

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 3, 2013

PROJECT ANALYST: Kim Randolph

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10152-13/ Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake and O2P LLC/ Develop a new 13-station dialysis facility in Raleigh by relocating 10 dialysis stations from BMA Wake and 3 dialysis stations from BMA Southwest Wake/ Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Northern Wake and O2P LLC propose to develop a new 13-station dialysis facility in Raleigh (Wake County) by relocating 10 dialysis stations from BMA Wake and 3 dialysis stations from BMA Southwest Wake, both of which are located in Wake County. The applicants do not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

The applicants are proposing to relocate dialysis stations within Wake County; therefore, the county and facility need methodologies in the 2013 State Medical Facilities Plan (2013 SMFP) are not applicable to this review. Additionally, Policy GEN-3: Basic Principles is not applicable because neither need methodology is applicable to this review.

However, Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities in the 2013 SMFP are 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 applicants propose to develop a new 13-station dialysis facility, FMC Northern Wake, in Wake County by relocating 10 existing dialysis stations from BMA Wake and 3 existing dialysis stations from BMA Southwest Wake. Since both facilities are located in Wake County, there is no change in dialysis station inventory in Wake County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The applicants propose to develop FMC Northern Wake, a new 13-station dialysis facility in Wake County, for a total capital cost of \$3,374,036. In Section XI.6, pages 95-96, the

applicants include written statements describing the plans to assure improved energy efficiency and water conservation. The applicants state the building will meet the requirements for energy conservation as set out in the 2012 North Carolina Conservation Code. The applicants also state that the FMC Facility Design and Maintenance Department continually evaluates the design plans and plumbing fixtures for energy efficiency and water conservation. The applicants include written statements describing the project's plan to assure improved energy efficiency sustainability and water conservation. Therefore, the application is consistent with Policy GEN-4.

The application is consistent with Policy ESRD-2 and Policy GEN-4. 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

BMA currently operates 11 dialysis facilities in Wake County. In this application, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake and O2P LLC propose to establish a new 13-station dialysis facility in north Raleigh, Wake County, by relocating 10 existing dialysis stations from the BMA Wake facility in Wake County, and 3 existing dialysis stations from the BMA Southwest Wake facility, also in Wake County. In Section II.1, pages 15-16, the applicants state there are 57 current Wake County BMA patients who have expressed an interest in transferring to the new facility. Of those 57 patients, the applicants project that 48 current BMA dialysis patients, who are residents of Wake County, will transfer to the new facility in north Raleigh. The applicants do not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section IV.1, page 56, the applicants identify the population of in-center and home patients served, as of December 31, 2012, at BMA Wake and BMA Southwest Wake, as shown in the tables below.

BMA Wake

| Patient's County of Residence | In-Center Patients | Home |
|-------------------------------|--------------------|------|
| Wake | 170 | 41 |
| Franklin | 3 | 0 |
| Johnston | 1 | 8 |
| Harnett | 0 | 1 |
| Total | 174 | 50 |

BMA Southwest Wake

| Patient's County of Residence | In-Center Patients | Home |
|-------------------------------|--------------------|------|
| Wake | 99 | 0 |
| Johnston | 6 | 0 |
| Total | 105 | 0 |

In Section III.3, page 42, the applicants project that a total of 48 in-center patients will transfer their treatment to the proposed Wake County facility when it becomes operational in December 31, 2014. The applicants project 21 patients will transfer from BMA Wake and 3 patients will transfer from BMA Southwest Wake, with the remaining patients transferring from other BMA facilities located in Wake County.

In Section III.7, page 53, the applicants provide a table showing the projected patient origin for the patients to be served at FMC Northern Wake for the first two years of operation following completion of the project, as shown below.

| County | Operating Year 1 CY 2015 | | Operating Year 2 CY 2016 | | County Patients as a Percent of Total | |
|--------|-----------------------------|------|-----------------------------|------|--|--------|
| | In-Center | Home | In-Center | Home | Year 1 | Year 2 |
| Wake | 48 | 10 | 48 | 12 | 100% | 100% |
| Total | 48 | 10 | 48 | 12 | 100% | 100% |

The applicants adequately identify the population to be served.

