

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 10, 2013
TEAM LEADER: Lisa Pittman
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: L-10079-13/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) / Construct additional space at BMA Roanoke Rapids to add 11 previously approved stations without transferring 10 stations to FMC Weldon as a change of scope for Project I.D. # L-8295-09 (Addition of 8 additional dialysis stations) and Project I.D. # L-8644-11 (Addition of 3 additional dialysis stations) for a total of 46 certified dialysis stations/ Halifax

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.

NA

The applicants, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor), propose to construct additional space at BMA Roanoke Rapids to add 11 previously approved stations without transferring 10 stations to FMC Weldon as a change in scope to two previously approved projects. BMA Roanoke Rapids, whose parent company is Fresenius Medical Care Holdings Inc. (FMC), operates 35 certified dialysis stations and 1 approved, but not yet certified station, at 260 Smith Church Road, Roanoke Rapids in Halifax County. The current application is for a Change in Scope of the two projects that approved the 11 additional stations. Those approvals were subject to 10 stations being transferred to develop a new dialysis facility at FMC Weldon. However, the applicants have decided they will not develop FMC Weldon by transferring 10 stations from BMA Roanoke Rapids, rather they propose keeping the stations at BMA Roanoke Rapids. Therefore, the applicants cannot add the 11 additional, approved stations without constructing additional space at BMA Roanoke Rapids.

In addition, the application's Change in Scope includes the addition of a co-applicant, Bernardo's, LLC. Dr. Bernardo, the manager of Bernardo's LLC, is also medical director of BMA Roanoke Rapids as well as a referring physician to BMA Roanoke Rapids. When a referring physician is the lessor in a proposed project, it is appropriate for the referring physician to be a co-applicant. In this case the co-applicant (Bernardo's, LLC) will have no ownership interests in the dialysis stations at BMA Roanoke Rapids.

The applicants do not propose to increase the number of stations in any category, add any new health services or acquire equipment for which there is a need determination in the 2013 State Medical Facilities Plan (2013 SMFP). Therefore, there are no need determinations in the 2013 SMFP that are applicable to this review. Further, there are no policies in the 2013 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

- (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

The applicants, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor), propose to construct additional space at BMA Roanoke Rapids to add 11 previously approved stations without transferring 10 stations to FMC Weldon as approved in a previous certificate of need. BMA Roanoke Rapids, whose parent company is Fresenius Medical Care Holdings Inc. (FMC), operates 35 certified dialysis stations and 1 approved, but not yet certified station, at 260 Smith Church Road, Roanoke Rapids in Halifax County. The current CON application is for a Change in Scope of the two projects that approved additional stations. Those approvals were based on the relocation of 10 stations to an approved new facility in Weldon that BMA could not develop.

In Section I.8, the applicants state:

"This is an Abridged Application for Change of Scope for CON Project IDs # L-8295-09, add eight dialysis stations to BMA Roanoke Rapids, and L-8644-11, add three dialysis stations to BMA Roanoke Rapids. BMA proposes to surrender its approved CON, Project ID # L-8289-09 to transfer ten certified dialysis stations and develop the FMC Weldon facility, and CON Project ID # L-8665-11, a Cost Overrun

CON for the FMC Weldon project. BMA now proposes to retain these 10 stations at BMA Roanoke Rapids, and further, BMA proposes to expand its BMA Roanoke Rapids facility to accommodate the 11 dialysis stations approved through Projects L-8295-09 and L-8644-11. In addition, BMA will incur a capital cost associated with expansion of the BMA Roanoke Rapids facility (where no capital costs had been anticipated for the 11 stations previously approved). As a result of these changes and this Change of Scope, BMA Roanoke Rapids will net 46 CON approved dialysis stations.”

