

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: May 2, 2012
PROJECT ANALYST: Bernetta Thorne-Williams
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-8777-12/ Bio-Medical Applications of North Carolina, Inc d/b/a FMC Central Raleigh/ Relocate four dialysis stations from BMA Raleigh for a total of 17 certified stations/ 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 FMC Central Raleigh, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), purposes to relocate four existing certified stations from BMA Raleigh to FMC Central Raleigh for a total of 17 stations at FMC Central Raleigh upon completion of the project. The applicant does not propose to add new stations or develop a new dialysis facility. Therefore, neither the county or facility need methodologies in the 2012 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a new institutional health service. However, Policy ESRD-2: Relocation of Dialysis Stations, on page 33, is applicable to this review. The policy states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

1. *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.*

The applicant proposes to relocate four existing dialysis stations within Wake County. Consequently, there is no change in the dialysis station inventory in Wake County, therefore, the application is consistent with Policy ESRD-2 and is conforming to this criterion.

- (2) Repealed effective July 1, 1987.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

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The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Central Raleigh, proposes to relocate four dialysis stations from BMA Raleigh for a total of 17 stations at FMC Central Raleigh, upon project completion.

Population to be Served

In Section IV.1, page 58, the applicant identifies the population it served, as of December 31, 2011. According to the January 2012 North Carolina Semiannual Dialysis Report (SDR), Wake County had a surplus of 7 dialysis stations. In Section II.1, page 19, the applicant reports an increase in its in-center patients as of January 31, 2012, as illustrated in the table below.

County of Residence	# of Patients Dialyzing In-Center 12-31-11	# of Patients Dialyzing In-Center 1-31-12
Wake	8	29

In Section III.3(b), page 47, 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 1/1/13-12/21/13		Year 2 1/1/14-12/21/14		County Patients as a Percent of Total	
	Home Patients	In-center Patients	Home Patients	In-center Patients	Year 1	Year 2
Wake	0.0	55.7	0.0	59.0	100.0%	100.0%
Total	0.0	55.7	0.0	59.0	100.0%	100.0%

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, pages 50-51 and 55-56, the applicant states:

“BMA is proposing to transfer four dialysis stations to FMC Central Raleigh resulting in 17 stations at FMC Central Raleigh. 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 54.4 patients rounded to 55 patients.

...

Assumptions:

- 1. FMC Central census on December 31, 2011 was only eight dialysis patients. BMA has surveyed all of its dialysis patients in Wake County and identified a significant number of patients who reside closer to FMC Central Raleigh than to the patient [sic] dialysis facility of record as of December 31, 2011. BMA has contacted these patients and as a result, the census of FMC Central Raleigh has increased to 29 patients as of January 31, 2011 [sic].*
- 2. There remain a large number of patients who have indicated an interest in transferring their care to FMC Central Raleigh. BMA anticipates that many of these patients will complete their transfer prior to the completion of this project. However, because these patients have not yet transferred, and in an effort to provide a most conservative approach to projections of future patient populations of the facility, BMA will reflect any further transfers as an occurrence contingent upon completion of this proposed project. The project is scheduled for completion*

by December 31, 2012. (BMA necessarily establishes January 31, 2012 as a cut-off date in order to prepare this application).

3. *BMA has included 22 letters of support from patients who have not yet transferred to FMC Central Raleigh. As noted above, these patients will be projected to transfer upon completion of this transfer project. The following table identifies the current facility and patient resident zip code for these patients.*

	Dialysis Patient Residence Zip Code						
Facility	27601	27604	27605	27606	27607	27608	27610
FMC New Hope	1		1				
BMA Raleigh	3	2		3		1	4
BMA Wake	3					1	2
BMA Fuquay-Varina				1			
Subtotals	7	2	1	4	1	1	6
Total	22						

In each of the above zip codes, some portion of the zip code is actually close [sic] to the FMC Central Raleigh facility than other dialysis facilities. BMA has only contacted those patients who are actually closer to the FMC Central Raleigh facility.

4. *The following maps [located on pages 51-54] depict the above noted zip codes and their proximity to FMC Central Raleigh.*
5. *Not every patient contacted has signed a letter of support. Some patients indicated a preference to remain in their current dialysis facility despite residing closer to FMC Central Raleigh. BMA does not force patients to transfer between facilities. BMA does generally seek to place new patients at the facility closest to the patient [sic] residence location. As new patients are referred for dialysis, BMA will continue efforts to place the patient in the facility closest to the patient [sic] residence.*
6. *BMA does not project to operate a third dialysis shift at FMC Central Raleigh due to a lack of patient interest.*
7. *BMA assumes that the patient population of FMC Central Raleigh 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%*
8. *BMA projects that this project will be completed and certified by December 31, 2012. Operating Year 1 is the period from January 1, 2013 through December 31,*

2013. Operating Year 2 is the period from January 1, 2014 through December 31, 2014.

Methodology

...