Demonstration of Need

The applicants propose to relocate 13 certified dialysis stations from two existing BMA facilities located in Wake County to develop a new facility in north Raleigh. The applicants project the stations will be utilized at 92.3% of capacity by the end of the first year of operation, with 48 patients dialyzing on 13 in-center dialysis stations [$48 / 13 = 3.69$; $3.69 / 4 = 92.3\%$].

In Section III.3, pages 41-42, the applicants state

“BMA proposes to relocate 13 dialysis stations to develop the FMC Northern Wake facility. Within this application, BMA has projected to be serving 48 patients at the end of the first year of operations for this facility; this equates to [sic] 92.3% utilization rate or 3.7 patients per station. ... This is an application to transfer a total of 13 dialysis

stations from two BMA facilities; the facility is projected to be serving 3.7 patients per station at the end of the first operating year. BMA has included 57 letters of support from dialysis patients, each indicating that a BMA facility in north Raleigh would be more convenient.”

In Section V.7, pages 64-65, the applicants state

“Approval of this application will not alter the competitive nature of dialysis facilities and providers serving Wake County. Approval of this application will not change the number of dialysis stations in the county. Approval of this application will enhance patient access to care.

BMA has included 57 patient letters of support from existing dialysis patients who reside in Wake County. While development of “bricks and mortar” may be construed as a change within the competitive environment in the county, BMA suggests that the competition between providers has been ongoing for many years.

Indeed, BMA has been providing dialysis treatment to the overwhelming majority of the Wake County ESRD patient population as may be noted within this application. Further, the physicians of Wake Nephrology are likewise providing medical coverage for patients from Wake County. In fact, the physicians of Wake Nephrology Associates report that at the present time they are providing care for a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients residing in north Raleigh and Wake County. Thus, while approval of this application will allow introduction of a new dialysis facility into the county, the reality is that approval of this application will not significantly alter the competitive climate of Wake County. BMA is already serving dialysis patients from Wake County.

BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Wake County. BMA projections of patients to be served by the facility are a function of the existing patient population served by BMA coupled with growth of that population. BMA has not asserted that it would capture 100% of new dialysis patients in Wake County. Rather, BMA projections of future patient populations to be served focus on the existing patient population served by BMA. BMA also anticipates that the patient population of the DaVita Wake Forest dialysis clinic will increase at the same rate proposed by BMA.”

Projected Utilization

In Section III.7, pages 51-53, the applicants present the assumptions and methodology used to project utilization at FMC Northern Wake. The applicants state

1. *“The project is scheduled for completion December 31, 2014.
Operating Year 1: January 1, 2015 through December 31, 2015.
Operating Year 2: January 1, 2016 through December 31, 2016.*

| | | | | | | | | | |
|---------------------|----|---|---|---|---|----|---|---|----|
| | | | | | | | | | |
| FMC Central Raleigh | 2 | | | | | | | | 2 |
| FMC Eastern Wake | | | | | | 2 | 4 | | 6 |
| FMC Millbrook | 4 | | | | 1 | 1 | | | 6 |
| FMC New Hope | 1 | 1 | | | | 3 | | | 5 |
| BMA Raleigh | 2 | | | | | 7 | | 1 | 10 |
| BMA Southwest Wake | 1 | 1 | | | | | 1 | | 3 |
| BMA Wake | 1 | 1 | 1 | 1 | 4 | 15 | 1 | 1 | 25 |
| Total | 11 | 3 | 1 | 1 | 5 | 28 | 6 | 2 | 57 |

In Section III.7, page 53, the applicants provide the following chart which projects utilization growth at FMC Northern Wake based on a starting census of 48 (of the 57 patients who provided letters of support) Wake County in-center dialysis patients, and using the Wake County 4.2% five year Average Annual Change Rate (AACR) as published in the January 2013 Semiannual Dialysis Report (SDR).