The following is a list of the certificate of need approvals related to this application:

- Project ID # L-8289-09 - A certificate of need was issued June 25, 2009 to BMA to develop a new facility in Weldon, in Halifax County, to be called FMC Weldon, by transferring ten of thirty-five stations from BMA Roanoke Rapids. The approved capital cost was \$384,955. **The applicants propose to relinquish this certificate of need and keep the ten stations at BMA Roanoke Rapids.**
- Project ID # L-8295-09 – A certificate of need was issued July 26, 2009 to BMA Roanoke Rapids for the addition of 8 dialysis stations at BMA Roanoke Rapids following the transfer of 10 stations to develop the FMC Weldon facility for a total of 33 stations. No capital costs were requested or approved. **This project will be developed with the approval of the proposed project to construct additional space at BMA Roanoke Rapids.**
- Project ID # L-8644-11 - A certificate of need was issued July 18, 2011 to BMA Roanoke Rapids for the addition of 3 dialysis stations at BMA Roanoke Rapids for a total of 36 stations. No capital costs were requested or approved for this project. **This project will be developed with the approval of the proposed project to construct additional space at BMA Roanoke Rapids.**
- Project ID # L-8665-11 - A certificate of need was issued July 8, 2011 to BMA, for a Cost Overrun for Project ID # L-8289-09 (the FMC Weldon project above). This Cost Overrun approved an additional capital cost of \$875,509. Total approved capital costs for the FMC Weldon project (L-8289-09 and L-8665-11) equal \$1,260,464 (\$384,955 + \$875,509). **This project will not be developed.**

There has been no capital expenditure on Project ID # L-8289-09. Furthermore, in Section II.1, the applicants state their intention to relinquish that certificate of need, (10 station transfer to FMC Weldon) and the certificate of need for Project I.D. #L-8665-11 (cost overrun). The 10 stations will remain at BMA Roanoke Rapids for a total of 46 stations upon completion of Project I.D. # L-8295-09 (add 8 stations), Project I.D. #. L-8644-11 (add 3 stations) and the currently proposed project to add additional space to house the 11 approved stations.

Population to be Served

BMA Roanoke Rapids proposes to relinquish its certificate of need for Project I.D. # L-8289-09, (transfer of 10 stations to FMC Weldon) and keep those 10 stations at BMA Roanoke Rapids. The applicants also propose to relinquish their certificate of need for Project I.D. # L-8665-11 (cost overrun). In addition, the applicants propose to develop the approved CON projects: Project I.D. # L-8295-09 (add 8 stations) and Project I.D. # L-8644-11 (add 3 stations) by developing additional space at BMA Roanoke Rapids for those 11 stations. The following table provides the projected census for BMA Roanoke Rapids as provided by the applicants in Section III.2(c):

BMA Roanoke Rapids Projected Census

COUNTY	Operating Year 1 (12/31/15)		Operating Year 2 (12/31/16)		County Patients as a Percent of Total	
	Home Patients	In-Center Patients	Home Patients	In-Center Patients	Year 1	Year 2
Halifax	27.3	129.3	31.0	135.6	80.0%	80.7%
Northampton	8.5	25.6	8.7	26.2	17.5%	16.9%
Warren	1.0	2.0	1.0	2.0	1.5%	1.5%
Vance	1.0	0.0	1.0	0.0	0.5%	0.5%
Brunswick, VA	0.0	1.0	0.0	1.0	0.5%	0.5%
Total	37.8	157.9	41.8	164.8	100%	100%

In Section II.3, the applicants state:

“BMA does propose to continue development of all CON approved dialysis stations. However, BMA proposes to retain all of the approved stations at a single location - BMA Roanoke Rapids dialysis facility.”

The applicants adequately identified the population to be served.

Demonstration of Need

The applicants submitted the original applications based on the facility-based need methodology for dialysis stations. The assumptions and methodology used to project utilization were provided in the original applications. The applicants provide updated utilization projections in Section II.7 of the current application. Projected utilization at BMA Roanoke Rapids for the end of the first operating year of the project is 85.3% [$157 / (4 \times 46) = 157 / 184 = 0.853$]. This exceeds the performance standards promulgated in 10A NCAC 14C .2203(b) which state the facility must operate at or above 80% utilization as of the end of the first project year. Furthermore, in Section III, the applicants state utilization as of June 30, 2012 was 101.43%.

