

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 27, 2015

Findings Date: October 27, 2015

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: J-11068-15

Facility: FMC Northern Wake

FID #: 130278

County: Wake

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Relocate three dialysis stations from Wake Dialysis Clinic to FMC Northern Wake for a total of 16 dialysis stations at FMC Northern Wake upon completion of this project and Project ID #J-10152-13 (develop a 13-station dialysis facility)

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. (BMA) d/b/a FMC Northern Wake (“the applicant”) proposes to relocate three existing dialysis stations from Wake Dialysis Clinic (aka BMA Wake) to FMC Northern Wake, for a total of 16 stations at FMC Northern Wake upon completion of this project and Project ID #J-10152-13 (develop a 13-station dialysis facility). According to the last progress report, received by the Healthcare Planning and Certificate of Need Section (“the Agency”) on May 8, 2015, construction of the dialysis facility was underway, and station certification is projected for the end of 2015. Both facilities are located in Wake County. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant proposes to relocate existing dialysis stations within Wake County; therefore, there are no need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 38 of the 2015 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2015 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 32 of the 2015 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS states:

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

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

The applicant proposes to relocate three existing Wake County dialysis stations from Wake Dialysis Clinic to FMC Northern Wake. Because both facilities are located in Wake County, there is no change in the total dialysis station inventory in Wake County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the applicable policy in the 2015 SMFP. 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 relocate three existing stations from Wake Dialysis Clinic (aka BMA Wake) in Raleigh to an approved but not yet developed dialysis facility, FMC Northern Wake, in Wake Forest. In Project ID # J-10152-13, BMA was approved to develop a new 13-station dialysis facility in Wake Forest by relocating 10 dialysis stations from Wake Dialysis Clinic and three dialysis stations from BMA Southwest Wake. The last progress report received by the Agency on May 8, 2015 reported that construction is underway, and station certification is projected for the end of 2015. Upon completion of both projects, Wake Dialysis Clinic will be certified for 47 dialysis stations and FMC Northern Wake will be certified for 16 dialysis stations.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

FMC Northern Wake will be a new facility in Wake County and therefore has no existing patient origin. In Section C.1, pages 21 – 22, the applicant states that the dialysis patients who transfer to FMC Northern Wake are a part of the entire Wake County BMA dialysis patient population, and 11 of those patients who currently dialyze at Wake Dialysis Clinic indicated that they would consider transferring their care to FMC Northern Wake because it would be a more convenient location.

In addition, in Section C.1, page 22, the applicant projects that 100% of the patients to be served at FMC Northern Wake in Operating Years (OY) 1 and 2 following completion of the project will originate from Wake County. See the following table from page 22, which includes in-center dialysis (IC) patients, home hemodialysis (HH) patients and home peritoneal dialysis (PD) patients.

FMC NORTHERN WAKE	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS % OF TOTAL	
	IC	PD	HH	IC	PD	HH	OY 1	OY 2
Wake	48	6	4	48	7	5	100%	100%
Total	48	6	4	48	7	5	100%	100%

Exhibit C-1 includes letters of support from 12 dialysis patients. Each letter states a BMA dialysis facility in northern Wake County would be more convenient for the patient, and he or she would consider transferring care to FMC Northern Wake. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, pages 24 – 25, the applicant discusses the need the population proposed to be served has for the relocation of three stations to FMC Northern Wake, stating that patients on dialysis require treatment three times per week, and that failure to receive these treatments on a regular and consistent basis can have grave consequences. Thus, it follows that patients would desire to receive their dialysis treatments at a facility that is located in close proximity to their residence.

In Section C.5, pages 27 – 28, the applicant states:

“This location is most appropriate for those patients residing in, and near, the new FMC Northern Wake. ... BMA consistently seeks to develop dialysis facilities and dialysis stations in an effort to offer community based delivery of health care when such is appropriate. In this case, BMA has included letters of support from a significant number of patients, each of whom has indicated their support for the project and a willingness to transfer their care to the proposed facility.”

In Section C.1, pages 21 – 24, the applicant reiterates the methodology and assumptions used in Project ID #J-10152-13, the application to develop FMC Northern Wake. Those assumptions included 57 letters signed by Wake County BMA dialysis patients who indicated that a BMA facility located in the north Raleigh area would be more convenient and that they would consider transferring their care to a new facility in that area. In that application, the applicant projected that FMC Northern Wake would be certified by December 31, 2015, and that it would serve 48 in-center patients and 12 home patients, which is an in-center utilization rate of 92% [48 in-center patients / 13 stations = 3.69; 3.69 / 4 = 0.923].

