change Rate (AACR)	$(76 \times .131) + 76 = 86.0$	$(6 \times .131) + 6 = 6.8$
Five patients to transfer to FMC Angier	$86.0 - 5 = 81.0$	6.8
Add patients from other counties projected to be served. This is beginning census for facility.	$81.0 + 15 = 96.0$	$6.8 + 5 = 11.8$
Project growth of Harnett County patient population for 12 months, the end of OY1	$(81 \times .131) + 81 = 89.6$	$(6.8 \times .131) + 6.8 = 7.7$
Add patients from other counties. Projected census for facility at end of OY1	$89.6 + 15 = 104.6$	$7.7 + 5 = 12.7$
Project growth of Harnett County patient population for 12 months, the end of OY2	$(89.6 \times .131) + 89.6 = 99.3$	$(7.7 \times .131) + 7.7 = 10.7$
Add patients from other counties. Projected census for facility at end of OY2	$99.3 + 15 = 114.3$	$10.7 + 5 = 15.7$

Therefore, in Operating Year one, the applicant projects to serve 104 in-center patients on 31 stations, which is 3.3 patients per station, or 84% utilization [$114 / 31 = 3.35$; $3.35 / 4 = 0.838$]. Likewise, in Operating Year two, the applicant projects to serve 114 in-center patients on 31 stations, which is 3.6 patients per station, or a 92% utilization rate [$114 / 31 = 3.67$; $3.67 / 4 = 0.919$]. In both operating years, the applicant projects to serve in excess of 3.2 patients per station per day, which exceeds the 3.2 patients per station required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth in the BMA Dunn facility, based on the historical utilization and the Five Year AACR in Harnett County.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for the seven additional dialysis stations at the BMA Dunn facility. Consequently, 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

The applicant proposes to add seven in-center dialysis stations to its existing facility, for a facility total of 31 stations after completion of this project, Project ID #M-8596-10 and Project ID #M-8649-11. The applicant states in Section III.9, pages 36 - 37, that it considered several alternatives before proposing this project, which include applying for fewer dialysis stations, applying for eight stations pursuant to the facility need methodology, and excluding the station for home hemo-dialysis. The applicant adequately explains why it chose the selected alternative over the other alternatives. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (13), (14), (18a) and (20) for additional discussion. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified need. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn shall materially comply with all representations made in its certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn shall develop no more than seven additional dialysis stations for a total of no more than 31 dialysis stations, which shall include any home hemodialysis or isolation stations, upon completion of this project and Project ID #M-8596-10 [add one station to existing facility] and Project ID #M-8649-11 [relocate 3 stations from BMA Dunn].**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn shall install plumbing and electrical wiring through the walls for no more than seven additional dialysis stations, which shall include any home hemodialysis or isolation stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

BMA proposes to add seven stations to the existing BMA Dunn dialysis facility, located in Eastern Harnett County, based on the facility need methodology found on page 366 of the 2012 SMFP. This methodology provides a basis for demonstrating a need for additional dialysis stations in facilities in which the County Need methodology shows none, but the current utilization is 3.2 patients per station or greater. The January 2012 SDR shows the BMA Dunn facility had a utilization rate of 98%, based on 3.92 patients per station [98 patients / 25 stations = 3.92], based on a schedule of two shifts per day, six days per week. This project will follow two other current BMA projects: Project ID #M-8596-10 (establish a new 10-station facility in Angier by transferring existing stations from BMA Cary, BMA Fuquay Varina, and BMA Dunn), and Project ID #M-8649-11 (Add one station to BMA Dunn). After completion of all three projects, BMA Dunn will have 31 in-center dialysis stations. The applicant adequately demonstrates that the 31 in-center dialysis stations will be utilized at a 91% utilization rate in the second year of operation, based on 114 patients per station [114 / 31 = 3.67]. This utilization is based on the Five Year Average Annual Change Rate (AACR) in Harnett County which has been 13.1% for the past five years, as published in the North Carolina State Health Coordinating Council's January 2012 Semi Annual Dialysis Report. The applicant adequately demonstrates the need to add seven dialysis stations to the existing facility for a total of 31 stations upon completion of these three projects. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Harnett County, and the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 52, the applicant provides current and projected staffing for the BMA Dunn facility following the addition of stations, as illustrated in the following table:

POSITION	CURRENT	# OF FTE POSITIONS	TOTAL FTE POSITIONS
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	FTEs	TO BE ADDED	
RN	3.0	0.5	3.5
LPN	1.0	0	1.0
Technician	10.0	2.0	12.0
Clinical Manager	1.0	0	1.0
Administrative	0.2	0	0.2
Social Worker	0.6	0	0.6
Dietician	0.75	0	0.75
Home Training Nurse	1.0	0	1.0
Medical Records	1.0	0	1.0
Chief Technician	0.10	0	0.10
Equipment Technician	1.0	0	1.0
In-Service	0.4	0	0.4
Clerical	1.0	0	1.0
Totals	21.05	2.5	23.55

In Section V.4(c), page 44, the applicant states that Dr. Sammi Moghazi currently serves as medical director of the BMA Dunn facility, and that the physician’s letter of support is provided in Exhibit 21. However, Exhibit 21 contains a letter dated January 10, 2012 signed by Dr. Michael Mohahan of Wake Nephrology Associates, P.A., committing to serve as medical director of the BMA Dunn facility. Thus the project analyst concludes that Dr. Sammi Moghazi’s name was included in the application in error. The remainder of the information provided in Section VII and the pro forma financial statements regarding projected staffing is reasonable and credible and supports a finding of conformity to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 40, the applicant states that Betsy Johnson Regional Hospital will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, and blood bank services. In addition, the applicant states that WakeMed and Duke University Medical Center will provide additional ancillary and support services, including acute dialysis in an acute care setting and laboratory services. The applicant states transportation services will be provided by Harnett Area Regional Transportation. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1, page 47, the applicant provides an analysis of the current patient population at BMA Dunn, as shown in the table below:

FACILITY	MEDICAID / LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Dunn	11.8%	40.2%	80.0%	47.1%	68.6%

In addition, in Section VI.1, page 48, the applicant provides the current in-center dialysis payor mix at BMA Dunn, as shown in the table below:

BMA DUNN PAYOR SOURCE	PERCENT OF TOTAL
Commercial Insurance	6.9%
Medicare	80.9%
Medicaid	10.7%
VA	0.8%
Other (Self/indigent]	0.7%
Total	100.0%

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 Calendar Year 2008 – 2009 respectively. The data in the table was obtained on May 23, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
Harnett	16.9%	6.2%	20.3%
Statewide	17.0%	6.7%	19.7%

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 with respect to dialysis services.

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.

The applicant demonstrates 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1, page 49, the applicant states low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and any other underserved group, including those underinsured and uninsured, will continue to have access to dialysis services at BMA Dunn following the addition of seven stations. In Section VI.6, pages 50 - 51, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against any BMA North Carolina facility in the last five years. In Section VI.1(f), page 49, the applicant states it is under no obligation from Federal Regulations to provide uncompensated care. In Section VI.1, page 47, the applicant states that in FY 2011, Medicare represented 79.7% of all dialysis treatments in North Carolina BMA facilities. Additionally, in Section VI.1(e), page 49, the applicant states it defines uncollectible accounts as 'Bad Debt' and states it provided for \$387,681 in bad debt in FY 2011. 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 Sections VI.1(c), page 48, the applicant projects the following payor mix at BMA Dunn, based on its historical payor mix:

SOURCE OF PAYMENT	PERCENT
Commercial Insurance	6.9%
Medicare	80.9%
Medicaid	10.7%
VA	0.8%
Other (Self/indigent]	0.7%
Total	100.0%

In Section VI.1(d), page 49, 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.” [emphasis in original] The applicant demonstrates it will provide adequate access to medically underserved groups. 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(b), page 50 of the application, the applicant states that all patients in need of dialysis treatment will be admitted to BMA Dunn through one of the Nephrologists on staff. In addition, the applicant states referrals will come from area hospitals such as Betsy Johnson Regional Medical Center and WakeMed, as well as practicing physicians in the area. In Exhibit 16 the applicant provides a copy of a hospital transfer agreement between BMA Dunn and Betsy Johnson Regional Medical Center. The application is conforming to this criterion

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

C

In Section V.3(a), page 43, the applicant states:

“All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment....”