Because the applicants decided not to develop Project I.D.s # L-8289-09 (relocation of 10 stations) and L-8665-11 (cost overrun for Project I.D. # L-8289-09), 10 stations will not be transferred to FMC Weldon. Thus, the applicants now need to develop space for the 11 stations approved in Project I.D.s # L-8295-09 (add 8 stations) and L-8644-11 (add 3 stations).

In Section VI.1, the applicants state that the projected capital cost for the proposed project is \$2,264,912 which includes Bernardo’s LLC’s capital cost of \$829,920 to expand the BMA Roanoke Rapids building and BMA’s capital cost of \$1,434,992 to upfit the building addition. The total projected capital cost is illustrated in the following table:

Projected Capital Cost Addition of 11 Stations at BMA Roanoke Rapids Dialysis		
	Bernardo’s LLC (Lessor)	BMA Roanoke Rapids (Lessee)
Site Costs		
Sub-Total Site Costs	N/A	N/A
Construction Contract		
Contractor Fees	\$829,920	\$893,760
Sub-Total Construction Contract	\$829,920	\$893,760
Miscellaneous Project Costs		
Dialysis Machines		Leased
(RO) Water Treatment Equip.		\$230,688
Equipment/Furniture		\$137,256
Architect/Engineering Fees		\$80,438
Sub-Total Miscellaneous		\$448,382
Subtotal Capital Costs	\$829,920	\$1,342,142
Contingency		\$92,850
Total Capital Costs	\$829,920	\$1,434,992
Combined Total Projected Capital Costs	\$2,264,912	

The applicants adequately demonstrate the need for the proposed project.

Equal Access

Section IV. 2, the applicants state:

“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 following table provides patient demographics for the facility:

December 31, 2012	Medicaid/	Elderly	Medicare	Women	Racial
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	Low Income	(65+)			Minorities
BMA Roanoke Rapids	41.9%	41.3%	90.4%	51.5%	81.4%

The original projects, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion and the applicants propose no changes in this current application to affect that determination. The applicants adequately identify the population to be served, demonstrate the need for the proposed services, and commit to equal access for all patients, including underserved groups. 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 most effective alternative has been proposed.

CA

In Section II.5, the applicants indicated that there are only two alternatives: 1) approve the change of scope, or 2) deny this application. The applicants propose to consolidate all approved, but not yet developed stations at BMA Roanoke Rapids, stating:

“Approval ... will ultimately allow for more and better patient care by the attending nephrology physician. The physician will not be involved in (even the short) commute between the two facilities ...

A second, and valid consideration is the[to] control operational costs and eliminate overhead expenses associated with operation of a second dialysis facility.

...However, under current economic circumstances, it is more effective to expand the current facility than develop the FMC Weldon facility. Further, BMA Roanoke Rapids has sufficient ground space to accommodate the expansion without compromising patient safety or convenience.”

The applicants adequately demonstrate that the proposal is their least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) shall materially comply with all representations made in this certificate of need application, and the certificate of need applications for Project I.D. # L-8295-09 and Project I.D. # L-8644-11 as amended by this project. In those instances in which any of these representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) shall materially comply with the last-made representations.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) shall develop and operate no more than 11 additional dialysis stations for a total of 46 certified stations which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) shall install plumbing and electrical wiring through the walls for 11 additional dialysis stations for a total of 46 dialysis stations which shall include any isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) shall surrender the certificates of need for Project I.D. # L-8289-09 (transfer of 10 stations from BMA Roanoke Rapids to FMC Weldon) and Project I.D. # L-8665-11 (Cost Overrun of Project I.D. # L-8289-09) with the applicants' letter of acceptance of these conditions prior to the issuance of the certificate of need.**
- 5. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
- 6. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Roanoke Rapids (lessee) and Bernardo's LLC (lessor) shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the 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.

