ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: December 22, 2014
PROJECT ANALYST: Celia C. Inman
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10331-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Central Raleigh / Add four dialysis stations for a total of 19 upon project completion / Wake

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Central Raleigh (FMC Central Raleigh) proposes to add four dialysis stations for a total of 19 certified dialysis stations upon completion of this project. The facility is located at 802 Semart Drive, Raleigh, Wake County.

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 12 dialysis stations in Wake County; therefore, based on the county need methodology, there is no need for additional stations in Wake County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the

utilization rate reported for FMC Central Raleigh (the applicant) in the July 2014 SDR is 3.73 patients per station. This utilization rate was calculated based on 56 in-center dialysis patients and 15 certified dialysis stations. (56 patients / 15 stations = 3.73 patients per station).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY 2014 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		93.33%
Certified Stations		15
Pending Stations		0
Total Existing and Pending Stations		**15**
In-Center Patients as of 12/31/13 (SDR2)		56
In-Center Patients as of 6/30/13 (SDR1)		35
Step	Description	
(i)	Difference (SDR2 - SDR1)	21
	Multiply the difference by 2 for the projected net in-center change	42
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.1200
(ii)	Divide the result of Step (i) by 12	0.1000
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	1.2000
(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	123.2000
(v)	Divide the result of Step (iv) by 3.2 patients per station	38.50
	and subtract the number of certified and pending stations as recorded in SDR2 [15 stations] to determine the number of stations needed	**23.50**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 23.50 (rounded to 24) stations, up to a maximum of 10. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: BASIC PRINICPLES, page 38 of the 2014 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."*

The applicant addresses Policy GEN-3 beginning on page 17 of the application.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 4-8, Section II, pages 17-18, Section V, pages 36-40, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 18-19, Section III, pages 30-33, Section V, pages 36-40, Section VI, pages 41-45, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section II, pages 19-20, Section III, pages 30-33, Section V, page 40, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than $2 million.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 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 proposes to add four dialysis stations to the existing FMC Central Raleigh dialysis facility for a total of 19 dialysis stations upon completion of the project.

Population to be Served

In Section IV.1, page 34, the applicant states the number of patients served at FMC Central Raleigh as of June 30, 2014 as follows:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Wake	0	55
Total	0	55

The applicant proposes to add four dialysis stations to the existing dialysis facility for a total of 19 certified dialysis stations. In Section II, page 12 and Section III.7, pages 29-30, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion on December 31, 2015, as summarized in the table below:

Projected Dialysis Patient Origin

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Wake	61.0	64.1	100.0%	100.0%
Total	61.0	64.1	100.0%	100.0%

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant describes FMC Central Raleigh's internal need for additional stations in Section III.7, page 30 and Section III.9, pages 31-33, as the applicant discusses its assumptions and methodology for projected utilization and the alternatives considered, respectively.

As discussed in Criterion (1), based on the facility need methodology for adding dialysis stations, the maximum number of stations the applicant could apply for based on the facility need methodology is ten stations. The applicant proposes to add four stations.

In Section II, pages 12-13, and Section III.7, pages 30-31, the applicant provides the assumptions and methodology it uses to determine the need for additional stations and to project FMC Central Raleigh's patient utilization.

The assumptions and methodology are summarized below:

- The applicant assumes that the Wake County patient population dialyzing at its Central Raleigh facility will increase at a rate of 5% annually, a rate that is slightly above the 4.1% Wake County Five Year Average Annual Change Rate published in the July 2014 SDR. The applicant states that this is a reasonable growth rate for its facility because:
  - The facility need methodology table demonstrates that the facility patient population increased at a rate of 120% in 2013.
  - FMC Central Raleigh increased in patient population from 35 to 56 during 2013.
  - The proposed rate of growth is less than the facility need methodology rate and less than the facility's one year increase in census.

- Operating Year One is January 1, 2016 – December 31, 2016.

- Operating Year Two is January 1, 2017 – December 31, 2017.

A review of the most recent four SDRs reveals the following FMC Central Raleigh historical utilization.

