

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

FINDINGS: June 28, 2013

PROJECT ANALYST: Gene DePorter

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10093-13/ Bio-Medical Applications of North Carolina Inc. d/b/a FMS-Apex / Add 1 dialysis station for a total of 17 certified dialysis stations upon completion of this project /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.

C

Bio-Medical Applications [BMA] of North Carolina, Inc. d/b/a FMS Apex, whose parent company is Fresenius Medical Care Holdings, Inc., proposes to add one dialysis station to its existing dialysis facility located at 1000 American Way, Apex for a total of 17 dialysis stations upon completion of this project.

The 2013 State Medical Facilities Plan [2013 SMFP] provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR) the county need methodology shows there is a surplus of 19 stations and thus no need for an additional facility in Wake County. However, the applicant is eligible to apply for an additional station in its existing facility based on the facility need methodology because the utilization rate reported for FMS Apex in the January 2013 SDR is 3.2857 patients per station and a utilization percentage of 82.14%.

Further, the January 2013 SDR shows that 14 dialysis stations were certified as of June 30, 2012 and 2 additional stations were conditionally approved as of December 21, 2012. Application of

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

Table 1
FMS Apex
 ESRD Facility Need Methodology
 Semiannual Dialysis Facility Need

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/12		82.14%
Certified Stations		14
Pending Stations		2
Total Existing and Pending Stations		16
In-Center Patients as of 6/30/12 (SDR2)		46
In-Center Patients as of 12/31/11 (SDR1)		39
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	35.90%
(ii)	Divide the result of step (i) by 12	0.0299
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the June 30, 2012 SDR (6) until the end of calendar year 12/31/2012) for the January 2, 2013 SDR.	0.1795
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	54.2564
(v)	Divide the result of step (iv) by 3.2 patients per station	16.9551
	And subtract the number of certified and pending stations as recorded in SDR2 [16] to determine the number of stations needed	1

As shown in the above table, based on the facility need methodology for dialysis stations there is a need for one dialysis station. Step (c) of the facility need methodology, page 381 of the 2013 SMFP, states; “The facility may apply to expand to meet the need established... up to a maximum of 10 stations.”

The applicant proposes to add one dialysis station and therefore is consistent with the facility need determination for dialysis stations.

POLICY GEN-3: Basic Principles, in the 2013 SMFP is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II., page 24, the applicant describes how this proposal will promote safety and quality:

“BMA is a high quality health care provider. BMA’s parent company, Fresenius Medical Care encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

In Section II.3, page 34, the applicant provides BMA goals for quality that the applicant states are more stringent than national averages. Reference the following table;

Table 2
BMA Core Indicators of Quality

Core Indicator	Measuring	FMS Apex
Dialysis Adequacy	% of patients with Ekt/V >1.2	93.2%
Nutrition	% of Patients with Albumin > 3.5	85.0%
Vascular Access	% of Patients with AV Fistula	68.8%
	% of Patients with Catheter	16.0%

The applicant identifies the following programs and methods it uses to insure and maintain quality care:

Table 3
Maintaining Quality Care Programs

Corporate Programs	Facility Programs
Technical Audits	Quality Improvement Program
Continuous Quality Improvement	Staff Orientation and Training
External Surveys-DFS Certification Surveys	In-Service Education
Core Indicators of Quality	
Single Use Dialyzers	

Source: Section II. 3), pages 32-34.

Exhibit 13 includes FMC's Quality Improvement Program.

The applicant adequately demonstrates the proposal will promote safety and quality of care.

Promote Equitable Access

In Section II, pages 26-27, the applicant describes how the proposal would promote equitable access for medically underserved groups, as follows:

"10A NCAC .2202 (b)(8), requires a commitment by BMA 'to admit and provide 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.' BMA provides such assurances within Section VI of this application.

...BMA is also keenly sensitive to the second element of 'equitable access' – time and distance barriers. BMA continually strives to develop facilities and site dialysis stations in close proximity to the patient residence. BMA is an advocate of community based treatment delivery when such is possible and appropriate. BMA suggests that the patient population of FMS Apex will continue to increase at a rate exceeding the Wake County Five Year Average Annual Change Rate as published in the January 2013 SDR; thus this additional station is necessary."

As noted in Section VI.1 (a), page 51 of this application:

"BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ...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."