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In Section VI, the applicants state that the projected capital cost for the proposed project is \$2,264,912 which includes Bernardo’s LLC’s capital cost of \$829,920 to expand the BMA Roanoke Rapids building and BMA’s capital cost of \$1,434,992 to upfit the building addition. The total projected capital cost is illustrated in the following table:

**Projected Capital Cost
Addition of 11 Stations at BMA Roanoke Rapids**

	Bernardo’s LLC (Lessor)	BMA Roanoke Rapids (Lessee)
Site Costs		
Sub-Total Site Costs	N/A	N/A
Construction Contract		
Contractor Fees	\$829,920	\$893,760
Sub-Total Construction Contract	\$829,920	\$893,760
Miscellaneous Project Costs		
Dialysis Machines		Leased
(RO) Water Treatment Equip.		\$230,688
Equipment/Furniture		\$137,256
Architect/Engineering Fees		\$80,438
Sub-Total Miscellaneous		\$448,382
Subtotal Capital Costs	\$829,920	\$1,342,142
Contingency		\$92,850
Total Capital Costs	\$829,920	\$1,434,992
Combined Total Projected Capital Costs	\$2,264,912	

In Section VII, the applicants state that the proposed project will not have start-up or initial operating expenses. BMA’s (lessee) capital costs for the project will be financed from cash reserves of Fresenius Medical Care. Exhibit 6 contains a letter from a Vice President, Fresenius Medical Care Holdings, Inc. authorizing and committing cash reserves for the proposed project. See Criterion (3) for additional discussion which is hereby incorporated by reference as if fully set forth herein. Bernardo’s LLC’s (lessor), capital costs will be financed with cash reserves of Valley Hypertension- Nephrology Associates, P.A. or a conventional loan of \$829,920. Exhibit 7 contains a letter from the president of Valley Hypertensions authorizing and committing the proposed capital expense, and a letter from a Vice President, Market Executive for First Citizens Bank in Roanoke Rapids regarding financing via a conventional loan.

Exhibit 8 provides the Consolidated Financial Statements of Fresenius Medical Care Holdings, Inc. and Subsidiaries. As of December 31, 2011 Fresenius had \$204,142,000 in cash and cash equivalents, \$13,864,530,000 in total assets and \$8,388,018,000 in Net Assets (Total Assets minus Total Liabilities).

Exhibit 7 contains a letter from a CPA with Pittard Perry & Crone, Inc. regarding the financial position of Bernardo's LLC. As of December 31, 2012, Bernardo's LLC had \$85,059 in Cash and Marketable Securities, Total Assets of \$1,018,828 and no Liabilities.

The applicants did not provide revised pro formas for the project. Instead, in Section VIII.4, the applicants provide a Table of Actual and Estimated Expenses for the current operating year and the first two operating years. In Section VIII.6, the applicants provide projected revenue. Net income is positive for the current year as well as the first two Operating Years, as shown in the table below:

	Current Operating Year CY 13	Operating Year 1 FY15	Operating Year 2 FY16
In-Center Projected Revenue	\$5,570,866	\$6,172,039	\$6,452,586
Home Hemo Projected Revenue	\$39,567	\$79,134	\$158,268
Home PD Projected Revenue	\$1,022,870	\$1,159,253	\$1,193,348
Drug Administration Revenue	\$94,290	\$108,510	\$117,638
Total Projected Gross Revenue	\$6,727,594	\$7,518,936	\$7,921,841
Deductions	\$486,202	\$542,454	\$572,457
Total Net Revenue	\$6,241,392	\$6,976,481	\$7,349,384
Operating Costs	\$5,851,409	\$6,521,252	\$6,855,688
Net Income	\$389,983	\$455,230	\$493,696

In Section VIII.1, the applicants provide the same allowable charge per treatment for each source of payment, except Medicare, as presented in the most recent original application Project I.D. # L-8644-11. Medicare charges are updated to the current allowable charge of \$234 versus \$229 in 2011.