FMC Central Raleigh Dialysis Utilization

Date of SDR	Certified Stations	In-Center Patients	Utilization Percent	Patients per Station
January 2013	13	17	32.69%	1.3077
July 2013	15	35	58.33%	2.3333
January 2014	15	35	58.33%	2.3333
July 2014	15	56	93.33%	3.7333

The compound average growth rate (CAGR) in facility patient census calculated for the four six-month SDR reporting periods in 2013 and 2014 is 49%, which supports the applicant's use of a 5% annual change rate in its projections.

Projected Utilization

The following table, illustrating projected utilization, is provided by the applicant on pages 13 and 30 of the application.

BMA begins with the Wake County patient population dialyzing at the facility as of June 30, 2014	*55 In-center patients*
BMA uses one half of the 5% Change Rate to project the census forward for 6 months to December 31, 2014.	*[55 x (.05 / 12 x 6)] + 55 = 55.4*
BMA projects this patient population forward for 1 year to December 31, 2015. This is the projected beginning census for this project.	*(55.4 x .05) + 55.4= 58.1*
BMA projects the patient population forward for 1 year to December 31, 2016. This is the projected ending census for Operating Year 1.	*(57.1 x .05) + 58.1 = 61.0*
BMA projects the patient population forward for 12 months to December 31, 2017. This is the projected ending census for Operating Year 2.	*(61.0 x .05) + 61.0 = 64.1*

The projected utilization in the table above, as provided by the applicant, results in an in-center patient census of 61 patients for a utilization rate of 80.2% or 3.21 (61 patients / 19 stations = 3.21 / 4 = .8026) patients per station at the end of Operating Year One which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b). However, there are calculation errors in the above table. The following table prepared by the Project Analyst demonstrates the accurate calculations for the projected in-center patient census for the first two operating years, using the applicant's proposed 5% change rate.

FMC Central Raleigh	In-Center Patients
The applicant begins with the Wake County patient population dialyzing at the facility as of June 30, 2014	55
The analyst uses a 5% annual change rate to project the census forward for 6 months to December 31, 2014.	[55 x (.05 / 12 x 6)] + 55 = 56.4
The analyst projects this patient population forward for 1 year to December 31, 2015. This is the projected beginning census for this project.	(56.4 x .05) + 56.4= 59.2
The analyst projects the patient population forward for 1 year to December 31, 2016. This is the projected ending census for Operating Year 1.	(59.2 x .05) + 59.2 = 62.2
The analyst projects the patient population forward for 1 year to December 31, 2017. This is the projected ending census for Operating Year 2.	(62.2 x .05) + 62.2 = 65.3

At the end of Operating Year One, December 31, 2016, the analyst's calculations using the applicant's proposed growth rate results in an in-center patient census of 62.2 patients for a utilization rate of 82% or 3.26 (62 patients / 19 stations = 3.26 / 4 = .8157) patients per station, which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b).. At the end of Operating Year Two, December 31, 2017, the in-center patient census is 65.3 patients for a utilization rate of 85.5% or 3.42 (65 patients / 19 stations = 3.42 / 4 = .8552) patients per station.

The applicant's calculation errors result in a slightly more conservative projection; therefore, the projected utilization is based on reasonable and supported assumptions regarding continued growth.

Thus the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed services.

Access

In Section VI.1(a), page 41, the applicant states:

> *"It is clear that BMA provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."*

On page 41, the applicant states that the patient population of the FMC Central Raleigh facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC Central Raleigh	50.9%	40.0%	98.2%	40.0%	89.1%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 98.2% of the facility treatment reimbursement is from Medicare.

