

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 25, 2012  
PROJECT ANALYST: Gene DePorter  
CON CHIEF: Craig Smith  
PROJECT I.D. NUMBER: J-8749-11/Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMS-Apex /Relocate 2 stations from BMA-Cary to FMS Apex for a total of 16 stations at FMS-Apex/ Wake County FID # 981041

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications (BMA) of North Carolina, Inc., d/b/a FMS-Apex, operates, Fresenius Medical Care of Apex at 1000 American Way, Apex, NC. FMS-Apex proposes to relocate 2 existing dialysis stations from BMA-Cary to FMS-Apex for a total of 16 dialysis stations at the Apex facility upon project completion.

Policy GEN-3 is not applicable because the applicant is not developing a new institutional health service for which there is a need determination in the 2011 SMFP.

However, Policy ESRD-2 is applicable to this review.

*“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 shall:*

- (A) *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 Dialysis Report, and*

*(B) 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 Dialysis Report.”*

The applicant proposes to relocate two existing dialysis stations within Wake County. Consequently, there is no change in the inventory in Wake County, so 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.

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMS-Apex, whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), proposes to relocate 2 existing dialysis stations from BMA-Cary to FMS-Apex for a total of 16 stations at FMS-Apex upon completion of this project. The applicant proposes to add two existing stations to an existing dialysis facility (FMS-Apex).

Population to be Served

In Section III.7, page 42, the applicant projects the number of in-center dialysis patients to be served at FMS-Apex in the first two years of operation following project completion:

**Table 1**  
**FMS-Apex**  
**Projected Dialysis Patients in Operating Years 2013 and 2014**

County	Operating Year 1 FY 2012/2013	Operating Year 2 FY 2013/2014	County Patients as a Percent of TOTAL	
			Year 1	Year 2
Wake	54.0	57.2	100.0%	100.0%
Total	54.0	57.2	100%	100%

The applicant indicates that all patients are currently, and will continue to be, residents of Wake County. Growing interest by BMA-Cary patients to relocate to FMS-Apex has increased from 4 to 8 patients during the preparation of this application. Exhibit 22 contains letters of support for FMS-Apex use.

The letters state in part:

*“The FMS Apex facility is closer to my home, and will be much more convenient for me and my transportation. Patients on dialysis have many hardships, especially arranging transportation three days per week. The location of this facility means that my commute to and from dialysis will be much shorter. This location is certainly more beneficial to me and my transportation.”*

The following table provides a comparison of operating measures for both BMA-Cary and FMS-Apex from the January 2011, July 2011 and January 2012 Semiannual Dialysis Reports (2011-2012 SDR). The applicant’s data is based upon the January and July 2011 SDRs. Data from the January 2012 SDR is shown for trend purposes only.

**Table 2**  
**Summary of BMA-Cary and FMS-Apex Recent Activity**

<i>Dialysis Facility</i>	<i>Certified Stations</i>	<i># Pts Dialyzing In-Center</i>	<i>Patient Per Station</i>	<i>Per cent Utilization</i>
<b><i>SDR-Jan. 2011/Jan.2012</i></b>				
<i>FMS-Apex(6/30/10)</i>	10	34	3.40	85%
<i>FMS-Apex(12/31/10)</i>	10	39	3.90	98%
<i>FMS-Apex (6/30/11)</i>	10	36	3.60	90%
<b><i>SDR-Jan. 2011/Jan.2012</i></b>				
<i>BMA-Cary(6/30/10)</i>	27	71	2.63	66%
<i>BMA-Cary(12/31/10)</i>	27	74	2.74	69%
<i>BMA-Cary (6/30/11)</i>	27	80	2.96	74%

North Carolina Semiannual Dialysis Reports-January 2011, July 2011 and January 2012.

The facility management maintains that they cannot start a third shift because of lack of patient interest. Meanwhile, FMS-Apex management is projecting that the patient population for dialysis will increase at a rate commensurate to the SDR Five Year Annual Average Change Rate for Wake County is currently 5.9%. Over the last year the number of patients dialyzing at FMS-Apex has been in a state of flux from 34 to 39 and then back to 36 patients. Concurrently, the decrease in stations at BMA-Cary has gone from 27 to 20, with stations relocated to FMS-Apex (4) and BMA-Angier (3). This proposal for 2 additional stations from BMA-Cary to FMS-Apex will reduce BMA-Cary operating stations to 18. The numbers in the above table reflect lag times from data collection to report development. FMS-Apex has been operating above the standard for the last three reporting periods while BMA-Cary patients per station and percent utilization have slowly increased, over the same historic reporting periods, while staying below the ESRD operating standard of 80% utilization and 3.2 persons per staff.