In Section II, page 27; BMA has projected that the facility will have the following demographic profile:

Table 4
FMS Apex Facility Demographics

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMS Apex	29.2%	52.1%	89.6%	52.1%	60.4%

In Section VI.2, page 54, the applicant states:

“The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It will be constructed in compliance with applicable sections of the North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”

In Section VI.7, page 55, the applicant states:

“The BMA admission policy states that ‘patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients’ attending physician. No arbitrary criteria with respect to the patient’s age or magnitude of complicating medical problems are established.

BMA also has an AIDS policy that states ‘a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not [an] acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’ (Reference Exhibit 8 FMC Business and Admission Policy and Exhibit 9, HIV/HBV Policy & Procedure).

The applicant adequately demonstrates the proposal will promote equitable access to medically underserved groups. See Criteria (13c) for additional discussion.

Maximize Healthcare Value

In Section II., page 26, the applicant states:

“BMA is projecting a capital expenditure of \$4,350 for this project. This expenditure is necessary in the normal course of doing dialysis business. BMA is not seeking State or Federal monies to accomplish this expansion; BMA is not seeking charitable contributions to accomplish this expansion. Rather, BMA, through its parent company, FMC is taking on the financial burden to complete this expansion in an effort to bring dialysis treatment closer to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 94% of the treatments are covered by Medicare and Medicaid. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a

consequence, BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates the proposal will maximize healthcare value. Consequently, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the January 2013 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant FMS Apex proposes to add one dialysis station to its existing facility for a total of 17 stations upon completion of the project.

Population to Be Served

In Section IV. 1, page 42, the applicant identifies the population it serves, as illustrated in the following table:

Table 5
FMS Apex March 15, 2013 Patient Origin

FMS Apex	In-Center
Wake	46
Lee	2
TOTAL	48

In application Section II, page 20, the applicant identifies the in-center population it proposes to serve during the first two operating years following project completion (FMS Apex does not provide Home Hemodialysis training) , as illustrated in the following table:

Table 6
FMS Apex-In-Center Patient Projections Operating Years 1 and 2

County	Operating YR 1 7/1/14-6-30/15		Operating YR 2 7/1/15-6/30/16		County Patients as a Percentage of Total	
	In-Center	Home Hemo	In-Center	Home Hemo	Year 1	Year 2
Wake	53.6	0	56.9	0	95.8%	95.8%
Lee	2.3	0	2.5	0	4.2%	4.2%
Total	55.9	0	59.4	0	100.0%	100.0%

The applicant adequately identified the population FMS Apex proposes to serve.

Need Analysis

In Section III.7, pages 37-40, the applicant states that; “BMA is proposing to add one dialysis station to FMS Apex resulting in 17 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 54.4, rounded to 55 patients.” The application is filed pursuant to the Facility Need Methodology utilizing data from the January 2013 SDR.

- The FMS Apex census has grown at a rate far exceeding the Wake County Five Year Average Change Rate of 4.2% for dialysis services (as published in the January 2013 SDR). The facility’s five year average change rate is 31.1% according to the applicant.
- The Facility Need Methodology indicated a potential need for one additional station at FMS Apex. The applicant has requested 1 dialysis station.
- Calculations in this application are based upon completion and certification of the station as of June 30, 2014.
- BMA does not believe it appropriate to use Wake County’s Five Year Average Annual Change Rate of ESRD population growth (4.2%) when the FMS Apex service area (within Wake County) has a change rate for the most recent five years of 31.1% (or 6.22% per year).
- BMA has chosen to use a rate of 6.25% as an appropriate growth rate for FMS Apex. This rate reflects the change in the number of stations for FMS Apex ($1/16 = .0625$). Furthermore, as the dialysis patient population of Wake County continues to increase, the need for dialysis stations will continue to increase.
- The applicant assumes the patient population of the facility will continue to increase at a rate faster than that of the county.

The applicant’s methodology is provided in the following table found on page 40:

Table 7
FMC Apex In-Center Methodology for Projected Patient Volume

June 30, 2013 through June 30, 2016

BMA begins with the in-center patient population for FMS Apex as reported in the January 2013 SDR for December 31, 2012.	46 Wake County Patients 2 Lee County Patients
BMA projects growth of this patient population using 6.25% Change Rate for one year to December 31, 2013	$(46 \times .0625) + 46 = 48.9$ $(2 \times .0625) + 2 = 2.1$
BMA projects this population forward for 6 months to June 30, 2014. This is the expected completion date for the station expansion project.	$[48.9 \times (.0625 / 12 \times 6)] + 48.9 = 50.4$ $[2.1 \times (.0625 / 12 \times 6)] + 2.1 = 2.2$
BMA projects the patient population forward for 12 months to June 30, 2015. This is the end of Operating Year 1.	$(50.4 \times .0625) + 50.4 = 53.6$ $(2.2 \times .0625) + 2.2 = 2.3$
BMA projects the patient population forward for 12 months to June 30, 2016. This is the end of Operating Year 2	$(53.6 \times .0625) + 53.6 = 56.9$ $(2.3 \times .0625) + 2.3 = 2.5$