In Section C.1, pages 21 – 24, the applicant provides the assumptions and methodology it uses to determine the need for the relocation of three stations from Wake Dialysis Clinic to FMC Northern Wake, and to project utilization of those stations. The assumptions and methodology are summarized below:

- The applicant assumes that eight of the 11 patients who signed letters of support for the relocation of three stations proposed in this application were not receiving dialysis treatments at the time the original application to develop FMC Northern Wake was approved.
- The applicant assumes that two patients per year will switch their dialysis treatment to home dialysis, with one patient choosing hemodialysis and one peritoneal dialysis treatment.
- The applicant projects growth of the patient population using the 5% Five Year Average Annual Change Rate (AACR) reported in the July 2015 Semi Annual Dialysis Report (SDR).
- The applicant assumes this project will be certified by March 31, 2016.
- The applicant states the operating years are calendar years; therefore, the “interim” period is from April 1 2016, the date following facility certification, to December 31, 2016.

Projected Utilization

In Section C.1, page 23, the applicant projects the following in-center and home dialysis patients for the interim period (April 1, 2016 – December 31, 2016) and for Operating Year 1 (January 1, 2017 – December 31, 2017) and Operating Year 2 (January 1, 2018 – December 31, 2018), as shown below:

FMC NORTHERN WAKE	TYPE OF DIALYSIS	CALCULATIONS
BMA begins with the J-10152-13 projected census for December 31, 2015. This is the starting census for Calendar Year 2016.	IC PD HH	48 5 3
BMA projects this census forward for three months to March 31, 2016. This is the projected certification date for the relocation of three stations to FMC Northern Wake.	IC PD HH	$[48 \times (.05 / 12 \times 3)] + 48 = 48.6$ $[5 \times (.05 / 12 \times 3)] + 5 = 5.1$ $[3 \times (.05 / 12 \times 3)] + 3 = 3.0$
BMA adds the 8 in-center patients projected to transfer to FMC Northern Wake upon completion of this project.	IC PD HH	$48.6 + 8 = 56.6$ 5.1 3.0
BMA projects this census forward for nine months to December 31, 2016.	IC PD HH	$[56.6 \times (.05 / 12 \times 9)] + 56.6 = 58.7$ $[5.1 \times (.05 / 12 \times 9)] + 5.1 = 5.3$ $[3.0 \times (.05 / 12 \times 9)] + 3.0 = 3.2$
BMA subtracts two in-center patients and adds one patient to each home modality. This is the projected census by modality for the end of the interim year.	IC PD HH	$58.7 - 2 = 56.7$ $5.3 + 1 = 6.3$ $3.2 + 1 = 4.2$
BMA projects the patient population forward for one year to December 31, 2017.	IC PD HH	$56.7 \times 1.05 = 59.6$ $6.3 \times 1.05 = 6.6$ $4.2 \times 1.05 = 4.4$
BMA subtracts two in-center patients and adds one patient to each home modality. This is the projected census by modality for the end of Operating Year 1.	IC PD HH	$59.6 - 2 = 57.6$ $6.6 + 1 = 7.6$ $4.4 + 1 = 5.4$
BMA projects the patient population forward for one year to December 31, 2018.	IC PD HH	$57.6 \times 1.05 = 60.4$ $7.6 \times 1.05 = 7.9$ $5.4 \times 1.05 = 5.6$
BMA subtracts two in-center patients and adds one patient to each home modality. This is the projected census by modality for the end of Operating Year 2.	IC PD HH	$60.4 - 2 = 58.4$ $7.9 + 1 = 8.9$ $5.6 + 1 = 6.6$

As shown in the table above, the applicant projects that, upon certification of this project in March 2016, the facility will have 56 in-center patients, rounded down from 56.6, dialyzing on 16 stations, which is a utilization rate of 87.5% [$56 \text{ patients} / 16 \text{ stations} = 3.5$; $3.5 / 4 = 0.875$]. Additionally, at the end of Operating Year 1, the applicant projects an in-center census of 57.6 patients, rounded to 57, for a utilization rate of 89.0% [$57 / 16 = 3.56$; $3.56 / 4 = 0.890$]. The projected utilization of 3.5 patients per station per week at the end of Operating Year 1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). In fact, the projected utilization exceeds the threshold requirement of 3.2 patients per station upon facility certification in March, 2016.