On pages 42 and 58, the applicant projects that 78.5% of its patients will be covered by some form of Medicare or Medicaid. Another 16.9% are covered by a combination of Medicare and commercial insurance. The applicant adequately demonstrates 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.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions and demonstrates the extent to which all residents of the area, and in particular, underserved groups, are likely to have access to the services. 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, pages 31-33, the applicant discusses the alternatives considered prior to the submission of its application, which include:

1) Maintain the Status Quo – the applicant states, *"BMA considered simply not applying. However, that would not resolve the growing ESRD patient population in Wake County."*

2) Apply for more than four stations – the applicant states, "*However, the addition of four stations is a modest and reasonable approach to growth of the facility. Moreover, at this time the facility can not accommodate more than 19 stations."*

3) Relocate stations from another Wake County facility – the applicant states,

> *"The BMA dialysis facilities in Wake County have been sited in order to provide for localized delivery of care to the patient population of the County. BMA has sought to develop facilities and stations where there is sufficient demand for services and in a way which minimizes patient need to travel for care."*

The applicant provides tables on pages 32-33 showing the December 31, 2013 and June 30, 2014 utilization of BMA's 11 dialysis facilities in Wake County. The June 30, 2014 census for BMA Wake County facilities has increased from 974 patients and 296 stations to 1,001 patients and 307 certified stations with a utilization rate of 81.7% and 3.27 patients per station.

4) Expansion of another facility in Wake County – the applicant states that it is simultaneously filing CON applications to add dialysis stations at BMA Zebulon, FMC Eastern Wake and BMA Fuquay-Varina. The applicant further states,

> *"Each of these projects involves a different part of Wake County, from Zebulon on the northeast side of the county, to Rolesville in the central area of the county, to inner city Raleigh, and finally to Fuquay-Varina on the south end of the county. Each facility is serving a different segment of the Wake County ESRD patient population."*

The applicant states that the chosen alternative to apply to expand the existing FMC Central Raleigh facility by adding four stations for a total of 19 certified dialysis stations is the most effective and least costly alternative for meeting the needs of the patients projected to receive treatment at that facility.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the continued growth of FMC Central Raleigh's patient population. See the discussion regarding need in Criterion (3) which is incorporated herein by reference.

Furthermore, the application is conforming or conditionally conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Central Raleigh shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Central Raleigh shall develop and operate no more than four additional dialysis stations for a total of no more than 19 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Central Raleigh shall install plumbing and electrical wiring through the walls for no more than four (4) additional dialysis stations for a total of 19 dialysis stations which shall include any home hemodialysis training stations or isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Central Raleigh shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to 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 the table in Section VIII, page 49, the applicant shows the capital cost of the project is $11,800, which includes $1,000 for water treatment equipment and other equipment and furniture totaling $10,800. In Section IX, page 53, the applicant states that because the project is not a proposal for a new facility, it does not involve startup or initial operating expenses.

In Section VIII.5, page 51, the applicant states, *"BMA is utilizing accumulated reserves to finance this project."* The applicant further states:

"Please refer to Exhibit 24 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project."

The letter in Exhibit 24 commits Fresenius Medical Care Holdings, Inc. funds for the development of the proposed project. Exhibit 4 contains the consolidated financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ending December 31, 2013 and 2012, which document cash and cash equivalents of $275,719,000 and total equity of more than $7 million.

Thus, the applicant adequately demonstrates the availability of sufficient funds to develop the project.

Based on information provided by the applicant in Section X.1, page 54, the dialysis facility's allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Private Pay	$1,425.00
Commercial Insurance	$1,425.00
Medicare	$ 239.00
Medicaid	$ 140.23
VA	$ 231.12
Medicare/Medicaid	$ 239.00
Medicare/Commercial	$ 239.00
State Kidney Program	$ 100.00
Other: Self/Indigent	$1,425.00

On page 55, the applicant states:

"In November 2013, Medicare announced further cuts to reimbursement for dialysis treatment. These cuts amount to a 12% reduction in revenues and will be phased in over several years. The following table demonstrates the projected Medicare reimbursement by calendar year. BMA will use these rates within in the application and its projections of revenues."