In summary, the applicants demonstrate the availability of funds for the capital needs of the project. The applicants adequately demonstrate that the financial feasibility of the original projects and the current project are based on reasonable assumptions regarding revenues and operating costs. The applicants propose no changes in this current application to affect that determination. 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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BMA Roanoke Rapids proposes to construct space to add 11 previously approved stations without relocating 10 stations to FMC Weldon for a total of 46 dialysis stations at BMA Roanoke Rapids upon project completion. BMA Roanoke Rapids was serving 142 patients weekly on 35 stations, which is 4.1 patients per station or 101% of capacity, as of June 30, 2012. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicants do not propose to establish a new facility. The applicants provide reasonable projections for the in-center patient population it proposes to serve in Section III of the application. The growth projections are based on the average annual change rate in the number of dialysis patients from Halifax and Northampton counties. At the end of Operating Year Two, BMA Roanoke Rapids projects the utilization will be 3.57 in-center patients per station (164 patients / 46 dialysis stations = 3.565), which is 89% of capacity.

The applicants adequately demonstrate the need to construct space to add 11 previously approved stations at the existing facility based on the number of in-center patients it proposes to serve. The applicants adequately demonstrate that the proposal will 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.

C

The original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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

C

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The original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion, however the applicants propose to house all approved stations at the BMA Roanoke Rapids locations and not relocate 10 stations to FMC Weldon. The following table reflects the number of FTEs proposed for 35 stations in Project I.D. # L-8644-11, current number of FTEs serving 35 stations and the number of FTEs proposed to serve 46 stations upon project completion.

POSITION	# FTEs PER PROJECT I.D. # L-8644-11	CURRENT # FTEs	TOTAL FTE'S YEAR 2
RN	5.75	5.00	6.00
Tech	14.00	13.00	15.00
Clinical Manager	1.00	1.00	1.00
Medical Director.	Contract Position*		
Administrator (FMC Area Mgr.)	0.30	0.20	0.20
Dietitian	1.00	1.00	1.00
Social Worker	1.23	1.00	1.00
Home Training Nurse	2.00	3.00	3.00
Medical Records	1.00		
Chief Tech	0.10	0.20	0.20
Equipment Tech	0.45	0.45	0.45
In-Service	0.15	0.15	0.15
Clerical	1.00	1.00	1.00
TOTAL	27.98	26.00	29.00

The applicant adequately documents the availability of resources, including health manpower and management personnel for the proposed project. Consequently, 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:

NA

- (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.
- (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.

C

This criterion was not applicable to the original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11. Those applications did not propose construction because the applicants planned to transfer 10 stations to FMC Weldon and back-fill with 11 stations from the original applications. Because 10 stations were not transferred to FMC Weldon, the applicants propose constructing an addition to house 11 stations.

In Section IX.3, the applicants state the proposed project includes 1,630 square feet of renovated space and 4,754 square feet of new space for a total of 6,384 square feet at project completion. Renovated and new space total 6,384 square feet (1,630 + 4,754). Capital costs for the proposed project equal \$2,264,912. Total cost per square foot is \$354.78; total cost per additional station is \$205,901.

	Previously Approved CON Projects		Proposed Project
	Project I.D. #	L-8295-09	L-8644-11
			L-10079-13
Construction Costs			\$1,723,680
Dialysis Machines			Leased
(RO) Water Treatment Equipment			\$230,688
Equipment/Furniture			\$137,256
Architect/Engineering Fees			\$80,438
Contingency			\$92,850

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Total Capital Costs	\$0	\$0	\$2,264,912
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In Section IX.5, the applicants state that applicable energy savings features will be incorporated into the plans. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the project they propose, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

- (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 original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion and the applicants propose no changes in this current application to affect that determination.