The applicant also projects that the facility will serve home hemodialysis and home peritoneal dialysis patients in each of the two Operating years as shown in the table above.

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Wake County.

Access

In Section C.3, pages 25 - 26, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

The applicant states that the patient population of the proposed FMC Northern Wake facility is expected to be comprised of the following:

FACILITY	MEDICAID/LOW INCOME	ELDERLY(65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Northern Wake	23.8%	32.8%	78.7%	48.5%	90.2%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 60% of the facility treatment reimbursement is from Medicare.

The applicant states that the above projections are based on Wake Dialysis Clinic where the majority of the patients are currently dialyzing. Additionally, the projections are based on the original application for development of FMC Northern Wake.

On page 26, the applicant states that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of dialysis treatments in BMA facilities in North Carolina in fiscal year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by BMA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed 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.

C

The applicant proposes to relocate three existing certified dialysis stations from Wake Dialysis Clinic in Raleigh to the approved but not developed FMC Northern Wake facility in Wake Forest. Both facilities are in Wake County. In Section C.13, pages 33 - 34, the applicant states that the decision to relocate the three dialysis stations is in response to patient choice. Since dialysis treatments last approximately four hours per treatment, travel becomes a critical factor when patients choose where to dialyze. The applicant states that the relocation of stations and transfer of patients will enhance patient quality of life by reducing travel times, distance and expense for BMA patients.

The applicant also states that Wake Dialysis Clinic is “*well above*” the utilization threshold of 80%. The July 2015 SDR reports that as of December 31, 2014, Wake Dialysis Clinic was operating at 96% utilization, with 193 in-center patients dialyzing on 50 stations. The relocation of three stations and transfer of eight patients will reduce utilization at an overcrowded facility. The applicant states that Wake Dialysis Clinic’s physical plant will not allow for facility expansion, and expansion of FMC Northern Wake “*will offer patients of northern Wake County another alternative for dialysis care and treatment, while simultaneously serving to retard the growth of the patient population at [Wake Dialysis Clinic].*” Furthermore, Wake Dialysis Clinic (aka BMA Wake) applied for a three-station addition in Project ID #J-11097-15, which is currently under review.

In Section D, pages 36 - 38, the applicant discusses how the needs of dialysis patients currently dialyzing at Wake Dialysis Clinic will continue to be met after the relocation of three stations and eight patients to FMC Northern Wake. In Project ID #J-10152-13, relying on patient letters, the applicant projected that 21 in-center patients would transfer their care from Wake Dialysis Clinic to FMC Northern Wake. In its projections for Wake Dialysis Clinic in this application, the applicant takes into account those 21 patients as well as the eight additional patients projected to transfer their care to FMC Northern Wake upon completion of this project.

On page 37, the applicant states that as of June 30, 2015, Wake Dialysis Clinic was serving 198 in-center patients, 194 of whom were residents of Wake County, on 50 stations. Using the 5% Five Year Average Annual Change Rate (AACR) for Wake County reported in the July 2015 SDR, the applicant projects growth of the patient population at Wake Dialysis Clinic. See the following table:

BMA begins with the Wake County ESRD patient population of Wake Dialysis Clinic as of June 30, 2015.	194
Project forward for six months to 12/31/15, using one-half the Five Year AACR for Wake County.	$[194 \times (.05 / 12 \times 6)] + 194 = 198.9$
Subtract 21 in-center patients to transfer to FMC Northern Wake upon completion of Project ID # J-10352-13.	$198.9 - 21 = 177.9$
Project forward for three months to March 31, 2016, projected certification date of Project ID J-11068-15	$[177.9 \times (.05 / 12 \times 3)] + 177.9 = 180.1$
Subtract eight patients projected to transfer to FMC Northern Wake upon completion of Project ID # J-10168-15	$180.1 - 8 = 172.1$
Add four patients who reside outside of Wake County. This is the projected beginning census for Project ID # J-10168-15	$172.1 + 4 = 176.1$

The applicant states the relocation of stations and transfer of patients is projected to occur by March 31, 2016, at which time Wake Dialysis Clinic will have 47 stations and 176 in-center patients. Utilization is projected to be 93.6% [$176 / 47 = 3.745$; $3.745 / 4 = 0.936$].