Consequently, the applicant projects it will serve 55 in-center patients or 3.235 patients per station ($55/17 = 3.235$) by the end of Year 1 and 59 in-center patients or 3.4705 in-center dialysis patients per station per week by the end of Year 2 [59 patients/17 stations = 3.4705 patients per station]. This exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI. 1(a), page 51, the applicant states that each of BMA's 93 facilities in 40 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons. The applicant projects that 94.0% of the patients at FMS Apex will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for medically underserved groups at FMS Apex.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population has for one additional dialysis station at FMS Apex and demonstrates all residents of the area, and in particular, underserved groups are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, page 41 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services, stating:

“BMA of North Carolina has considered several alternatives to this project. Following is a brief discussion of the alternatives considered:

- a) BMA could have elected to not apply. However, considering the high growth rate at FMS Apex, not applying was not an appropriate position.*
- b) BMA could have utilized a growth factor of up to 31.1%. BMA elected to use a much more conservative growth factor of only 6.25% as is explained within our assumptions. A growth rate of greater than 6.25% would have overstated patient projections and resultant projections of revenues and expenses.*

Considering the alternatives, BMA has chosen the most effective and least costly alternative for meeting the needs of the patients choosing to receive treatment at the FMS Apex facility.”

The applicant adequately demonstrated the need for one additional station based on the number of in-center patients it now serves and proposes to serve. See Criterion (3) for discussion on need which is hereby incorporated by reference as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria and is thus approvable. The applicant adequately demonstrates that this project is its least costly or most effective alternative to meet the need for additional dialysis stations at this facility. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Apex shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc., d/b/a FMS Apex shall develop and operate no more than one additional dialysis station for a total of no more than 17 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 FMS Apex shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station for a total of 17 stations, which shall include any home hemodialysis training or isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Apex shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**

5. Bio-Medical Applications of North Carolina, Inc. 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.

C

In Section VIII. 1(b), Table VIII 1, page 60; the applicant shows that the total capital costs of this project are \$4,350. The applicant further indicates that FMS Apex facility is an operational facility. Consequently, there is no associated “start-up” expense involved. The applicant further states the following on page 63:

“Exhibit 10 is a copy of the most recent FMC audited financial reports. The 2011 Consolidated Balance Sheet reflects more than \$204 million in cash, and current assets exceeding \$13 billion. It is obvious that FMC has the resources necessary for all projects.”

In Exhibit 24 of the application, the applicant states the following in a letter dated March 15, 2012 [2013]:

“BMA proposes to add one dialysis station to its FMS Apex facility for a total of 17 dialysis stations. The project calls [for] the following capital expenditures on behalf of BMA:

Capital Expenditure \$4,350

As Vice President, I am authorized and do hereby authorize addition of one new dialysis station for a total capital cost of \$4,350. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$4,350.”

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

The rates in the following table were provided by the applicant in application Section X.1, page 66 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

Table 8

In-Center Medicare/Medicaid Rates

	In-Center
Commercial Insurance	\$ 1,375.00
Medicare	\$ 234.00

Medicaid	\$ 137.29
VA	\$ 146.79
Private Pay	\$ 1,375.00

In the revenue and expense statements in Section X. 2, page 67 and Section X.4, page 69-70, the applicant projects that revenues will exceed operating costs in each of the first two years of operation. The following table illustrates projected revenues and expenses during the first two years after project completion.

**Table 9
 Revenue, Costs and Profit**

	Operating Year 1 7/1/14-6/30/15	Operating Year 2 7/1/15-6/30/16
Total Net Revenue	\$2,254,026	\$2,382,660
Total Operating Costs	\$2,217,965	\$2,332,688
Net Profit	\$ 36,061	\$ 49,972

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 67-69, 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

The applicant proposes to add one dialysis station to the existing FMS Apex facility for a total of 17 dialysis stations upon completion of this project. The applicant adequately demonstrates the need for one additional station based on the number of in-center patients it proposes to serve. As of June 30, 2012, the 14 station FMS Apex was operating at 82.1% capacity ($46/14 = 3.2857$; $3.2857/4 = .8214$). The target utilization is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 17 stations serving 55 patients in Year 1 which is a utilization rate of 81.25% ($55/17 = 3.24$; $3.24/4 = .8100$). Therefore, the applicant is conforming with the requirement in 10A NCAC 14C .2203.