Table X.1-2
Anticipated Medicare Reimbursement by Year

YEAR	*MEDICARE RATE*
2014	*$239.02*
2015	*$239.02*
2016	*$229.46*
2017	*$220.28*
2018	*$211.47*
2019	*$211.47*

In Sections X.2-X.4, pages 56-62, the applicant reports projected revenues and expenses as follows:

	OPERATING YEAR 1 1/1/16-12/31/16	**OPERATING YEAR 2 1/1/17-12/31/17**
Total Net Revenue	$2,411,492	$2,461,415
Total Operating Costs	$2,354,612	$2,419,812
Net Profit	$56,880	$41,602

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 57-59 for the applicant's assumptions, including number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments) for in-center patients. The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. See further discussion on the applicant's assumptions for projections in Criterion (3) which is incorporated herein by reference.

In Section VII.1, page 46, the applicant provides projected staffing and salaries. The financials in Sections X.4 and X.5, pages 60-62, budget operating costs adequate to cover the projected staffing.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of 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.

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The following table identifies the existing and approved kidney disease treatment centers located in Wake County as reported in the July 2014 SDR.

WAKE COUNTY DIALYSIS CENTERS AS OF DECEMBER 31, 2013				
FACILITY	LOCATION	STATIONS	PATIENTS	UTILIZATION
BMA of Fuquay-Varina Kidney Center	Fuquay-Varina	19	66	86.84%
BMA of Raleigh Dialysis	Raleigh	43	146	84.88%
Cary Kidney Center	Cary	24	84	97.50%
FMC Apex	Apex	17	51	75.00%
FMC Central Raleigh	Raleigh	15	56	93.33%
FMC Eastern Wake	Rolesville	14	53	94.64%
FMC Millbrook	Raleigh	17	62	91.18%
FMC New Hope Dialysis	Raleigh	36	85	59.03%
FMC Northern Wake (new site)	Raleigh	0	0	0.00%
Southwest Wake County Dialysis	Raleigh	31	109	87.90%
Wake Dialysis Clinic	Raleigh	50	163	81.50%
Wake Forest Dialysis Center	Raleigh	15	59	98.33%
Zebulon Kidney Center (BMA Zebulon)	Zebulon	30	99	82.50%
Total Wake County (excluding FMC Northern Wake		311	1033	83.00%

As shown in the table above, of the thirteen Wake County dialysis facilities, only two operational facilities were operating under the 80% utilization threshold as of December 2013. Northern Wake is a new site. The average utilization for all operational dialysis facilities in Wake County is 83%.

An analysis of the most recent dialysis data submitted by the Wake County ESRD providers to the Medical Facilities Planning Branch shows all Wake County dialysis facilities operating at an average of 81.3% as of June 30, 2014.

The applicant is eligible to add ten stations to the FMC Central Raleigh facility based on facility need and proposes to add four dialysis stations for a total of 19 certified dialysis stations upon completion of this project. The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. See the discussion on need in Criterion (3) which is incorporated herein by reference. Also see the discussion on competition in Criterion (18a) which is incorporated herein by reference.

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

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

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The following table illustrates the projected staffing for FMC Central Raleigh, as provided by the applicant in Section VII.1, page 46.

Position	Total FTE Positions
RN	2.50
LPN	1.00
Technician	7.50
Clinical Manager	1.00
Administrator(FMC Dir. Operations)	0.15
Dietician	0.50
Social Worker	0.50
Chief Tech	0.25
Equipment Technician	0.80
In-Service Technician	0.25
Clerical	1.00
Total	**15.45**

As shown in the above table, the applicant proposes to employ a total of 15.45 full-time equivalent (FTE) positions to staff the Central Raleigh facility upon completion of the proposed project. The Medical Director position is a contract position and not a facility FTE. In Section VII.4, page 47, the applicant states, *"BMA anticipates no difficulties in filling staff positions."*

The following table shows the projected number of direct care staff for each shift offered at FMC Central Raleigh after the addition of the four dialysis stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am to 12:00 pm	7	7	7	7	7	7
Afternoon	12:00 pm to 5:00 pm	7	7	7	7	7	7
Evening	N/A	0	0	0	0	0	0