| | |
|--|---|
| The applicants begin with the 48 Wake County in-center dialysis patients currently served plus the eight home patients projected to transfer to the new facility upon certification of the facility. | 48 in-center patients 8 home patients |
| The applicants project this in-center patient population forward for 12 months to December 31, 2015, using the Wake County five year AACR of 4.2%. | $(48 \times 0.042) + 48 = 50$ |
| The applicants subtract two in-center patients projected to change to home dialysis in the first year of operation. This is the projected census for the first operating year. | $50 - 2 = 48$ in-center patients $8 + 2 = 10$ home patients |
| The applicants project this in-center patient population forward for 12 months to December 31, 2016, using the Wake County five year AACR of 4.2%. | $(48 \times 0.042) + 48 = 50$ |
| The applicants subtract two in-center patients projected to change to home dialysis in the second year of operation. This is the projected census for the second operating year. | $50 - 2 = 48$ in-center patients $10 + 2 = 12$ home patients |

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires the applicants to “ ... *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...*” In this application, the applicants adequately demonstrate that FMC Northern Wake will serve a total of 48 in-center patients on 13 stations at the end of the first operating year, which is 3.69 patients per station per week, or a utilization rate of 92.3% of capacity. Therefore, the applicants demonstrated that the proposed Wake County facility would meet the minimum performance standard requirements in the Rule.

Access to Services

In Section VI.1, page 66, the applicants state

“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. For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012, [sic] Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

The applicants adequately demonstrate the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need the population projected to be served has for the proposed north Raleigh facility, and demonstrate all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

C

The applicants propose to establish a new dialysis facility in north Raleigh by transferring existing dialysis stations from two different BMA facilities located in Wake County. In Section III.3, page 41, the applicants state

“This proposal is designed to make more effective use of existing certified dialysis stations and bring dialysis closer to the residence location of patients residing in north Raleigh.

This application is based primarily upon geographic accessibility of services and patient convenience. Exhibit 22 includes 57 patient letters of support for this project. In each case, the patient has indicated that the proposed FMC Northern Wake would be more convenient for the patient; further, each patient has indicated their willingness to transfer their care to the FMC Northern Wake facility upon completion of the project.”

In Section III.3, pages 42-50, the applicants describe the impact of the proposed transfer of stations from BMA Wake and BMA Southwest Wake. In Section III.3, pages 42-45, the applicants describe the impact of the proposed transfer of stations from the BMA Wake facility as follows

“BMA Wake

BMA Wake is currently certified for 50 dialysis stations. According to the January 2013 SDR, the facility was operating at 81% utilization with 162 patients as of June 30, 2012. As of December 31, 2012 the facility had 174 in-center patients (BMA has recently completed submission of facility census information to Medical Facilities Planning Section). BMA will utilize the most current numbers in its projections.

Transferring 10 stations from BMA Wake to FMC Northern Wake will result in the facility having 40 stations. In this application, BMA projects that 21 dialysis patients will transfer from BMA Wake to the FMC Northern Wake facility upon completion of the project and certification of the stations at FMC Northern Wake.”

The following table identifies the county of residence for the patients at BMA Wake as of December 31, 2012

| BMA Wake | December 31, 2012 |
|----------|-------------------|
| | In-Center |
| Wake | 170 |
| Franklin | 3 |
| Johnston | 1 |
| Total | 174 |

The applicants propose to relocate 10 existing dialysis stations from BMA Wake, along with 21 current patients who are residents of Wake County, to FMC Northern Wake.