There are twelve dialysis facilities in Wake County, with utilization ranging from 32.69% to 102.50%. The following table shows the distribution of ESRD facilities in Wake County and utilization of dialysis stations based upon data in the January 2013 North Carolina Semiannual Dialysis Report.

**Table 10
 Wake County Dialysis Facilities**

Facility and (Certified Dialysis Stations)	Location	% Utilizat	Patients Per
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		ion	Station
FMS Apex (14)	Apex	82.14%	3.2
Cary Kidney Center (23)	Cary	76.09%	3.0
BMA of Raleigh (49)	Raleigh	75.51%	3.0
FMC of New Hope (30)	Raleigh	67.05%	2.7
FMC of Central Raleigh (13)	Raleigh	32.69%	1.3
BMA of Fuquay Varina (22)	Fuquay-V	86.36%	3.5
Zebulon Kidney Center (30)	Zebulon	72.50%	2.9
Wake Dialysis Clinic (50)	Raleigh	81.00%	3.2
FMC of Eastern Wake (14)	Rolesville	82.14%	3.3
FMC of Millbrook (16)	Raleigh	81.25%	3.3
SW Wake County (30)	Raleigh	86.67%	3.5
Wake Forest Dialysis (10)	Wake Forest	102.0%	4.1

Source: 2013 North Carolina Semiannual Dialysis Report Table A, page 5, Wake County.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 56, the applicant provides the current and projected staffing for FMS Apex as shown in the following table:

Table 11
FMS Apex Current and Projected Staffing

	# of Current (FTE) Positions	# of (FTE) Positions to be added	# of Projected (FTE) Positions
RN	1.75	0.50	2.25

Tech.	5.00	2.00	7.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position not a facility FTE.		
Administrator	0.15	0.00	0.15
Dietitian	0.40	0.10	0.50
Social Worker	0.40	0.10	0.50
Medical Records	0.64	0.25	0.89
Chief Tech	0.20	0.05	0.25
Equipment Tech	0.50	0.25	0.75
In-Service	0.20	0.10	0.30
Clerical	0.40	0.20	0.60
Total	10.64	3.55	14.19

The applicant indicates a total of 10.64 FTEs current staff and projects staffing of 14.19 FTEs which includes 3.55 FTEs of additional staff, upon project completion. The applicant indicates in Section VII.4, page 57; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in application Section VII and the estimated annual salaries and revenues are reasonable and credible.

In Exhibit 21, Jason Eckel, M.D. indicates that he will continue as Medical Director of FMS Apex. 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.

C

FMS Apex is an existing kidney disease treatment center certified by the Centers for Medicare and Medicaid. In Section V. 1, page 44, the applicant includes a list of providers for the necessary ancillary and support services.

Exhibit 16 contains a copy of an Affiliation Agreement between WakeMed Hospital and FMS Apex. Exhibit 17 contains a copy of a Transplant Center Evaluation Services Agreement between Duke University Medical Center and FMS Dialysis Services of Apex and a Transplant Services Agreement between UNC Hospitals and the Apex Dialysis Center. Section V.4 (b), pages 47-48 contains two tables listing physicians a) by specialty who support this application and b) who have expressed a willingness to provide medical coverage for ESRD patients. Exhibit 21 contains a letter from Jason Eckel, M.D. who is and will continue to serve, as the Medical Director for the facility. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be available and coordinated with the existing health 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 51, the applicant states the following;

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 93 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 12
 FMS Apex Patient Profile**

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMS Apex	29.2%	52.1%	89.6%	52.1%	60.4%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 89.6% of the facility treatment reimbursement is from Medicare.

It is clear that FMS Apex projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved...For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities in FY 2012, Low income and medically underinsured persons will continue to have access to all services provided by BMA.

The facility will conform to the North Carolina Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other applicable requirement of federal, state, and local bodies.”