In Section V.4, pages 38-39, the applicant states that So Yoon Jang, M.D., of Capital Nephrology Associates, P.A. will continue to serve as Medical Director of the proposed facility. Exhibit 21 contains a letter signed by Dr. Jang, expressing support for the addition of dialysis stations and agreeing to continue the relationship with the facility. In Section V, page 39, the applicant lists 20 nephrologists who will have privileges to admit patients and perform rounds on dialysis patients at the facility. In Section VII, page 48, the applicant states that the nephrologists have admitting privileges at *"Rex Hospital, Western Wake Medical Center, Johnston Medical Center, Wake Medical Center and Duke Health Raleigh."*

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. 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 36, the applicant provides a list of providers of the necessary ancillary and support services. WakeMed and/or Rex Hospital will provide acute dialysis in an acute care setting, diagnostic and X-ray services. See Exhibit 25 for the back-up hospital services agreement with WakeMed. WakeMed will provide blood bank services. Transplantation services will be provided by Duke University Medical Center and Carolinas Medical Center (Exhibit 26). Wake County Health Department will provide psychological counseling. Pediatric nephrology will be referred to UNC Hospitals. Vascular surgery will be provided by Rex Vascular or Premier Surgical. All BMA staff are trained to respond to emergencies and there is a fully stocked crash cart available on-site. If needed, patients will be transported by ambulance to the hospital for further acute care. Spectra will provide laboratory services (Exhibit 15). Lab services will be provided by Spectra (Exhibit 15). Self-care training, including hemodialysis, peritoneal dialysis, CAPD and CCPD will be provided by BMA Raleigh (Exhibit 20). The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health 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

NA

(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

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

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

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In Section VI.1(a), page 41, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 102 dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). The applicant further states, *"Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*" The patient population of the FMC Central Raleigh facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC Central Raleigh	50.9%	40.0%	98.2%	40.0%	89.1%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 98.2% of the facility treatment reimbursement is from Medicare.

On pages 41-42, the applicant further states:

> *"BMA notes that the historical performance as reported here represents the payor mix for FMC Central Raleigh as of June 30, 2014. The historical performance is not a guarantee of future performance as the payor source does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing."*

In Section VI.1(b), page 42, the applicant reports that 95.4% of the patients who were receiving treatments at FMC Central Raleigh as of June 30, 2014, had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for the facility.

FMC CENTRAL RALEIGH HISTORICAL PAYOR MIX

SOURCE OF PAYMENT	IN-CENTER %
Commercial Insurance	3.8%
Medicare	76.2%
Medicaid	2.3%
VA	0.8%
Medicare/Commercial	16.9%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Wake County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	**2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population ***	**2009 % Uninsured (Estimate by Cecil G. Sheps Center) ***
Wake County	9.8%	3.3%	18.4%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

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 dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99.)*[1]

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race 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.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

> *"The December 31, 2011 prevalent population included 430,273 patients on dialysis …."*[2] (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

> *"In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant." (p. 216).*

The *2013 USRDS Annual Data Report* (p. 332) provides 2011 ESRD spending by payor, as follows:

[1] http://www.esrdnetwork6.org/utils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf
[2] www.usrds.org/adr.aspx

ESRD Spending by Payor		
Payor	**Spending in Billions**	**% of Total Spending**
Medicare Paid	$30.7	62.4%
Medicare Patient Obligation	$4.7	9.6%
Medicare HMO	$3.6	7.3%
Non-Medicare	$10.2	20.7%
Total	**$49.2**	**100.0%**

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	**% of Dialysis Population**
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.[3]

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;

[3]http://www.esrdnetwork6.org/utils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf

C

In Section VI.1(f), page 43, 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 44, 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

In Section VI.1(d), page 43, the applicant states:

> *"BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."* [emphasis in original]

On page 42, the applicant reports that it expects over 95.4% of the in-center patients who received treatments at FMC Central Raleigh to have all or part of their services paid for by Medicare or Medicaid as indicated below.