In Section III.3, page 43, the applicants provide the following chart to project utilization at BMA Wake based on a starting census of 170 Wake County in-center dialysis patients, and using the “... Wake County Five Year Average Annual Change Rate of 4.6% [sic] as published in the January 2013 SDR.”

| | |
|---|------------------------------------|
| The applicants begin with the 170 in-center patient population residing in Wake County as of December 31, 2012. | 170 in-center patients |
| The applicants project the growth of this in-center patient population for one year to December 31, 2013, using the Wake County five year AACR of 4.2%. | $(170 \times 0.042) + 170 = 177.1$ |
| The applicants project the growth of this in-center patient population for one year to December 31, 2014, the projected | $(177 \times .042) + 177 = 184.6$ |

| | |
|--|---------------------------------------|
| certification date of FMC Northern Wake, using the Wake County five year AACR of 4.2%. | |
| The applicants subtract the 21 patients from Wake County projected to transfer to FMC Northern Wake. | $184.6 - 21 = 163.6$ |
| The applicants add one patient from Johnston County.* | $163.6 + 1 = 164.6$ rounded to 165 |

* Note: In Section III.1, page 43, the applicants project that the one patient from Johnston County will continue to dialyze at BMA Wake; however, the three patients from Franklin County will transfer to another BMA facility.

Thus, the applicants project BMA Wake will operate at 103% of capacity, with 165 in-center patients dialyzing on 40 stations as of December 31, 2014, which is the projected certification date of the proposed FMC Northern Wake facility [$165 / 40 = 4.3$; $4.3 / 4 = 103\%$].

The applicants demonstrate that the needs of the population presently served at BMA Wake will continue to be adequately met following the proposed relocation of 10 dialysis stations from BMA Wake to FMC Northern Wake and that access for medically underserved groups will not be negatively impacted.

In Section III.3, pages 46-50, the applicants describe the impact of the proposed transfer of stations from the BMA Southwest Wake facility as follows

“BMA Southwest Wake

BMA Southwest Wake is currently certified for 31 dialysis stations. According to the January 2013 SDR, the facility was operating at 86.67% utilization with 104 patients as of June 30, 2012 (the facility was certified for 31 stations effective December 17, 2012). As [of] December 31, 2012 the facility had 105 patients dialyzing on 31 stations.

In this application, BMA projects that three BMA Southwest Wake patients will transfer to the FMC Northern Wake facility upon completion of the project and certification of the stations at FMC Northern Wake. The following table identifies the county of residence for the patients at BMA Southwest Wake as of December 31, 2012:

| <i>BMA Southwest Wake</i> | <i>December 31, 2012</i> |
|---------------------------|--------------------------|
| | <i>In-Center</i> |
| <i>Wake</i> | 99 |
| <i>Johnston</i> | 6 |
| <i>Total</i> | 105 |

In addressing the needs of patients continuing to dialyze at BMA Southwest Wake subsequent to the transfer of three stations to FMC Northern Wake, BMA will project growth of the BMA Wake [sic] patient population to the projected date of project completion and certification of the new FMC Northern Wake facility: December 31, 2014. However, BMA will only project a change in the Wake County ESRD patient population of BMA Southwest Wake. The patients from Johnston Counties [sic] are assumed to be dialyzing at BMA Wake [sic] as a function of patient choice. Thus BMA assumes that the six patients from Johnston County will continue to dialyze at BMA Southwest Wake. The Johnston County patients are added back to the projected number of BMA Southwest Wake in-center dialysis patients as of December 31, 2014.”

The applicants propose to relocate three existing dialysis stations from BMA Southwest, along with three current patients who are residents of Wake County, Wake to FMC Northern Wake. On page 46, the applicant states that as of December 31, 2012, BMA Southwest Wake was serving 105 patients.