Furthermore, in Section IV.2, the applicants the current patient population at BMA Roanoke Rapids, as shown in the table below:

FACILITY	MEDICAID / LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Roanoke Rapids	41.9%	41.3%	90.4%	51.5%	81.4%

In Section IV.2, the applicants state:

“BMA of North Carolina has historically provided substantial care and services to all of the above persons. For example, Medicare and Medicaid represented 94.4% of in-center dialysis patients in Project ID # L-8644-11 for BMA Roanoke Rapids. Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

The applicants demonstrate that they provide 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

The original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion. Furthermore, in Section IV.2, the applicants state:

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

Thus, the applicants show that minorities and handicapped persons will continue to have access to dialysis services at BMA Roanoke following the addition of eleven stations. In Section II.8, the applicants state:

“The applicant consistently conforms to all relevant certification standards for ESRD services. ... the applicant routinely demonstrates conformity in its every day practice of providing dialysis services.”

Therefore, the application is conforming to this criterion.

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

C

In Section IV.6, the applicants provide the payor mix that was provided in the most recent original application and the current projected payor mix, which has shifted slightly but not significantly, as shown in the following table:

Payor Mix Projections – BMA Roanoke Rapids

Payor Category	Original Projected Payor Mix Project I.D. # L-8644-11	Current Projected Payor Mix Project I.D. # L-10079-13
Commercial Insurance	3.3%	4.0%
Medicare	89.5%	90.3%
Medicaid	4.9%	4.6%
VA	2.0%	1.1%
Other: Self Pay/Indigent	0.4%	0.1%
Total	100.0%	100.0%

The applicants stated in the original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, that no change was anticipated in the payor mix as a result of the additional stations. The original applications were conforming to this criterion and demonstrated that medically underserved populations would have adequate access to the proposed services. As shown in the table above, the applicants propose no changes in this current application to affect that determination. 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

The original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion and the applicants propose no changes in this current application to affect that determination. 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

The original applications, Project I.D. # L-8295-09 and Project I.D. # L-8644-11, were conforming to this criterion and the applicants propose no changes in this current application to affect that determination. 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 of the original applications, Project I.D. #L-8295-09 and Project I.D. # L-8644-11. Effective July 26, 2009, BMA Roanoke Rapids was issued a certificate of need for Project I.D. #L-8295-09, to add 8 dialysis stations to the existing facility in Halifax County following the transfer of 10 stations to FMC Weldon, for a total of 33 certified dialysis stations upon project completion. Effective July 18, 2011, BMA Roanoke Rapids was issued a certificate of need for Project I.D. #L-8644-11, to add 3 dialysis stations to the existing facility in Halifax County, for a total of 36 certified dialysis stations upon project completion. The original applications were conforming to this criterion and the applicants propose no changes in this current application to affect that determination.

In this application, BMA Roanoke Rapids proposes to construct space to add the 11 previously approved stations without transferring 10 stations for a total of 46 dialysis stations at BMA Roanoke Rapids upon project completion. Based on the historical utilization of the BMA Roanoke Rapids facility, and based on the Five Year AACR for Halifax and Northampton counties as reported in the January 2013 SDR, the applicant projects to serve 157 patients in Operating Year One, and 164 patients in Operating Year Two. In both operating years, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b).

The only other dialysis facility in Halifax County is FMC of Halifax County, a 15-station dialysis facility also operated by BMA. There is no other provider of in-center dialysis services in Halifax County.

See Section II.1, and II.5, where the applicant discusses the impact of the project on cost-effectiveness, quality and access to dialysis services in Halifax County.

The information provided by the applicants in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal include a positive impact on cost-effectiveness, quality and access to dialysis services in Halifax County. This determination is based on the information in the application and the following analysis:

- ◆ The applicants adequately demonstrate the need to construct space to add 11 previously approved stations without transferring 10 stations and that it is a cost-effective alternative;
- ◆ The applicants have and will continue to provide quality services; and
- ◆ The applicants have and will continue to provide adequate access to medically underserved populations.

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 applicants currently provide dialysis services at BMA Roanoke Rapids. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Roanoke Rapids operated in compliance with all Medicare Conditions of participation within the eighteen months immediately preceding the date of this decision. The facility was determined to be in compliance with the Medicare Conditions of Participation. 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.

NA