FMC CENTRAL RALEIGH
PROJECTED PAYOR MIX

SOURCE OF PAYMENT	IN-CENTER %
Commercial Insurance	3.8%
Medicare	76.2%
Medicaid	2.3%
VA	0.8%
Medicare/Commercial	16.9%
Total	100.0%

The applicant demonstrates that medically underserved populations will 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, page 44, the applicant states that:

> *"Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Central Raleigh will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.*
>
> *Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. Transient patients are accepted upon proper coordination of care with the patient's regular nephrologist and a physician with staff privileges at the facility."*

The applicant adequately demonstrates that it provides a range of means by which a person can access the proposed 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 Section V.3, pages 37-38, the applicant states:

"Exhibit 19 contains a letter to Wake Technical Community College encouraging the school to include the FMC Central Raleigh facility in their clinical rotations for nursing students.

...

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. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease."

Exhibit 19 contains a copy of a letter from Fresenius Medical Care to the Department of Nursing at Wake Technical Community College inviting the college to include FMC Central Raleigh in the clinical rotation for its nursing students. The information provided in Section V.3 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 four dialysis stations to its existing Central Raleigh facility for a total of 19 certified dialysis stations upon completion of this project. According to the July 2014 SDR, Wake County has thirteen dialysis centers, as shown below:

WAKE COUNTY DIALYSIS CENTERS		
FACILITY	**LOCATION**	**UTILIZATION**
BMA of Fuquay-Varina Kidney Center	Fuquay-Varina	86.84%
BMA of Raleigh Dialysis	Raleigh	84.88%
Cary Kidney Center	Cary	97.50%
FMC Apex	Apex	75.00%
FMC Central Raleigh	Raleigh	93.33%
FMC Eastern Wake	Rolesville	94.64%
FMC Millbrook	Raleigh	91.18%
FMC New Hope Dialysis	Raleigh	59.03%
FMC Northern Wake (new site)	Raleigh	0.00%
Southwest Wake County Dialysis	Raleigh	87.90%
Wake Dialysis Clinic	Raleigh	81.50%
Wake Forest Dialysis Center	Raleigh	98.33%
Zebulon Kidney Center (BMA Zebulon)	Zebulon	82.50%
Total Wake County (excluding FMC Northern Wake)		83.00%

As the table above demonstrates, Wake County dialysis facilities are highly utilized.

In Section V.7, page 40, 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. Wake Forest Dialysis Center, as the applicant discusses below, is the only non-BMA facility in Wake County. The applicant states it does not expect this proposal to have any effect on the competition within County. The applicant states:

> *"The patients to be served by this facility are existing dialysis patients, and future patients residing in Wake County. Another provider, DaVita, operates a dialysis facility in Wake Forest. The DaVita Wake Forest facility is approximately 15 miles from the FMC Central Raleigh facility. Consequently, this facility is not likely to be serving patients who might otherwise choose to receive dialysis treatment at the DaVita location. The DaVita facility is not operated the same as the BMA facility. The DaVita facility has its own medical director.*
>
> *Capital Nephrology,* [sic] *and Wake Nephrology, the two predominant nephrology practices in Wake County have been working with BMA, to serve patients in the Wake, Franklin, Johnston and Harnett County areas for more than 20 years. This facility has added value stemming from the strength of our relationship with both nephrology practices.*
>
> *…*
>
> *BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 96% of the In-*

center patients will be relying upon government payors. The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

…

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives."

See also Sections II, III, V, VI and VII, where the applicant discusses the impact on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the addition of two stations to the existing facility will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add four certified dialysis stations to the existing 15-station Wake County facility. See the discussion regarding need in Criterion (3) which is incorporated herein by reference.

- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to patients in Wake County. See the discussion regarding cost-effectiveness in Criterion (4) which is incorporated herein by reference.

- The applicant adequately demonstrates it will continue to provide quality services. See the discussion regarding quality in Criteria (1) and (20) which is incorporated herein by reference.

- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. See the discussions regarding access in Criteria (3) and (13a) which are incorporated herein by reference.