Projections of future patient populations of FMC Central Raleigh are based upon the information provided within the assumptions. The patient population of FMC Central Raleigh is expected to 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%. The following table demonstrates the calculations used to arrive at the projected census for Operating Years One and Two.

Wake County	In-Center
BMA begins with Wake County patients utilizing the FMC Central Raleigh dialysis facility as January 31, 2012.	29 Wake Count patients
BMA projects growth of this patient population using the Wake County Five Year Average Annual Change Rate for 11 months to December 31, 2012.	$[29 \times (.059 / 12 \times 11)] + 29 = 30.6$
BMA adds the 22 patients projected to transfer to the facility upon completion of the project. This is the beginning census for this project.	$30.6 + 22 = 52.6$
BMA projects the patient population for 12 months at 5.9%. This is the projected Wake County patient population for December 31, 2013. This is the end of Operating Year 1.	$(52.6 \times .059) + 52.6 = 55.7$
BMA projects the patient population for 12 months at 5.9%. This is the projected Wake County patient population for December 31, 2014. This is the end of Operating Year 2.	$(55.7 \times .059) + 55.7 = 59.0$

... BMA has rounded down to the whole number.

BMA projected utilization calculation are a function of the projected year end census rounded down to the whole number. Utilization at FMC Central Raleigh is expected to be:

Operating Year 1

*55 patients dialyzing on 17 stations = 3.24 patients per station
 $55 / (4 \times 17) = 0.809$ or 80.9%*

Operating Year 2

*59 patients dialyzing on 17 stations = 3.47 patients per station
 $59 / (4 \times 17) = 0.868$, or 86.8%*

The utilization rates as calculated meet or exceed the requirements of this rule.”

In Section III.7, pages 51-54, the applicant provides ZIP code maps which identify the proximity of the patients that the applicant proposes will transfer to FMC Central Raleigh by their zip codes. The applicant states in step 3 of its assumptions that 22 patient letters of support are included in Exhibit 22, however, the applicant only provides 19 patient letters of interest expressing a willingness to consider transferring to the FMC Central Raleigh facility. The applicant failed to submit letters of support for three patients that would increase the number from 19 patient letters of support to 22 letters of support [19+3=22]. Out of the 19 letters submitted with this application, four of those patients had previously expressed an interest in switching to the FMC Central Raleigh facility in its original application (See Project I.D. J-8259-08). Therefore, using the applicant’s same assumptions and assuming that the beginning transfer count is 19 and subtracting the four patients that appear to be double counted; it might be more reasonable to assume an additional 15 [(22-3=19, 19-4=15)] patients would consider transferring to the FMC Central Raleigh facility from other BMA facilities within Wake County, as illustrated in the table below:

Wake County	In-Center
BMA begins with Wake County patients utilizing the FMC Central Raleigh dialysis facility as January 31, 2012.	29 Wake Count patients
BMA projects growth of this patient population using the Wake County Five Year Average Annual Change Rate for 11 months to December 31,	$[29 \times (.059 / 12 \times 11)] + 29 = 30.6$

2012.	
BMA adds the 15 patients projected to transfer to the facility upon completion of the project. This is the beginning census for this project.	$30.6 + 15 = 45.6$
BMA projects the patient population for 12 months at 5.9%. This is the projected Wake County patient population for December 31, 2013. This is the end of Operating Year 1.	$(45.6 \times .059) + 45.6 = 48.2$
BMA projects the patient population for 12 months at 5.9%. This is the projected Wake County patient population for December 31, 2014. This is the end of Operating Year 2.	$(48.2 \times .059) + 48.2 = 51.0$

Therefore, it is reasonable to conservatively project utilization for the first two years of operations as follow:

Operating Year 1

48 patients dialyzing on 17 stations = 2.82 patients per station
 $48 / (4 \times 17) = 0.705\%$ or 70.5%

Operating Year 2

51 patients dialyzing on 17 stations = 3.0 patients per station
 $51 / (4 \times 17) = .075\%$ or 75.0%