As shown in the following table, 94.0% of FMS Apex current in-center patients have some or all of their care paid for by Medicare or Medicaid. In Section VI.1 (b) & (c), page 52, the applicant provides the current and projected payer mix for FMS Apex. The applicant projects no change in reimbursement, between current and projected reimbursement, as shown in the following table:

**Table 13
 FMS Apex
 Current and Projected Payor Mix**

Payor Source	Current & Projected Percent of Total
Private	0.0%
Commercial Insurance	6.0%

Medicare	86.3%
Medicaid	7.7%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	0.0%
Other: Self Pay/Indigent	0.0%
Total	100.0%

The applicant demonstrated that medically underserved populations currently have adequate access to dialysis services provided at FMS Apex. Therefore, the application is conforming to this criterion.

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 for Wake County and Statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

Table 14
Percent of Medicaid Eligible
By County and State

County	Total # of Medicaid Eligible as % of Total Population ^①	Total # of Medicaid Eligible Age 21 and older as % of Total Population ^②	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Wake	9.8%	3.3%	18.4%
Statewide	17.0%	6.7%	19.7%

Source: www.ncdhhs.gov/dema-Medicaid Eligible-Wake County June 2010.

① Medicaid Eligible by Age for Wake County and State, June 2010.

② Medicaid Eligible Age 21+ for Wake County and State, June 2010.

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. In fact, in 2011 only 5.8 of all newly diagnosed ESRD patients (Incident ESRD patients) in North Carolina's Network 6 were under the age of 35. ^③

^③ Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

The Office of Budget and Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition data are available by race, age or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standing. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”

In addition, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides the following national statistics for FY 2010:

Table 15
The 2012 United States Renal Data System
Selected National Statistics as of December 31, 2010 ④

Patients Receiving Hemodialysis Nationally- 376,000			
African American	38.23%	Male	55.65%
White	55.38%	65+	44.35%

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39% covered solely by Medicare, and 32% covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients respectively.”

④ United States Renal Data System 2012 USRDS Report, Chapter 1, page 225.

The report provides 2010 ESRD spending, by payor as follows:

Table 16
ESRD Spending Nationally by Payor ⑤

Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%

Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%
Total ESRD Expenditures	\$47.5	100.00%

The Southeastern Kidney Council (SKC) provides Network 6, 2011 Incident ESRD patient data by age, race and gender, as shown in the following table:

Table 17
2011 Number and Percent of Dialysis Patients
By Age, Gender, and Race ⑤

Age	# of ESRD Patients	% of Dialysis Population
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.30%
Total	9,342	100.00%

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

⑤ Source: 2012 United States Renal Data System (USRDS) Annual Data Report, Chapter 11, page 340.

⑥ Source: Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

- (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 application Section VI.1 (f), page 53, the applicant states, “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service*”

under any federal regulations.” In Section VI.6 (a), page 55, the applicant states, “There have been no Civil Rights access complaints lodged against any BMA North Carolina facilities in the past five years.”

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 52, the applicant provides the projected payor mix for the proposed services at FMS Apex. The applicant projects no change from the current payor mix for dialysis visits as shown in the table in Criteria (13a) above. The applicant projects that 94% of the patients will be Medicare or Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. 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 54 the applicant states, “Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMS Apex will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.

The applicant adequately demonstrates that FMS Apex offers a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

In application Section V.3 (a), pages 46-47, the applicant states:

“Exhibit 19 is a letter from ...FMC Director of Operations to Wake Technical Community College nursing programs encouraging the school to include 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.

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

The information provided in application Section V 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

The applicant proposes to add one dialysis station for a total of 17 stations upon completion of the project.

The following table repeats the earlier profile of the twelve dialysis facilities in Wake County.

Table 18
Wake County Dialysis Facilities 7

Facility and (Certified Dialysis Stations)	Location	% Utilization	Patients Per Station
FMS Apex (14)	Apex	82.14%	3.3
Cary Kidney Center (23)	Cary	76.09%	3.0
BMA of Raleigh (49)	Raleigh	75.51%	3.0
FMC of New Hope (30)	Raleigh	67.05%	2.7
FMC of Central Raleigh (13)	Raleigh	32.36%	1.3

BMA of Fuquay Varina (22)	Fuquay-V	86.69%	3.5
Zebulon Kidney Center (30)	Zebulon	72.50%	2.9
Wake Dialysis Clinic (50)	Raleigh	81.00%	3.2
FMC of Eastern Wake (14)	Rolesville	82.14%	3.3
FMC of Millbrook (16)	Raleigh	81.25%	3.3
SW Wake County (30)	Raleigh	86.67%	3.5
Wake Forest Dialysis (10)	Wake Forest	102.0%	4.1

Eight of the twelve Wake County dialysis facilities are operating at or close to the operating measure of 80% utilization (3.2 patients per station). Nine of the twelve dialysis facilities in Wake County are owned and operated by Fresenius Medical Care Holdings, Inc.