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

FMC Central Raleigh currently provides dialysis services. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Fresenius Medical Care Central Raleigh facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of the decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(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 promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) Utilization rates;

-C- In Section II.1, page 10, the applicant states that the utilization rate is reported in the July 2014 SDR. The July 2014 SDR shows a utilization rate of 93.33% for FMC Central Raleigh. The rate was calculated based on 56 in-center dialysis patients and 15 certified dialysis stations as of December 31, 2013 (56 patients / 15 stations = 3.73 patients per station; 3.73 patients per station / 4.00 patients per station = 93.33%). In Section II, page 12, the applicant projects serving 61 dialysis patients on 19 stations for a utilization rate of

80.26% (61 / 19 = 3.21/ 4 = 0.8026) in operating year one and 64 dialysis patients on 19 stations for a utilization rate of 84.21% (64 / 19 = 3.37 / 4 = 0.8421) in year two. The analyst's analysis of the projections, using the applicant's assumptions, revealed errors in the applicant's calculations which would have otherwise yielded a slightly higher number of patients and higher utilization rates as discussed in Criterion (3) and incorporated herein by reference.

(2) Mortality rates;

-C- In Section II, page 10, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 0.0%, 18.6% and 8.8%, respectively.

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

-NA- In Section II, page 10, the applicant states, *"FMC Central Raleigh is not certified to offer home training. Patients who are candidates for home dialysis are referred to the BMA Raleigh facility."*

(4) The number of transplants performed or referred;

-C- In Section II, page 10, the applicant provides information showing FMC Central Raleigh referred 10 patients for transplant in 2012 and 20 patients in 2013; FMC Central Raleigh did not have any transplants performed on facility dialysis patients in 2012 or 2013.

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

-C- In Section II, page 10, the applicant states, *"FMC Central Raleigh has two patients on the transplant waiting list."*

(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

-C- In Section II, page 10, the applicant states that there were 69 hospital admissions in 2013, 37 (53.6%) of which were dialysis related and 32 (46.4%) non-dialysis related.

(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.

-C- In Section II, page 11, the applicant provides information that shows there were no patients dialyzing at FMC Central Raleigh with Hepatitis B Conversions during 2012 and 2013 and no current patients with infectious disease (Hepatitis B).

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form*:

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

-NA- FMC Central Raleigh is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

(A) timeframe for initial assessment and evaluation of patients for transplantation,

(B) composition of the assessment/evaluation team at the transplant center,

(C) method for periodic re-evaluation,

(D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and

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

-NA- FMC Central Raleigh is an existing facility.

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

-NA- FMC Central Raleigh is an existing facility.

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

-C- See Exhibit 12, in which the applicant provides copies of written policies and procedures, including back up procedures in the event of a power outage.

(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue

acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- FMC Central Raleigh is an existing facility.

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

-C- In Section II, page 12, the applicant states:

"BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC Central Raleigh."

In Section XI.6(g), page 67, the applicant states,

"BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements. Information detailing conformity can be found in Sections II and VII and exhibits referenced therein. Additionally, this applicant has confirmed its commitment to provide services in conformity with the law on the Certification page provided in the front of the application."

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

-C- The applicant provides the following projected patient origin for Operating Years One and Two (January 1, 2016 – December 31, 2016 and January 1, 2017 – December 31, 2017, respectively) on page 12 of the application, as shown below.

Projected Dialysis Patient Origin

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Wake	61.0	64.1	100.0%	100.0%
Total	61.0	64.1	100.0%	100.0%

The applicant's assumptions and methodology are provided on pages 12-13.

(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 is not proposing a new facility.

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

-C- In Section II, page 14, the applicant states,

> *"BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."*

.2203 PERFORMANCE STANDARDS

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

-NA- The applicant proposes to add stations to an existing facility.

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

-C- In Section II, page 12, the applicant projects serving 61 dialysis patients on 19 stations for a utilization of 3.21 (61 /19 = 3.21) patients per station per week at the end of the first operating year, based on the methodology and assumptions found in Section II, pages 12-13 and in Section III of the application. See discussion on projected utilization in Criterion (3) which is incorporated herein by reference.