This does not exceed 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). Therefore, projected utilization is based on unreasonable and unsupported assumptions regarding continued growth. However, the applicant has demonstrated, based on its assumptions and methodology, the need for 2 additional dialysis stations at FMC Central Raleigh. The applicant states in this application that 22 patients receiving services at other BMA facilities in Wake County have expressed an interest in transferring to the FMC Central Raleigh facility because of its close proximity to those patients. However, the applicant only provided 19 letters from patients who have expressed an interest in transferring from other BMA facility's in Wake County to FMC Central Raleigh. Four of the 19 letters provided were duplicate patient letters from FMC Central Raleigh's initial application. Beginning with 19 patient transfers the project analyst subtracted the four patients that are double counted for a beginning patient transfer census of 15 patients [19-4=15]. Therefore, the applicant can reasonably expect to provide services to 48 patients in Operating Year One and 51 patients in Operating Year Two. Consequently, the applicant can conservatively project utilization for the first two years of operations, as follow:

Operating Year 1

48 patients dialyzing on 15 stations = 3.2 patients per station

Operating Year 2

51 patients dialyzing on 15 stations = 3.4 patients per station

Consequently, the transfer of two stations instead of four stations from the BMA Raleigh facility to FMC Central Raleigh is more reasonable. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). It should be noted that 15 stations at 21 patients per station (100% of capacity) can dialyze 60 patients.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for two additional stations following project completion. Therefore, the application is conforming to this criterion subject to the following condition.

The applicant shall relocate no more than two dialysis stations from its BMA Raleigh facility to its FMC Central Raleigh facility for a total of 15 stations at FMC Central Raleigh.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

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In Section III.9, pages 56-57, the applicant discusses the alternatives considered including relocating fewer stations and not applying to relocate additional stations to the FMC Central Raleigh facility. The applicant, as conditionally approved, adequately demonstrated the need for two additional stations based on patient letter's of support expressing an interest to transfer to FMC Central Raleigh from other BMA Wake County area dialysis facilities and the facility's projected utilization. See Criterion (3) for discussion. The application is conforming or conditionally 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, as conditioned, is its least costly or most effective alternative. Consequently, the application is conforming to this criterion subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Central Raleigh shall materially comply with all representations made in the certificate of need application, as amended by the conditions of approval.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Central Raleigh shall develop no more than two additional stations for a total of no more than 15 stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Central Raleigh shall install plumbing and electrical wiring through the walls for no more than a total of 15 dialysis stations, including any home hemodialysis training or isolation stations.**
 4. **After certification of the two additional stations relocated from BMA Raleigh to FMC Central Raleigh, BMA Raleigh shall take the steps necessary to decertify 2 stations at BMA Raleigh for a total of no more than 47 certified stations.**
 5. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Central Raleigh 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 74, the applicant projects the total capital cost of the project will be \$18,376 including \$2,200 for water treatment equipment and \$16,176 for equipment/furniture (not included above). In Section IX, page 78, the applicant projects no start-up or initial operating expenses for the proposed project. In Section VIII.2, the applicant states the capital cost for the proposed project will be funded by accumulated reserves from Fresenius Medical Care, the parent company of FMC Central Raleigh.

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Exhibit 14 includes a letter dated February 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 transfer four existing and certified dialysis stations from BMA Raleigh to the new FMC Central Raleigh dialysis facility. The project calls [sic] the following capital expenditures on behalf of BMA.

Capital Expenditure \$18,376

As Vice President, I am authorized and do hereby authorize the transfer of four stations to FMC Central Raleigh for capital costs of \$18,376."

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2009 and 2010. As of December 31, 2010, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$163,292,000 with \$12,017,618,000 in total assets and \$6,561,629,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the capital needs of the 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	\$2,511,282	\$2,655,571
Operating Expenses	\$2,055,609	\$2,165,764
Profit	\$455,673	\$489,807

Source: Application pages 80 and 83

The applicant's projections are based on a higher utilization than is reasonable based on patient letter's of support and future utilization projections. However, it is reasonable to conclude, based on the revised projected utilization that revenues will exceed expenses in each of the first two operating years. In Section VIII.1, page 74, the applicant reports the dialysis machines will be leased. In Exhibit 26 the applicant includes a copy of a dialysis machine lease agreement.

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 four dialysis stations to the existing facility for a total of 17 stations upon completion of the proposed project. However, based on patient letters of interest the applicant was unable to reasonably project the utilization by the end of operating year one would reach the 3.2 patient per station threshold. However, it was determined that the relocation of two dialysis stations would meet the minimum threshold of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). The applicant adequately demonstrated the need for two additional stations based on the number of in-center patients it proposes to serve. Therefore, 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 71, the applicant states the current number of FTE positions and projects that an additional 4.10 FTEs will be added to FMC Central Raleigh following completion of the proposed project, as illustrated in the table below.