In Section D.2, page 38, the applicant states:

“The relocation of stations from BMA Wake will not alter or affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”

The applicant also states the facility will qualify and apply for additional dialysis stations pursuant to the Facility Need Methodology, thereby assuring that the needs of the population presently served will continue to be adequately met. On September 15, 2015, BMA applied for a three-station addition to Wake Dialysis Clinic (aka BMA Wake). That application is currently under review.

The applicant demonstrates that the needs of the population presently served at Wake Dialysis Clinic will continue to be adequately met following the proposed relocation of three dialysis stations to FMC Northern Wake, and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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 E.1, pages 39 - 40, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option ignores the patient population dialyzing with BMA and residing near FMC Northern Wake.
2. Apply to relocate more than three stations - BMA states that it evaluated its existing patient populations and projections of future patient populations and determined the BMA patient population will be sufficiently served by the development of 16 stations.
3. Relocate stations into existing BMA facilities elsewhere in Wake County - BMA evaluated the locations of its 11 existing facilities in Wake County, and determined the relocation of stations proposed in this application is the most effective alternative to serve the BMA patient population in northern Wake County at this time.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at FMC Northern Wake, and the physical plant capacity issues, BMA believes the most effective alternative is the relocation of stations as proposed in this application.

Furthermore, the application is 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 this 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 FMC Northern Wake shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake shall relocate no more than three dialysis stations from Wake Dialysis Clinic, for a total of no more than 16 certified dialysis stations which shall include any isolation or home hemodialysis stations upon completion of this project and Project ID #J-10152-13.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at Wake Dialysis Clinic for a total of no more than 47 dialysis stations at Wake Dialysis Clinic upon project completion.**

5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate three existing dialysis stations from Wake Dialysis Clinic (aka BMA Wake) to FMC Northern Wake, for a total of 16 dialysis stations at FMC Northern Wake upon completion of this project and Project ID #J-10152-13.

Capital and Working Capital Costs

In the table in Section F.1, page 42, the applicant states the capital cost of the project is \$13,150, for equipment and furniture. The applicant states dialysis machines will be leased, and the facility is an existing facility and thus no construction costs will be incurred.

In Section F.10, page 45, the applicant states no working capital needs are projected for this project, since FMC Northern Wake will be operational when the stations proposed in this application are relocated.

In Section F.5, page 43, the applicant states:

“BMA is utilizing accumulated reserves to finance this project. Please refer to Exhibit F-1 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.”

Exhibit F-1 contains an August 15, 2015 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which confirms the availability of the funds needed for the capital cost of the project, as well as a commitment to use those funds for the development of the project.

Availability of Funds

In Exhibit F-2, the applicant provides a copy of the most recent audited FMC Holdings, Inc., consolidated balance sheets for 2012 and 2013. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents with

\$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities).

In Section F.8, page 44, the applicant states that all BMA projects are funded with accumulated reserves, and in Exhibit F-3, the applicant lists the currently financed BMA projects.

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

Financial Feasibility

The applicant projects revenues and expenses in Section R, Form B, page 100, as summarized in the table below:

Revenue and Expenses, Total Facility		
FMC NORTHERN WAKE	OPERATING YEAR 1 CY 2017	OPERATING YEAR 2 CY 2018
Gross Patient Revenue	\$40,495,214	\$44,186,933
Deductions from Gross Patient Revenue	\$31,136,577	\$34,320,761
Net Patient Revenue	\$ 9,358,637	\$ 9,866,172
Operating Expenses	\$ 5,362,979	\$ 4,215,916
Net Profit	\$ 3,995,659	\$ 4,215,916

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H.1, page 57, the applicant provides projected staffing and salaries. Form A in Section R, page 94, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

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.

C

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to relocate three existing stations from Wake Dialysis Clinic in Raleigh to an approved but not yet developed dialysis facility, FMC Northern Wake, in Wake Forest. In Project ID # J-10152-13, BMA was approved to develop a new 13-station dialysis facility in Wake Forest by relocating 10 dialysis stations from Wake Dialysis Clinic and three dialysis stations from BMA Southwest Wake.