In Section III.3, the applicants project utilization at BMA Southwest Wake based on a starting census of 99 Wake County in-center dialysis patients, and using the Wake County 4.2% five year Average Annual Change Rate (AACR) as published in the January 2013 SDR. The projections also include six in-center patients who are residents of Johnston County as shown below.

| | |
|---|---------------------------------------|
| The applicants begin with the in-center patient population residing in Wake County as of December 31, 2012. | 99 in-center patients |
| The applicants project the growth of this in-center patient population for one year to December 31, 2013, using the Wake County five year AACR of 4.2%. | $(99 \times .042) + 99 = 103.2$ |
| The applicants project the growth of this in-center patient population for one year to December 31, 2014, the projected certification date for FMC Northern Wake, using the Wake County five year AACR of 4.2%. | $(103.2 \times .042) + 103.2 = 107.5$ |
| The applicants subtract the three patients from Wake County projected to transfer to FMC Northern Wake. | $107.5 - 3 = 104.5$ |
| The applicants add the six patients from Johnston County. | $104.5 + 6 = 110.5$ rounded to 111 |

Thus, the applicants project BMA Southwest Wake will operate at 99.11% of capacity, with 111 in-center patients dialyzing on 28 stations as of December 31, 2014, the projected certification date of the proposed FMC Northern Wake facility [$111 / 28 = 3.96$; $3.96 / 4 = 99.11\%$].

Therefore, the applicants demonstrate that the needs of the population presently served at BMA Southwest Wake will continue to be adequately met following the proposed relocation of three dialysis stations from BMA Southwest Wake to FMC Northern Wake and that access for medically underserved groups will not be negatively impacted.

The applicants propose to develop a new 13-station dialysis facility in north Raleigh, in Wake County, by relocating existing stations from two BMA dialysis facilities in Wake County. The applicants adequately demonstrate that the two facilities from which dialysis stations would be transferred would have sufficient capacity following the transfer of stations to the proposed Wake County facility. Thus, the applicants adequately demonstrate that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. 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 III.9, pages 54-55, the applicants discuss the alternatives considered prior to submitting this application, which include

- 1) Maintain the Status Quo - the applicants state this alternative is not as effective because they currently serve patients who reside in north Raleigh and Wake County. In Exhibit 22, the applicants included 57 letters of support for this project from 57 current BMA patients. Additionally, the applicants project the patient population will continue to increase.
- 2) Selecting a different location within Wake County to develop the facility – the applicants state this alternative is not as effective because north Raleigh is the “most logical” choice, given the residence locations of current BMA patients.

With regard to location, in Section III.3, page 49, the applicants state

“As BMA has evaluated its existing patient population of Wake County dialysis patients BMA has sought to find a point most common to all patients and in close proximity to the Wake Med. By locating on the north side of Raleigh BMA will create dialysis treatment at a location closer to the patient residence for those patients residing in north Raleigh and Wake County.”

After considering the above alternatives, the applicants state the alternative represented in the application is the most effective alternative.

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 applicants adequately demonstrate that this proposal is the least costly or most effective alternative to meet the 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 and O2P LLC 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 and O2P LLC shall relocate no more than 13 dialysis stations to FMC Northern Wake, which shall include any isolation or home hemodialysis stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake and O2P LLC shall install plumbing and electrical wiring through the walls for no more than 13 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 10 dialysis stations at BMA Wake for a total of no more than 40 dialysis stations at BMA Wake.**
 - 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at BMA Southwest Wake for a total of no more than 28 dialysis stations at BMA Southwest Wake.**
 - 6. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Northern Wake and O2P LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 75, the applicants project that the total capital cost will be \$3,374,036, including \$1,859,035 in building and construction costs for O2P and \$1,515,001 in up-fitting and equipment costs for BMA. O2P's costs include \$548,856 in site costs, \$1,196,079 in contractor fees, and \$114,100 in contingency fees. BMA's costs include \$1,006,938 in construction costs, \$156,270 for water treatment equipment, \$151,412 for additional equipment, and \$200,381 in architect/engineering fees and contingencies. In Section VIII.2, page 76, the applicants state Fresenius Medical Care Holdings, Inc., parent company of BMA, will finance their part of the project with accumulated reserves and O2P, LLC will fund their part of the project with a bank loan. In Section IX.1, page 80, the applicants state there will be \$154,499 in start-up expenses. In Section IX.2, page 81, the applicants state there will be \$1,686,192 in initial operating expenses, for a total working

capital requirement of \$1,840,691, listed in Section IX.3, page 82. In Exhibit 24, the applicants provide a June 17, 2013 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states

“This is to inform you that Fresenius Medical Care Holding, Inc is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc. Working together with O2P LLC, BMA proposes to develop a new 13 station dialysis facility to serve the growing ESRD patient population of north Raleigh and Wake County.