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
RN	1.00	1.00	2.00
Tech	2.50	2.00	4.50
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position – Not an FTE		
Admissions	0.15	0.00	0.15
Dietitian	0.10	0.20	0.30
Social Worker	0.20	0.15	0.35
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.20	0.25	0.45
In-Service	0.10	0.10	0.20
Clerical	0.20	0.40	0.60

Total	5.55	4.10	9.65
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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 60, the applicant lists the providers of the necessary ancillary and support services. The information regarding coordination of services in Section V.1, page 60, of the application and referenced 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 April 4, 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)
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Wake	10%	2.9%	18.4%
Statewide	17%	2.4%	19.7%

Data for FMC Central Raleigh is not available on the DMA web site.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by FMC Central Raleigh.

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, page 66, the applicant states, *“BMA has a long history of providing dialysis services to the underserved populations of North Carolina.”* Further, on page 66, 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 FMC Central Raleigh is comprised of the following:

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC Central Raleigh</i>	<i>64.0%</i>	<i>44.0%</i>	<i>84.0%</i>	<i>20.0%</i>	<i>80.0%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 84.0% of facility treatment reimbursement is from Medicare.

It is clear that BMA provides 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 67, the applicant indicates that 82.0 percent of patients at FMC Central Raleigh 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	11.9%
Medicare	82.0%
Medicaid	6.0%
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;

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In Section VI.1(f), page 68, 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 69, 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

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In Section VI.1(c), page 67, 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
Commercial Insurance	11.9%
Medicare	82.0%
Medicaid	6.0%
Other: Self/Indigent	0.1%
Total	100.0%

As shown in the table above, the applicant projects that 88.0% of all in-center patients would continue to have some or all of their services paid for by Medicare or Medicaid.

The applicant demonstrated that it will provide adequate access to the 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.

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In Section VI.5(a), page 69, the applicant states:

“Those Nephrologist who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Central Raleigh 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, Nephrologist or hospitals.”

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.

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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 FMC Central Raleigh 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.

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See Sections II.6, II.7, III.1, III.2, III.3, III.6, III.7, V.7, VI, VII, and XI.7. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services, as conditioned, because:

- The applicant demonstrates that the proposal, as conditioned to add two dialysis stations, is needed and that it is a cost-effective alternative to meet the need for additional dialysis stations at BMA Central Raleigh;
- The applicant has and will continue to provide quality services;
- The applicant has and will continue to provide adequate access to medically underserved populations.

In Section VI.1, page 66, the applicant provides the following table to demonstrate that the medically underserved population will have access to its services, as illustrated below.

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC Central Raleigh</i>	<i>64.0%</i>	<i>44.0%</i>	<i>84.0%</i>	<i>20.0%</i>	<i>80.0%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 84.0% of facility treatment reimbursement is from Medicare.

The application is conforming to this criterion

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant currently provides dialysis services at FMC Central Raleigh. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Central Raleigh was certified on October 19, 2011. Since receiving its certification, FMC Central Raleigh, has operated in compliance with all Medicare Conditions of Participation within the five 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.

CA

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 or conditionally 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, the applicant states that FMC Central Raleigh was not certified until October 19, 2011. The ending census for December 31, 2011 was eight patients. The January 2012 SDR does not report utilization rates for the facility. However, the applicant reports that as of the end of January 2012, the facility had a census of 29 patients. See Section III.7, pages 50-56 and IV.1, page 58.

(2) Mortality rates;

-C- In Section II.1, page 10 and Section IV.2, page 58, the applicant provides the mortality rates illustrated below.

FMC Central Raleigh	Beginning In-Center and Home Patients	Ending In-Center and Home Patients	Average	Deaths	% Gross Mortality
		8	4		

(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, “*FMC Central Raleigh does not have a home training program. Patients desiring to perform home dialysis are referred to 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 states that FMC Central Raleigh was certified on October 19, 2011. Therefore, in Section II.1, page 10 and Section IV.4, page 58, the applicant reports that no transplants have been performed or referred.

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

- C- In Section II.1, page 10 and Section IV.5, page 58, the applicant states, “*FMC Raleigh has two 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 58, the applicant states in 2011 that there was one hospital admission that was 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 59, the applicant states in 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- FMC Central Raleigh 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- FMC Central Raleigh is an existing facility.

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

-NA- FMC Central Raleigh 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 FMC Central Raleigh'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- FMC Central Raleigh does not propose to operate a new 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 FMC Central of Raleigh.*"

(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 50-56, 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- FMC Central Raleigh is an exiting 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 18, 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- FMC Central Raleigh 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.