The July 2015 SDR indicates there are 12 existing or approved dialysis facilities in Wake County, as follows:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
BMA of Fuquay Varina	19	67	3.53	88.16%
BMA of Raleigh	50	162	3.24	81.00%
Cary Kidney Center	28	76	2.71	67.86%
FMC Apex	17	49	2.88	72.06%
FMC Central Raleigh	15	57	3.80	95.00%
FMC Eastern Wake	14	56	4.00	100.00%
FMC Millbrook	17	60	3.53	88.24%
FMC New Hope	36	110	3.05	76.39%
Southwest Wake County Dialysis	31	106	3.42	85.48%
Wake Dialysis Clinic	50	193	3.86	96.50%
Wake Forest Dialysis Center	20	73	3.65	91.25%
Zebulon Kidney Center	30	99	3.30	82.50%
FMC Northern Wake	0	0	0	0.00%

Data reported in the July 2015 SDR, as of 12/31/14.

The applicant operates all but one of the dialysis facilities listed in the table above. Zebulon Kidney Center is operated by DaVita. Seven of the dialysis facilities operated by BMA are operating above 80% utilization.

In addition, in Section C.1, page 21, the applicant projects that 100% of the patients to be served at FMC Northern Wake in Operating Years (OY) 1 and 2 following completion of the project will originate from Wake County. See the following table from page 21, which includes in-center dialysis (IC) patients, home hemodialysis (HH) patients and home peritoneal dialysis (PD) patients:

	OPERATING YEAR 1			OPERATING YEAR 2			PATIENTS AS % OF TOTAL	
	IN-CTR	HOME HD	HOME PD	IN-CTR	HOME HD	HOME PD	OY 1	OY 2
Wake	57.6	5.4	7.6	58.4	6.6	8.9	100%	100%
Total	57.6	5.4	7.6	58.4	6.6	8.9	100%	100%

In Section C.1, page 23, the applicant demonstrates that FMC Northern Wake will serve a total of 57 in-center patients on 16 stations at the end of the first operating year, which is 3.6 patients per station per week, or a utilization rate of 89% [$57 / 16 = 3.56$; $3.56 / 4 = 0.8906$]. The applicant states that the projected utilization rates are based on patients currently dialyzing at BMA dialysis facilities who have expressed their willingness to consider transferring to the proposed FMC Northern Wake facility because it will be more convenient for them.

The applicant adequately demonstrates the need to relocate three existing BMA stations from Wake Dialysis Clinic to FMC Northern Wake based on the number of and geographical location of the BMA in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) 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 in Wake County. 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 H.1, page 57, the applicant provides the following table to illustrate projected staffing in Full Time Equivalents (FTEs) for FMC Northern Wake. The facility is not yet developed, so the staffing table illustrates projected staff following completion of the facility pursuant to Project ID # J-11052-15 and completion of this project. The applicant states the Medical Director is a contracted position and not reflected in the staffing chart.

POSITION	# FTEs
Registered Nurse	3.50
Technician (Patient Care)	7.50
Clinical Manager	1.00
Admin. (Dir. Ops)	0.15
Dietician	0.50
Social Worker	0.50
Home Training RN	1.50
Chief Technician	0.15
Equipment Technician	0.85
In-Service	0.50
Clerical	1.00
Total	17.15

On page 59, in Section H.7, the applicant illustrates the projected direct care staff for FMC Northern Wake in Operating Year 2, as shown below:

DIRECT CARE POSITIONS	# FTES	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.5	2,080	7,280	3,900	1.87
Patient Care	7.5	2,080	15,600	3,900	4.00

The hours of operation are based on the applicant’s experience in other BMA facilities in North Carolina.

In Section I.3, page 62, the applicant identifies Dr. Mark Rothman as the Medical Director of the proposed facility. In Exhibit I-6, the applicant provides an August 17, 2015 letter signed by Dr. Rothman of Wake Nephrology Associates, P.A., supporting the project and confirming his commitment to serve as Medical Director. Exhibit I-7 contains Dr. Rothman’s curriculum vitae. In Section H.3, page 58, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*” In Section I.3, pages 62 - 63, the applicant lists four nephrologists who will provide medical coverage at the proposed facility.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed 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.