The applicant adequately identified the population to be served.

### Need Analysis

In Section III.; questions 1, 3, 4, 5 and 6 on pages 41-42, are not applicable. This application is for the relocation of two existing stations to an existing facility (FMS-Apex) to balance the number of patients and stations, satisfy geographic access and timeliness to services and met the growth in dialysis patient population in southern Wake County. If the adjustment of stations trend continues the two facilities will achieve and maintain operating numbers above the standards before the close of calendar year 2013.

In Section III.7. page 42, the applicant notes the following;

*“BMA is proposing to add 2 dialysis stations to FMS-Apex resulting in 16 stations at FMS-Apex. In order to meet the review criteria for need, BMA must demonstrate that the facility will serve 3.2 patients per station at the end of the first operating year. This is, 51.2, rounded to 52 patients.”* The first full operating year closes on 12/31/13.

The relocation of dialysis patients from BMA-Cary to FMS-Apex is dependent upon completion of the additional stations at FMS-Apex (CON Project ID # J-8615-10 relocate 4 stations from BMA-Cary to FMS-Apex). On December 29, 2011, the DHSR, Certificate of Need Section received a copy of correspondence between the North Carolina Director of Market Development for BMA and FMS and the Chief of Licensure and Certification Section of DHSR indicating that CMS has been given notice of the dialysis station increase at FMS-Apex from 10 to 14 stations and decrease in stations at BMA Cary from 27 to 23. The Certification date was 12/19/11(Reference the Correspondence File for a copy of the letter).

The following table from page 47 illustrates the applicant's assumptions and methodology used to project the utilization and dialysis patient growth at FMS-Apex:

**Table 3**  
**Projected FMS-Apex Utilization**

FMS-Apex/Wake County Projected Utilization	Applicant Calculation for Future In-Center Dialysis Patients
<i>BMA begins with Wake County patients currently utilizing the FMS Apex dialysis facility as of December 31, 2010.</i>	39 Wake County patients
<i>BMA projects growth of the patient population using the Wake County Five Year Average Annual Rate for a period of six months to December 31, 2011.</i>	$[39 \times (0.59 / 12 \times 6)] + 39 = 40.2$
<i>BMA adds the eight patients proposed to transfer from BMA Cary upon completion of the Project ID #J-8615-10, December 31, 2011.</i>	$40.2 + 8 = 48.2$
<i>BMA projects the patient population from Wake County to increase at 5.9%. This is the projected Wake County patient population for December 31, 2012. This is the expected completion date for the two station expansion project.</i>	$(48 \times .059) + 48.2 = 51.0$
<i>BMA projects the patient population from Wake County forward for 12 months at 5.9%. This is the projected Wake County population for December 31, 2013 and the end of Operating Year One.</i>	$(51.0 \times .059) + 51.0 = 54.0$
<i>BMA projects the patient population from Wake County forward 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 Two.</i>	$(54.0 \times .059) + 54 = 57$

The preceding table (Table 3) projects 53 (analyst adjusted from 54) in-center patients by the end of Year One [12/31/13] or 3.31 patients per station  $[53 / 16 = 3.31]$ , and 56.0 (analyst adjusted from 57) in-center patients by the end of Year Two [12/31/14] or 3.50 patients per station  $[56 / 16 = 3.50]$ . The projected utilization rate is 83%, at the end of Year One  $[3.3 / 4.0 = 0.825]$  and 88% in Year Two  $[3.5 / 4.0 = 87.5]$ . The analyst has identified that the above calculations are minimally incorrect from the 2<sup>nd</sup> through 6<sup>th</sup> rows. However, the difference is one patient. With the reduction of one dialysis patient the applicant will still achieve the operating standard by the end of the first full year of operation. All patients are projected to be from Wake County. However, the applicant notes that BMA will not restrict admissions based upon county of residence. The applicant demonstrates that the needs of the population presently served at FMS-Cary will continue to be adequately served following the relocation of two existing stations from BMA-Cary. Projected utilization at FMS-Apex is based on reasonable and supported assumptions. Therefore, the application is conforming to this criterion.