In addition, in Section V.3(c), page 43, the applicant states:

“BMA seeks to establish a relationship with Wake Technical Community College health educational training program. ...FMC facilities are available to local health professional training programs.”

In Exhibit 19 the applicant provides a copy of a January 9, 2012 letter from FMC Director of Operations to Wake Technical Community College, inviting nursing students to include BMA Dunn in their clinical rotation training. The applicant adequately demonstrates that it will continue to accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming 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 45 - 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 dialysis services in Harnett County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to add seven dialysis stations to the existing facility and that it 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, as shown below:

FACILITY	MEDICAID / LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Dunn	11.8%	40.2%	80.0%	47.1%	68.6%

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

BMA Dunn is an existing dialysis facility in Harnett County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.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- See Section II, page 10, and Section III.7, pages 33 - 36.
- (2) *Mortality rates;*
-C- See Section II, page 10, and Section IV, page 38.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- See Section II, page 10, and Section IV, page 38.
- (4) *The number of transplants performed or referred;*
-C- See Section IV, page 23.
- (5) *The number of patients currently on the transplant waiting list;*

- C- See Section II, page 10, and Section IV, page 38.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- See Section II, page 10.
 - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- See Section II, page 11, and Section IV, page 39.
 - (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 Dunn 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 Dunn is an existing facility.
 - (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- BMA Dunn is an existing facility.
 - (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- In Exhibit 12, the applicant provides copies of written policies and procedures for back up for 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 Dunn 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 XI.6(g), page 70, the applicant provides documentation that services will be provided in conformity with applicable laws and regulations concerning staffing, fire safety, physical environment, and health and safety.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 12 - 13, and in Section III, pages 33 - 36 of the application.
- (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 Dunn 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- The applicant states in Section II, page 11 of the application that “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.”

.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 Dunn is an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall*

document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

- C- In Section II, pages 12 – 13, 16 - 17, and in Section III, pages 33 - 36, the applicant documents the need for seven additional stations at the BMA Dunn facility based on utilization of 3.6 patients per station per week as of the end of the first operating year of the additional stations. See Criterion (3) for discussion.
- (c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*
- C- The applicant provides documentation of its assumptions in Section II, pages 12 - 13, 16 - 17, and in Section III, pages 33 - 36. See Criterion (3) for discussion.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
 - C- See Section V.1, page 40.
- (2) *maintenance dialysis;*
 - C- See Section V.1, page 40.
- (3) *accessible self-care training;*
 - C- See Section V.1, page 40.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1, page 40.
- (5) *x-ray services;*
 - C- See Section V.1, page 40.
- (6) *laboratory services;*
 - C- See Section V.1, page 40, and Exhibit 18.
- (7) *blood bank services;*
 - C- See Section V.1, page 40.
- (8) *emergency care;*
 - C- See Section V.1, page 40.
- (9) *acute dialysis in an acute care setting;*
 - C- See Section V.1, page 40.
- (10) *vascular surgery for dialysis treatment patients;*
 - C- See Section V.1, page 40.
- (11) *transplantation services;*
 - C- See Section V.1, page 40 and Exhibit 17.

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

-C- See Section V.1, page 40.

(13) *transportation.*

-C- See Section V.1, page 40.

.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- The applicant states in Section II that staffing at the proposed facility will be sufficient to meet the requirements in 42 CFR 405.2100. See also Section VII.1, page 52, and Section VII.10, page 54.

(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 Section VII.5, page 53, and Exhibits 14 and 15.