C

In Section I.1, page 61, the applicant lists the providers of the necessary ancillary and support services to be provided at the proposed facility. The applicant discusses coordination with the existing health care system on page 63. Exhibits I-3, I-4 and I-5 contain documents from Spectra Labs, WakeMed and Duke University Medical Center, respectively, as evidence of laboratory, patient transfer and transplant services that will be available to dialysis patients. 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 care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity 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.

C

In Section K.2, page 67, the applicant provides a table to illustrate the square feet proposed for the facility previously approved in Project ID #J-10152-13. The project calls for 3,847 total square feet in the treatment area, which includes home training and isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The line drawing shows a 9,473 square foot facility with 13 main floor dialysis stations, one isolation dialysis station, two stations for home hemodialysis training, and one room for home peritoneal dialysis training, for a total of 16 hemodialysis stations.

In this application, in Section F.1, page 42, the applicant states the only project costs associated with this project are for equipment and furniture, since there will be no additional construction

costs. In Section K.1, pages 65-66, the applicant describes its plans for maintaining energy-efficiency in the facility, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods include ensuring the latest HVAC design, water saving designs in sinks and faucets, water treatment equipment that includes phased electric motors for less energy utilization, and energy efficient lighting and plumbing fixtures.

Costs and charges are described by the applicant in Section F, pages 41-53, and in the proforma financial statements in Section R. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 71, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 102 dialysis facilities in 42 North Carolina counties, which includes its affiliations with Renal Research Institute facilities. The applicant further states that each of its facilities serves low income persons, racial and ethnic minorities, women, handicapped, the elderly, and other “*traditionally underserved*” persons.

In addition, the applicant states that BMA of North Carolina has historically provided “*substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.*” In Section L.1, pages 71 - 72, the applicant states that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of North Carolina dialysis treatments in BMA facilities in FY 2014

In Section L.7, page 75, the applicant reports that as of December 31, 2014, 84.3% of the in-center patients who were receiving treatments at Wake Dialysis Clinic 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 Wake Dialysis Clinic:

PAYOR TYPE	PERCENT IN-CENTER PATIENTS	PERCENT TOTAL PATIENTS
Private Pay	3.40%	3.20%
Commercial Insurance	10.95%	15.37%
Medicare	81.60%	78.21%
Medicaid	2.70%	2.30%
VA	1.40%	0.92%
Total	100.00%	100.00%

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

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Wake	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.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).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. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, on page 59, provides prevalence data on North Carolina dialysis patients by age, race and gender, summarized as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

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 applicants;

C

In Section L.3(e), page 74, 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.”

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In Section L.6, page 74, 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 C.3, page 25, the applicant projects the patient population of FMC Northern Wake will be comprised of the following, based on its experience in Wake County; in particular, Wake Dialysis Clinic:

FACILITY	MEDICAID/LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Northern Wake	23.8%	32.8%	78.7%	48.5%	90.2%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 60% of the facility treatment reimbursement is from Medicare.

In Section L.3(c), page 73, 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.”

In Section L.3(b), page 72, the applicant reports that it expects 80.6% of the in-center patients who receive treatments at FMC Northern Wake to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

PAYOR TYPE	TOTAL PATIENTS	IN-CENTER	HOME HEMODIALYSIS	HOME PERITONEAL DIALYSIS
Private Pay	2.7%	3.4%	0.0%	0.0%
Commercial Insurance	15.3%	10.9%	33.3%	37.5%
Medicare	77.8%	81.6%	66.7%	62.5%
Medicaid	2.8%	2.8%	0.0%	0.0%
VA	1.3%	1.3%	0.0%	0.0%
Total	100.0%	100.0%	100.0%	100.0%

On page 73, the applicant states it assumes the payor mix for FMC Northern Wake will mirror the payor mix for Wake Dialysis Clinic.

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 L.4, page 74, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Northern Wake 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 will offer a range of means by which patients will have access to 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 M.1, page 76, the applicant states:

“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 M-1 contains a copy of a letter from Fresenius Medical Care to the Nursing Program Department Head at Wake Technical Community College inviting the college to include FMC Northern Wake in the clinical rotation for its nursing students. The information provided in

Section M and referenced exhibits is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to relocate three existing stations from Wake Dialysis Clinic in Raleigh to an approved but not yet developed dialysis facility, FMC Northern Wake, in Wake Forest. In Project ID # J-10152-13, BMA was approved to develop a new 13-station dialysis facility in Wake Forest by relocating 10 dialysis stations from Wake Dialysis Clinic and three dialysis stations from BMA Southwest Wake.