Table 4 is a profile of both the recent operating history and projected future activity for FMS-Apex and BMA-Cary facilities.

**Table 4**  
**Summary of BMA-Cary and FMS-Apex Historic and**  
**Projected Activity- 2012 and 2014**

<i>Dialysis Facility FMS-Apex</i>	<i>Certified Stations</i>	<i># Pts Dialyzing In-Center</i>	<i>Patient Per Station</i>	<i>Per cent Utilization</i>
<b><i>SDR-Jan. 2011/Jan.2012</i></b>				
<i>FMS-Apex(6/30/10)</i>	10	34	3.40	85%
<i>FMS-Apex(12/31/10)</i>	10	39	3.90	98%
<i>FMS-Apex (6/30/11)</i>	10	36	3.60	90%
<b><i>Projected Operating Outcomes for 2012, 2013 and 2014.</i></b>				
<i>FMS-Apex (12/31/2012)</i>	16	51	3.20	80%
<i>FMS-Apex (12/31/2013)</i>	16	54	3.40	84%
<i>FMS-Apex (12/31/2014)</i>	16	57	3.60	90%
<b><i>Dialysis Facility BMA-Cary</i></b>				
<b><i>SDR-Jan. 2011/Jan.2012</i></b>				
<i>BMA-Cary(6/30/10)</i>	27	71	2.63	66%
<i>BMA-Cary(12/31/10)</i>	27	74	2.74	69%
<i>BMA-Cary (6/30/11)</i>	27	80	2.96	74%
<b><i>Projected Operating Outcomes for 2012, 2013 and 2014</i></b>				
<i>BMA-Cary(12/31/2012)</i>	18	85	5.00	125%
<i>BMA-Cary(12/31/2013)</i>	18	90	5.00	125%
<i>BMA-Cary (12/31/2014)</i>	18	95	5.30	133%

The analyst referenced the North Carolina Semiannual Dialysis Reports for January 2011, July 2011 and January 2012. The analyst applies the same methodology in order to project future in-center patient volume, patients per station and utilization while holding the projected average annual rate of change constant at the current 5.9%.

In Section III 6.(a) (2) and (3), pages 45-47, the applicant has identified the following zip codes as patient origins within Wake County (refer to maps on pages 45 and 46 of the application);

- Zip Code 27519 is on the west side of Cary. Patients residing in this zip code are closer to FMS-Apex than BMA-Cary,
- Zip Code 27603 encompasses a large area from the center of Raleigh, extending south to the Wake-Johnston County line and east of Fuquay-Varina. Patients in

the Central areas of this zip code would actually be closer to FMS-Apex than BMA-Cary,

- Zip Codes 27622 and 27623 the current FMS-Apex patients in these zip codes are P.O. Box holders. These patients were interviewed to determine their interest in utilizing FMS-Apex.

The applicant states that 100% of its future patients will live within Wake County and travel 30 miles or less for their dialysis treatments. FMS-Apex does not have a home dialysis program. Patients desiring to perform home dialysis are referred to the BMA Raleigh facility.

In summary, the applicant adequately identified the population to be served and demonstrated the need for the additional two stations based on the population it proposes to serve. 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, 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

BMA/FMS-Apex proposes to add two existing dialysis stations relocated from BMA-Cary for a total of 16 dialysis stations at FMS-Apex.

- (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; a), b), and c), page 48, the applicant provides three alternatives for meeting the needs for the proposed project. The applicant concludes that transferring two dialysis stations to FMS-Apex is the most effective and least costly alternative. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (13), (14), (18a), (20), and the Criteria and Standards for End State Renal Disease Services, promulgated in 10A NCAC 14C .2200. Therefore, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS-Apex shall materially comply with all representations made in its certificate of need application.**
  2. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS-Apex shall be certified for no more than 16 dialysis stations, which shall include any home hemodialysis or isolation stations.**
  3. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS-Apex shall not develop or offer home dialysis services as a part of this project.**
  4. **After certification of 2 stations relocated to FMS-Apex, BMA-Cary shall take the steps necessary to decertify 2 dialysis stations for a total of no more than 18 stations at BMA-Cary.**
  5. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS-Apex shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 67, the applicant projects the total capital cost will be \$4,750, including \$500 for ancillary water equipment, \$1,250 for patient chairs and \$3,000 for patient TVs. The dialysis stations will be leased. In Section IX, page 70, the applicant states that there are no start-up or initial operating expenses. Exhibit 24 contains a letter signed by the Vice President of Fresenius Medical Care Holdings, Inc., which states:

*"This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA proposes to relocate two dialysis stations from BMA Cary to the FMS Apex dialysis facility in Wake County. The project calls for the following capital expenditures on behalf of BMA.*

*Capital Expenditure:                    \$4,750*

*As Vice President, I am authorized and do hereby authorize the relocation of these two dialysis stations, for the capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$4,750 as may be needed for this project."*

The applicant adequately documents the availability of sufficient funds for the capital needs of the project.