BMA and O2P LLC propose to develop a new 13 station dialysis facility by transferring 13 existing and certified dialysis stations from BMA Wake (10 stations) and BMA Southwest Wake (three stations) dialysis facilities. The project calls the following capital expenditures on behalf of BMA.

| | |
|--|--------------------|
| <i>Capital Expenditure</i> | <i>\$1,515,001</i> |
| <i>Start-up Expenses</i> | <i>\$ 154,499</i> |
| <i>Working Capital (first eight months operations)</i> | <i>\$1,686,192</i> |
| <i>Total Required</i> | <i>\$3,355,692</i> |

As Vice President, I am authorized and do hereby authorize the development of this 13 station dialysis facility, Fresenius Medical Care Northern Wake, for capital costs of \$1,515,001 and \$1,840,691 in startup and working capital. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the capital expenditure, start up and working capital which may be needed for this project.”

In Exhibit 24, the applicants also provide a June 17, 2013 letter from the Member Manager of O2P, LLC, which states in part

“... The project calls [sic] the following capital expenditures:

| | |
|------------------------------------|--------------------|
| <i>O2P LLC Capital Expenditure</i> | <i>\$1,859,035</i> |
| <i>BMA Capital Expenditure</i> | <i>\$1,515,001</i> |

As Member Manager of O2P, LLC, I am authorized and do hereby authorize the capital costs of \$1,859,035 as may be necessary for this project. I am authorized and do hereby authorize and commit for the O2P capital cost of \$1,859,035 as may be needed for this project.”

Exhibit 24 contains a June 4, 2013 letter from the Vice President of North State Bank, which states in part

“We have examined your current financial status and the initial project parameters, and have interest in providing your organization with the financing for the proposed

project.... We have traditionally financed up to 100% of your costs and anticipate the same in this project.”

In Exhibit 10, the applicants provide the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2012 and 2011. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$341,071,000 in cash and cash equivalents with \$17,841,509,000 in total assets and \$8,957,724,000 in net assets (total assets less total liabilities). The applicants adequately demonstrated the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 83, the applicants provide projected allowable charges per treatment for each payment source in the table below.

FMC Northern Wake

| Source of Payment | In-Center Charge Per Treatment | Home PD | Home Hemo |
|----------------------|--------------------------------|----------|------------|
| Commercial Insurance | \$1,375.00 | \$550.20 | \$1,375.00 |
| Medicare | \$234.00 | \$234.00 | \$234.00 |
| Medicaid | \$137.29 | \$137.29 | \$137.29 |
| VA | \$146.79 | \$147.85 | \$147.85 |
| Private Pay | \$1,375.00 | \$550.20 | \$1,375.00 |

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

The applicants project net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application, pages 84-89, as illustrated in the table below.

| FMC Northern Wake | Operating Year 1 CY 2015 | Operating Year 2 CY 2016 |
|--------------------------|-------------------------------------|-------------------------------------|
| Total Net Revenue | \$2,641,146 | \$2,964,846 |
| Operating Expenses | \$2,529,288 | \$2,754,160 |
| Profit (Loss) | \$111,858 | \$210,686 |

The applicants project that revenue will exceed operating expenses in each of the first two operating years. Operating costs and revenues are based on reasonable assumptions including projected utilization. See Sections X.3, pages 84-87, of the application for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein.