The July 2015 SDR indicates there are 12 existing or approved dialysis facilities in Wake County, as follows:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
BMA of Fuquay Varina	19	67	3.53	88.16%
BMA of Raleigh	50	162	3.24	81.00%
Cary Kidney Center	28	76	2.71	67.86%
FMC Apex	17	49	2.88	72.06%
FMC Central Raleigh	15	57	3.80	95.00%
FMC Eastern Wake	14	56	4.00	100.00%
FMC Millbrook	17	60	3.53	88.24%
FMC New Hope	36	110	3.05	76.39%
Southwest Wake County Dialysis	31	106	3.42	85.48%
Wake Dialysis Clinic	50	193	3.86	96.50%
Wake Forest Dialysis Center	20	73	3.65	91.25%
Zebulon Kidney Center	30	99	3.30	82.50%
FMC Northern Wake	0	0	0	0.00%

Data reported in the July 2015 SDR, as of 12/31/14.

The applicant operates all but one of the dialysis facilities listed in the table above. Zebulon Kidney Center is operated by DaVita. Seven of the dialysis facilities operated by BMA are operating above 80% utilization.

In Section N.1, pages 77 – 78, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Wake County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Northern Wake facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Wake County five year average annual change rate of 5.0% as published within the July 2015 SDR.

According to the July 2015 SDR there were 12 dialysis facilities operating within Wake County. There are two providers of dialysis services operating within Wake County: BMA and DaVita. These providers and dialysis facilities offer 327 dialysis stations to the more than 1200 ESRD patients of Wake County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who are already choosing dialysis at a BMA facility.”

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive

impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and cost-effective alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates BMA will continue to provide quality dialysis services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) 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

In Section O, pages 79 - 84, the applicant discusses the methods it uses to ensure and maintain quality. In Section O.3, pages 82 - 83, the applicant states:

“BMA has incurred two Immediate Jeopardy citations within the recent 18 month period.”

The applicant states the two Immediate Jeopardy citations were in BMA Lumberton in Robeson County on May 6, 2015, and BMA East Charlotte in Mecklenburg County on August 11, 2015. On page 84, the applicant states:

“The BMA Lumberton facility is back in full compliance with all CMS Guidelines.”

Based on publicly available information, the analyst determined the BMA East Charlotte facility is also back in full compliance with all CMS Guidelines.

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company.

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming or conditionally conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section P, page 86, and Exhibit G-1 (copy of the July 2015 SDR, Tables A and B), the applicant provides the utilization rates for Wake Dialysis Clinic. The December 31, 2014 utilization rate was reported as 96.5% with 193 in-center patients dialyzing on 50 stations.

.2202(a)(2) Mortality rates;

- C- In Section P, page 86, the applicant states, “*The CMS Compare web site reports that the South Greensboro mortality rates are, “As Expected.” See Exhibit P-1.*” Exhibit P-1 shows the data from the CMS Compare website.

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

- C- In Section P, page 86, the applicant states that Wake Dialysis Clinic had eight home hemodialysis patients and 34 home peritoneal dialysis patients as of June 30, 2015.

.2202(a)(4) *The number of transplants performed or referred;*

- C- In Section P, page 86, the applicant reports that Wake Dialysis Clinic referred 44 patients for transplant evaluation in 2015.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

- C- In Section P, page 86, the applicant states that Wake Dialysis Clinic has 15 patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

- C- In Section P, page 86, the applicant reports hospital admission rates are, according to the CMS Compare website, “*as expected.*” Again, the applicant refers to Exhibit P-1.

.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- In Section P, page 87, the applicant reports that Wake Dialysis Clinic has four patients dialyzing in isolation due to hepatitis. The applicant states there were no conversions to infectious status during the last calendar year.

(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:

.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 (Replaced with 42 CFR Part 494).*

- NA- This application is to relocate existing stations and does not propose a new 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- This application is to relocate existing stations and does not propose a new facility.

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

-NA- This application is to relocate existing stations and does not propose a new facility.