In Section X, page 72, the applicant provides the dialysis facility's allowable charge per treatment for each payment source as follows:

**Table 5**  
**FMS-Apex Charge per Treatment**  
**By Payer Source**

<b>Payer</b>	<b>In-Center</b>
Commercial Insurance	\$1,375.00
Medicare	\$234.00
Medicaid	\$137.29
VA	\$146.79
Private Pay	\$1,375.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X, pages 73 and 76, the applicant projects those revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 74-76, for the applicant's assumptions.

In summary, the applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. 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.

C

BMA proposes to relocate two existing dialysis stations from BMA-Cary to FMS-Apex for a total of 16 stations at FMS-Apex upon project completion. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. The applicant adequately demonstrates the need to relocate two existing stations to FMS-Apex based on letters of support from existing BMA-Cary patients proposing to transfer to FMS-Apex. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposed project would not result in 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.1, page 64, the applicant provides projected staffing for FMS-Apex upon project completion, as illustrated in the following table:

**Table 6**  
**FMS-Apex Additional Staffing**

	<b># of Full-Time Equivalent (FTE) Positions</b>
RN	0.75
Tech.	1.75
Clinical Manager	0.00
Administrator	0.00
Dietitian	0.00
Social Worker	0.00
Chief Tech	0.00
Equipment Tech	0.20
In-Service	0.20
Clerical	0.25
<b>Total</b>	<b>3.15</b>

The applicant projects a total of 3.15 FTE additional positions upon project completion and states in Section VII, page 62 that it does not expect any difficulty in recruiting staff. In Section V.4, (c) page 54, the applicant identifies the current Medical Director as Dr. Robert Schmidt. Exhibit 21 contains a letter from the Medical Director which states he will continue to serve in that role. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. 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.

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In Section V.1, page 51, the applicant lists the providers of the necessary ancillary and support services. On pages 52-56 the applicant describes how the facility will coordinate services with the existing health care system. Exhibit 21 contains a letter of support from the eight Nephrologists of Capital Nephrology Associates, P.A. The applicant adequately

demonstrates that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of

determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1 (a), page 47, the applicant states,

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. BMA currently operates 86 facilities in 40 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has seven facilities under development or pending CON approval. 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 FMS Apex facility is comprised of the following:*

**Table 7  
 FMS-Apex Patient Mix Profile**

<i>Facility</i>	<i>Medicaid/Low Income</i>	<i>Elderly (65 +)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMS Apex</i>	<i>25.6%</i>	<i>53.8%</i>	<i>79.5%</i>	<i>56.4%</i>	<i>66.7%</i>

In Section VI.1, (b) and (c) page 58, the applicant provides the current and proposed payer mix for FMS-Apex, as shown in the following table:

**Table 8  
 FMS-Apex Current and Proposed  
 Payer Mix**

<b>Payer Source</b>	<b>Percent of Total</b>
Commercial Insurance	19.6%
Medicare	77.6%
Medicaid	2.8%
VA	0.0%
Total	100.00%

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 2008-2009, respectively. The data in the table was obtained on January 19, 2012. More current

data, particularly with regard to the estimated uninsured percentages, is not available.

**Table 9**  
**Wake County Percent Medicaid and Uninsured**

County	Total # of Medicaid Eligible's as % of Total Population	Total # of Medicaid Eligible's Age 21 and older as % of Total Population	% Uninsured CY 2008& 2009 (Estimate by Cecil G. Sheps Center)
Wake	10%	33.5%	18.4%
Statewide	17%	40.6%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by FMS-Apex dialysis center.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible's 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 45.9% for those age 20 and younger and 30.6% 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. However, as of January 2011, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

As shown in the table above, 80.4 percent of FMS-Apex in-center patients are Medicare or Medicaid recipients (77.6 percent Medicare plus 2.8 percent Medicaid). The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1 (f), page 61, 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 62, the applicant states:

*“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

The application is conforming to this criterion.