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of this project. The applicants also adequately demonstrate

that the financial feasibility of the proposal 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

The applicants propose to develop a new 13-station dialysis facility, FMC Northern Wake, in north Raleigh, by relocating 10 existing dialysis stations from BMA Wake and 3 existing dialysis stations from BMA Southwest Wake, both located in Wake County. In Section II, page 20, the applicants state

*BMA is **NOT** projecting that patients currently served by the DaVita Wake Forest dialysis facility will transfer their care. (BMA will not prohibit any patient from changing providers; the only requirement is proper referral from a physician with admitting privileges at the facility). [Emphasis in original]*

In Section V.7, page 64, the applicants state

“Approval of this application will not alter the competitive nature of dialysis facilities and providers serving Wake County. Approval of this application will not change the number of dialysis stations in the county. Approval of this application will enhance patient access to care.

BMA has included 57 patient letters of support from existing dialysis patients who reside in Wake County. While development of “bricks and mortar” may be construed as a change within the competitive environment in the county, BMA suggests that the competition between providers has been ongoing for many years.

Indeed, BMA has been providing dialysis treatment to the overwhelming majority of the Wake County ESRD patient population as may be noted within this application. Further, the physicians of Wake Nephrology are likewise providing medical coverage for patients from Wake County. In fact, the physicians of Wake Nephrology Associates report that at the present time they are providing care for a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients residing in north Raleigh and Wake County. Thus, while approval of this application will allow introduction of a new dialysis facility into the county, the reality is that approval of this application will not significantly alter the competitive climate of Wake County. BMA is already serving dialysis patients from Wake County.

BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Wake County. BMA projections of patients to be served by the facility are a function of the existing patient population served by BMA coupled with growth of that population. BMA has not asserted that it would capture 100% of new dialysis patients in Wake

County. Rather, BMA projections of future patient populations to be served focus on the existing patient population served by BMA. BMA also anticipates that the patient population of the DaVita Wake Forest dialysis clinic will increase at the same rate proposed by BMA.”

In Section II, page 16, the applicants state “...The January 2013 SDR, Table A identifies 12 dialysis facilities within Wake County. BMA operates 11 of these facilities and DaVita operates the 12th facility.” The following table shows the utilization rates of the Wake County facilities based on data reported in the January 2013 SDR.

| Facility | # of In-Center Patients | # of Certified Stations | % Utilization as of June 30, 2012 |
|--------------------------------------|--------------------------------|--------------------------------|--|
| Cary Kidney Center | 70 | 23 | 76.09% |
| FMS of Apex | 46 | 14 | 82.14% |
| BMA of Raleigh | 148 | 49 | 75.51% |
| FMC of New Hope | 81 | 30 | 67.50% |
| FMC of Central Raleigh | 17 | 13 | 32.69% |
| BMA of Fuquay-Varina | 76 | 22 | 86.36% |
| Zebulon Kidney Center | 87 | 30 | 72.50% |
| Wake Dialysis Clinic | 162 | 50 | 81.00% |
| FMC of Eastern Wake | 46 | 14 | 82.14% |
| FMC of Millbrook | 52 | 16 | 81.25% |
| Southwest Wake County Dialysis | 104 | 30 | 86.67% |
| Wake Forest Dialysis Center (DaVita) | 41 | 10 | 102.50% |

BMA is not adding dialysis stations in Wake County but is transferring stations from two existing facilities, BMA Wake and BMA Southwest Wake. As shown on the table above, both facilities were operating at over 80% of capacity as of June 30, 2012.

In Section III.7, page 53, the applicants demonstrate that FMC Northern Wake will serve a total of 48 in-center patients on 13 stations at the end of both the first and second operating years, which is 3.69 patients per station per week, or a utilization rate of 92.3% of capacity [$48 / 13 = 3.69$; $3.69 / 4 = 92.3\%$]. Also, the applicants’ utilization rate projections are based entirely on patients currently served at BMA facilities in Wake County who have expressed their intention to consider transferring to the proposed north Raleigh facility because it will be more convenient for them.