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

-C- The applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage in Exhibit K-3.

- .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- This application is to relocate existing stations and does not propose a new facility.

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

-C- In Section P, page 88, 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.” See also Section B.4 and B.5, pages 12 -

20; Section H.2 and H.2, page 58; Section K.1, pages 65 - 67; and Exhibits K-2 and K-3.

.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- In Section C.1, page 21, the applicant provides projected patient origin by county for FMC Northern Wake, based on the patients who currently dialyze at and who are expected to transfer from Wake Dialysis Clinic. The applicant's assumptions and methodology for its projections are provided on pages 21 - 24 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.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- This application is to relocate existing stations and does not propose a new facility.

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

-C- In Section P, page 88, 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."

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- This application is to relocate existing stations and does not propose a new facility.

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

- C- In Section C.1, pages 21 - 24, the applicant documents the need for the project and demonstrates that it will serve a total of 57 in-center patients on 16 stations at the end of the first operating year, which is 3.6 patients per station per week, or a utilization rate of 89%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C.1, pages 21 - 24, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .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- In Section P, page 89, and Section I.1, page 61, the applicant states that diagnostic and evaluation services will be referred to WakeMed Hospital.

.2204(2) Maintenance dialysis;

- C- In Section P, page 89, and Section I.1, page 61, the applicant states BMA will provide in-center and home training for dialysis maintenance at FMC Northern Wake.

.2204(3) Accessible self-care training;

- C- In Section P, page 90, and Section I.1, page 61, the applicant states candidates for self-care are referred to the facility home training department. On page 90, the applicant states, *“Upon completion of the training, the patient will perform self-care dialysis at the facility.”*

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

- C- In Section P, page 90, and Section I.1, page 61, the applicant states that patients who are candidates for home training will be referred to the FMC Northern Wake home training department.

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

- C- In Section P, page 90, and Section I.1, page 61, the applicant states that patients in need of x-ray services will be referred to WakeMed Hospital.

.2204(6) *Laboratory services;*

- C- In Section P, page 90, and Section I.1, page 61, the applicant states laboratory services will be provided on-site by the applicant through a contract with Spectra Labs. Exhibit I-3 contains a copy of a letter from the Vice President at Spectra Laboratories and an agreement documenting their intention to provide the above services to the proposed facility.

.2204(7) *Blood bank services;*

- C- In Section P, page 90, and Section I.1, page 61, the applicant states that patients in need of blood bank services will be referred to WakeMed Hospital.

.2204(8) *Emergency care;*

- C- The applicant states, in Section P, page 90, and Section I.1, page 61, that facility staff will provide emergency care on site until emergency responders arrive, and that a fully stocked 'crash cart' will be available for use at the proposed facility. Patients in need of emergency care at a hospital are transported via emergency services.

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

- C- In Section P, page 90, and Section I.1, page 61, the applicant states that patients in need of acute dialysis services will be referred to WakeMed Hospital.

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

- C- In Section P, page 90, and Section I.1, page 61, the applicant states that patients in need of vascular surgery will be referred to Carolina Vascular, Wake Surgical, North Raleigh Surgical or Carolina Surgery.

.2204(11) *Transplantation services;*

- C- In Section P, page 90, and Section I.1, page 61, the applicant states that transplantation services will be referred to Duke University Medical Center. Exhibit I-5 contains a copy of an agreement between BMA and Duke University Medical Center, documenting the provision of transplantation services to the proposed facility.

.2204(12) Vocational rehabilitation counseling and services; and

- C- In Section P, page 90, and Section I.1, page 61, the applicant states Vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services of Wake County.

.2204(13) Transportation

- C- In Section P, page 91, and Section I.1, page 61, the applicant states that transportation services will be provided by Tri-Star, Johnston Ambulance Services, and Wake Coordinated Transportation.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).

- C- In Section H.1, page 57, the applicant provides a proposed staffing chart. In Section H.2, page 58, the applicant states the proposed facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

.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- In Section P, page 91, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated by the In-Service Instructor and Director of Nursing. In Section H.4, page 58, the applicant further discusses its ongoing training program. See also Exhibit H-1, which contains the FMC Training Program Outline and Exhibit H-2, which contains an outline of FMC's continuing education programs, annual training requirements and a training module content summary.