- CA- See Section III.7, pages 50-56, for the assumption used by the applicant in determining its utilization for the FMC Central Raleigh would be 3.2 patients per station per week as of the end of the first operating year of the additional stations. The applicant bases its utilization projections on letters of support from patients currently dialyzing at Raleigh Dialysis, New Hope Dialysis and Wake Dialysis Clinic willingness to transfer to FMC Central Raleigh. Based on the letters of support, the number of patients willing to transfer to FMC Central is illustrated below.

Name of Facility Currently Receiving Treatment	# of Pts who have expressed a willingness to transfer to FMC Central Raleigh
Raleigh Dialysis Facility	14
New Hope Dialysis	2
Wake Dialysis Clinic	3
Total	19

In Step 3 of the assumptions, the applicant states, “*BMA has included 22 letters of support from patients who have not yet transferred to FMC Central Raleigh. ... these*

patients will be projected to transfer upon completion of this transfer project.” The applicant provides the following table, as illustrated below, to demonstrate the facilities from which patients will transfer.

Facility	Dialysis Patient Residence Zip Code						
	27601	27604	27605	27606	27607	27608	27610
FMC New Hope	1		1				
BMA Raleigh	3	2		3		1	4
BMA Wake	3					1	2
BMA Fuquay-Varina				1			
Subtotals	7	2	1	4	1	1	6
Total	22						

However, there are no letters of support from the one patient at BMA Fuquay-Varina indicating a willingness to transfer to FMC Central Raleigh. Furthermore, the number of letters of patient’s interested in transferring to FMC Central Raleigh provided in Exhibit 22 total 19 letters and not 22 letters as stated by the applicant. Beginning with the possibility of 19 patient transfers the project analyst subtracted the four patients that are double counted for a beginning patient transfer census of 15 patients [19-4=15]. Therefore, based on 15 patients who have the potential to transfer to the FMC Central Raleigh facility, it is reasonable to transfer 2 stations from the BMA Raleigh facility. Consequently, this would allow 48 patients dialyzing on 15 stations to have a utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations. This meets the minimum required by 10A NCAC 14C .2203(b).

(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 24-30.

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 32, the applicant states, *“Patients will be referred to WakeMed Raleigh 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 32, *“The facility will provide in-center dialysis.”*
- (3) accessible self-care training;
- C- In Section II.1, page 32 the applicant states that self-care in home-dialysis will be provided by BMA Raleigh. 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 32, the applicant states, *“Patients desiring to dialyze at home will be referred to the BMA Raleigh home training department for on site training and follow-up.”* See Exhibit 20 for a copy of the home training center program agreement.
- (5) x-ray services;
- C- In Section II.1, page 32, the applicant states that x-ray services will be provided at WakeMed Raleigh. See Exhibit 16 for a copy of the hospital agreement with WakeMed Hospital.
- (6) laboratory services;
- C- In Section II.1, page 32, the applicant states, *“BMA provides on site laboratory services through contract with Spectra Labs.”* See Exhibit 16 for the laboratory services agreement with Spectra Laboratories.
- (7) blood bank services;
- C- In Section II.1, page 32, the applicant states that blood bank services will be provided by WakeMed Raleigh. See Exhibit 16 for a copy of the hospital agreement with WakeMed Hospital
- (8) emergency care;
- C- In Section II.1, page 32, 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 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 Wake Med 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 32, the applicant reports that patients in need of vascular surgery will be referred to the Capital Vascular Access Center in Raleigh or to WakeMed Raleigh.
- (11) transplantation services;
 - C- In Section II.1, page 33, the applicant states that is has an agreement with Duke UMC for transplant services for the patients at FMC Central Raleigh. See Exhibit 17 for copies of the transplantation agreement.
- (12) vocational rehabilitation counseling and services; and
 - C- In Section II.1, page 33, 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 33, the applicant states, *“Transportation services will be provided by Raleigh Transportation, Wake County Transportation and CAT public bus.”*

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, the applicant provides the following current and projected number of FTE for RMC Central Raleigh following completion of the proposed project, as illustrated in the table below:

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
RN	1.00	1.00	2.00
Tech	2.50	2.00	4.50
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position – Not an FTE		

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Admissions	0.15	0.00	0.15
Dietitian	0.10	0.20	0.30
Social Worker	0.20	0.15	0.35
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.20	0.25	0.45
In-Service	0.10	0.10	0.20
Clerical	0.20	0.40	0.60
Total	5.55	4.10	9.65

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 33, the applicant states that FMC Central Raleigh will provide ongoing program training for nurses and technicians in dialysis techniques. See Section VII.5, page 72, of the application. Exhibit 14 contains copies of FMCNA Dialysis Services Training Manual which outlines its training program and Exhibit 15 for an outline of the continuing education programs.