In Section V.7, page 49, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states that this proposal will not have any effect on competition in Wake County. Fresenius Medical Care Holdings, Inc., as the parent of FMS Apex, owns and operates the majority of the dialysis facilities in Wake County. The patients to be served by FMS Apex are existing dialysis patients, and future dialysis patients living in Wake County. See Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

⑦ Source: 2013 North Carolina Semiannual Dialysis Report Table A, page 5 Wake County.

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

- The applicant adequately demonstrates the need to add one dialysis station, and that it is a cost-effective alternative to meet the patient volume at FMS Apex dialysis center;
- The applicant adequately demonstrates that it will continue to provide quality services;
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this application.

- (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 several facilities in North Carolina. According to files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMS Apex operated in compliance with the 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 Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- Utilization-2013 SDR-82.14% or 3.2857 patients per station

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 42 the applicant provides the following mortality rates-Year 2010-26.9%, 2011-17.5%, and 2012-9.3%.

.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;

-C- See Section IV.3, page 42, FMS Apex does not provide home

training.

- .2202(a)(4) *The number of transplants performed or referred;*
-C- See Section IV.4, page 42, Transplants referred-2 and Transplant performed-0, in 2011.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- See Section IV.5, page 42, 4 patients on the waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related-65.*
-C- See Section IV.6, page 42.-Dialysis related-2 and non-dialysis related-27.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-C- See Section IV.7, page 43-0.

(b) An applicant that proposed develop a new facility, to 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- FMS Apex is an existing facility.
- .2202(b)(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- FMS Apex is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-NA- FMS Apex is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- See Section XI.6 (f), page 74 and Exhibit 12 regarding back-up capabilities.

- .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- FMS Apex is an existing 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, and other relevant health and safety requirements.*
-C- See Section XI.6 (g), page 74 and Exhibits 11 and 12.
- .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 III.7, pages 37-40, and discussion in Criterion (3) which is hereby incorporated by reference as if fully set forth herein.
- .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- FMS Apex is an existing 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- See Section II, 10A NCAC 14C .2202 (9) page 15.

.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 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- FMS Apex is an existing 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.7, pages 37-40 the applicant projects to serve 55 in-center patients by the end of Year 1, which equates to 3.2352 patients per station per week [55 / 17 = 3.2352]. Further, the applicant projects to serve 59 in-center patients by the end of Year 2, which equates to 3.4705 patients per station per week [59 / 17 = 3.4705]. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

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

-C- See Section II.1, pages 12-21, and Section III.7, pages 37-40, where the applicant provides the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

.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 (e), page 44. Western Wake and WakeMed

.2204(2) *Maintenance dialysis;*

-C- See Section V.1 (c), page 44. Provided on Site

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

-C- See Section V.1 (d), page 44. BMA Raleigh

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

-C- See Section V.1 (d), page 44. BMA Raleigh

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

-C- See Section V.1 (g), page 44. Western Wake Hospital

.2204(6) *Laboratory services;*

-C- See Section V.1 (h), page 44. Spectra (Exhibit 18).

.2204(7) *Blood bank services;*

-C- See Section V.1, page 44. Western Wake and Rex Hospitals

.2204(8) *Emergency care;*

-C- See Section V.1 (b), page 44. All staff is trained to respond, a fully stocked crash cart is maintained, and ambulance transport to hospital is accessible.

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

-C- See Section V.1 (a), page 44. WakeMed Hospital.

- .2204(10) *Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1 (p), page 44. Referral to Capital Access Center, Premier Surgical, Carolina Vascular, Millenium Vascular and Duke Vascular Surgery.
- .2204(11) *Transplantation services;*
 - C- See Section V.1 (f), page 44. Duke UMC
- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- See Section V. 1 (o), page 44. Wake County Vocational Rehabilitation Services.
- .2204(13) *Transportation*
 - C- See Section V.1 (q), page 44. Wake County Transportation .

.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 494 (formerly 405.2100)*
 - C- See Section VII.1, page 56 the applicant provides the proposed staffing. In Section VII, 2, page 57 the applicant states that the proposed facility will comply with all staffing requirements set forth in the Federal code. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- .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.5, page 57 and Exhibits 14 and 15 for outline of continuing education programs.