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

C

On page 60 the applicant projects that 80.4 percent of patients served at FMS-Apex will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrated that it will provide adequate access to medically underserved populations. See the table below.

Table 10

Payer	Percent of Total
Commercial Insurance	19.6%
Medicare	77.6%
Medicaid	2.8%
VA	0.0%
Total	100.00%

Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

## C

In Section VI.5 (a), page 60, the applicant states:

*"FMS Apex will have an open policy, which means that any Nephrologist may apply to admit patients at the facility."*

The information provided is reasonable and credible and supports a finding of conformity with this criterion.

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

## C

In Section V.3 (a), page 54, the applicant states:

*"Exhibit 19 contains letters [sic] from Sylvia Barber, FMC Director of Operations, to Wake Technical Community College nursing programs encouraging the school to include the facility in its clinical rotation for nursing students. Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations."*

The information provided in Section V.3 and Exhibit 19 is reasonable and credible and supports a finding of conformity with 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. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the FMS-Apex Dialysis Service addition of two dialysis stations for a total of 16 stations will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The FMS-Apex Dialysis Services adequately demonstrates the need to add two dialysis stations. The proposal is a cost-effective alternative to meet the demonstrated need for additional dialysis stations at The FMS-Apex Dialysis Center (see Criteria (1), (3), (4) and (5) for additional discussion);
- The applicant has, and will continue to, provide quality services (see Criteria (7), (8) and (20) for additional discussion);
- The applicant has and will continue to provide adequate access to medically underserved populations (see Criterion (13) for additional discussion).

Therefore, the application is conforming to this criterion.

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

C

BMA currently provides dialysis services at more than 80 facilities in North Carolina. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMS-Apex operated in compliance with all Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching

hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .Section .2200. The specific criteria are discussed below.

**.2202 INFORMATION REQUIRED OF APPLICANT**

*(b) An applicant that proposed 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:*

*.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

*-NA- The applicant does not propose a new facility.*

*.2202(b)(2) For new facilities, a letter of intent to sign 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 for transplantation, and*

*(E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*

*-NA- The applicant does not propose a new facility.*

*.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*

*-NA- The applicant does not propose a new or replacement facility.*

*.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

*-C- In Exhibit 12, the applicant provided power failure*

procedures as required by this rule.

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- The applicant does not propose a new facility.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Section II, page 13, Section VII, pages 62-65, and Section XI, pages 79-83.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- See Section II, pages 14-15.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- The applicant does not propose a new facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1, page 17, the applicant states that it will admit and provide services as required by this rule.

## **.2203 PERFORMANCE STANDARDS**

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant does not propose a new facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section III, page 46, the applicant states that FMS-Apex projects to serve 54 in-center patients by the end of the first operating year, for a utilization of 3.4 patients per station. See Criterion (3) for discussion.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section III.7, pages 42-48, the applicant provided the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion.

#### **.2204 SCOPE OF SERVICES**

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

.2204(1) *Diagnostic and evaluation services;*

-C- See Section V.1, page 51.

.2204(2) *Maintenance dialysis;*

C- See Section V.1, page 51.

.2204(3) *Accessible self-care training;*

-C- See Section V.1, page 51.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See Section II. (3), page 28.

.2204(5) *X-ray services;*

-C- See Section V.1, page 51.

.2204(6) *Laboratory services;*

-C- See Section V.1, page 51.

.2204(7) *Blood bank services;*

-C- See Section V.1, page 51.

.2204(8) *Emergency Care*

-C- See Section V.1, page 51.

.2204(9) *Acute dialysis in an acute care setting;*

-C- See Section V.1, page 51.

.2204(10) *Vascular surgery for dialysis treatment patients;*

-C- See Section V.1, page 51.

.2204(11)

*Transplantation services;*

-C- See Section V.1, page 51.

.2204(12)

*Vocational rehabilitation counseling and services;*

-C- See Section V.1, page 51.

.2204(13)

*Transportation*

-C- See Section V.1, page 51.

**.2205 STAFFING AND STAFF TRAINING**

.2205(a)

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

-C- See Sections VII, pages 64-65, and Exhibits 14 and 15.

.2205(b)

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

-C- See Section VII, pages 64-65, and Exhibits 14 and 15.