.2204 SCOPE OF SERVICES

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

(1) diagnostic and evaluation services;

-C- Section II, page 15 and the table in Section V.1, page 36 state patients will be referred to WakeMed or Rex Hospital for diagnostic and evaluation services.

(2) maintenance dialysis;

-C- Section II, page 15 and the table in Section V.1, page 36, state the applicant will provide in-center maintenance dialysis.

(3) accessible self-care training;

-C- In Section II, page 15, the applicant states, "*Patients who are candidates for self-care are referred the BMA Raleigh home training department."* The table in Section V.1, page 36, shows patients will receive in-center hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD at BMA Raleigh.

(4) accessible follow-up program for support of patients dialyzing at home;

-C- In Section II, page 15, the applicant states, "*Patients who are candidates for home dialysis are referred to the BMA Raleigh facility home training department."* The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 37, stating,

> *"Currently, patients who desire to perform home dialysis will be trained and referred to the BMA Raleigh facility home training program. Patients who are candidates for home dialysis are referred by their attending nephrologists to facility BMA Raleigh Home Training Clinic. The applicant will*

provide back-up hemo-dialysis treatments to any home patient in need of temporary hemo-dialysis.

Services offered to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician."

(5) x-ray services;

-C- Section II, page 15 and the table in Section V.1, page 36, state patients will be referred to WakeMed or Rex Hospital for x-ray services.

(6) laboratory services;

-C- Section II, page 15 and the table in Section V.1, page 36, state the facility provides on-site laboratory services through contract with Spectra Labs. Exhibit 15 contains a laboratory services agreement.

(7) blood bank services;

-C- Section II, page 15 and the table in Section V.1, page 36, state patients will be referred to WakeMed for blood bank services.

(8) emergency care;

-C- Section II, page 15 and the table in Section V.1, page 36, state emergency care is provided on site from the trained staff and fully stocked crash cart. Emergency services will be summoned via phone call to 911 in the event transport by ambulance to a hospital is required.

(9) acute dialysis in an acute care setting;

-C- Section II, page 16 states patients will be referred to WakeMed for acute dialysis in an acute care setting. The table in Section V.1, page 36, states patients will be referred to WakeMed or Rex Hosptial for acute dialysis in an acute care setting. Exhibit 25 contains a copy of an executed agreement between WakeMed and FMC Central Raleigh for the provision of hospital services.

(10) vascular surgery for dialysis treatment patients;

-C- Section II, page 16 and the table in Section V.1, page 36, state dialysis patients will be referred to Rex Vascular or Premier Surgical for vascular surgery.

(11) transplantation services;

-C- In Section II, page 16, the applicant states, *"FMC Central Raleigh has a transplant agreement with Duke UMC and Carolinas Medical Center. A copy of an executed transplant agreement is included in Exhibit 26."* Exhibit 26 contains executed transplant agreements between the facility and both Duke University Medical Center and Carolinas Medical Center.

(12) vocational rehabilitation counseling and services; and

-C- Section II, page 16 and the table in Section V.1, page 36, state patients will be referred to Wake County Vocational Rehabilitation for vocational counseling and services.

(13) transportation.

-C- Section II, page 16 and the table in Section V.1, page 36, state transportation services for FMC Central Raleigh dialysis patients are provided by Wake Coordinated Transportation or TRACS.

.2205 STAFFING AND STAFF TRAINING

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

-C- In Section VII.1, page 46, the applicant provides the proposed staffing for FMC Central Raleigh. On page 47, the applicant states, *"FMC Central Raleigh will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100)."* See additional staffing details in Section 1.13 (b and c), pages 7-8 and Section II.2. A, pages 21-22.

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

-C- In Section VII.5, page 47, the applicant refers to Exhibit 9 for an outline of the training program and Exhibit 10 for an outline of continuing education programs. The applicant also states that each new employee will be required to successfully complete a 10-week training program, including training in the clinical aspects of their job, facility and corporate policies and procedures, safety precautions, OSHA regulations, and CPR.