Consequently, the applicants adequately demonstrate the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Wake County. Therefore, the application is conforming with this criterion.

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

C

In Section VII.1, page 71, the applicants project the number of FTE positions following completion of the proposed project, as illustrated in the table below.

| Position | Projected # of FTEs |
|-----------------------------------|----------------------------|
| RN | 3.50 |
| Tech | 7.50 |
| Clinical Manager | 1.00 |
| Administration – FMC Area Manager | 0.15 |
| Dietitian | 0.20 |
| Social Worker | 0.20 |
| Home Training Nurse | 1.00 |
| Medical Records | 0.50 |
| Chief Tech | 0.15 |
| Equipment Tech | 0.85 |
| In-Service | 1.00 |
| Clerical | 0.50 |
| Total | 16.55 |

Note: The Medical Director is a contract position, not an FTE of the facility.

In Section V.4, page 62, the applicants state Dr. Michael Casey, Wake Nephrology, will be the Medical Director for FMC Northern Wake. In Exhibit 21, the applicants provide a June 17, 2013 letter signed by Dr. Casey that confirms his commitment to serve as Medical Director. In Section VII.4, page 72, the applicants state they anticipate no difficulty in hiring the necessary staff for the FMC Northern Wake dialysis facility, and describe the experience they have recruiting and hiring staff necessary to operate dialysis facilities. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed 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 V.1, page 58, the applicants lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicants discuss coordination with the existing health care system on pages 60-63. Exhibits 16-19 contain documents which demonstrate 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 V.1 and Exhibits 16-19 is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (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 XI.6, page 97 of the application, the applicants state O2P, LLC will construct 9,308 square feet of shell space for the proposed dialysis facility in north Raleigh which BMA will upfit and lease. On pages 95-96, the applicants state O2P, LLP is committed to ensuring the building is designed to improved energy efficiency and the plumbing system is designed to conserve water. Applicable energy saving features and water treatment equipment will be incorporated into the construction plans in the following ways

- HVAC system operating efficiency will equal “*industry standards for high seasonal efficiency.*”

- Facility will use energy efficient exit signs, external insulation wrap for hot water heaters, water flow restrictors at sink faucets, and other methods of energy conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors, which use less amperage.

Costs and charges are described by the applicants in Section X of the application, pages 83-88. See discussion in Criterion (5) regarding costs and charges which is incorporated hereby as if set forth fully herein.

The applicants adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, 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 VI.1, page 66, the applicants state

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the FMC Northern Wake facility is expected to be similar to the facilities contributing stations to the project, and will likely be comprised of the following:

| <i>Facility</i> | <i>Medicaid/ Low Income</i> | <i>Elderly (65+)</i> | <i>Medicare</i> | <i>Women</i> | <i>Racial Minorities</i> |
|--------------------------|---------------------------------|--------------------------|-----------------|--------------|------------------------------|
| <i>FMC Northern Wake</i> | <i>23.8%</i> | <i>32.8%</i> | <i>78.7%</i> | <i>48.5%</i> | <i>90.2%</i> |

...It is clear that FMC Northern Wake projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients

regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

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.

| | 2011 Total # of Medicaid Eligibles as % of Total Population * | 2011 Total # of Medicaid Eligibles Age 21 and older as % of Total Population * | 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) * |
|-------------|--|---|--|
| Wake County | 10% | 3.3% | 18.4% |
| Statewide | 17% | 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 dialysis services offered by BMA’s Wake County facilities that will be contributing stations to the proposed FMC Northern Wake facility. In fact, according to the Southeastern Kidney Council’s ESRD Network 6 2011 Annual Report, only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants’ current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

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

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

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

prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: “*On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.*” Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states

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

The report provides the following 2010 ESRD spending by payor.

| ESRD Spending by Payor | | |
|-------------------------------|-----------------------------|----------------------------|
| Payor Source | Spending in Billions | % of Total Spending |
| Medicare Paid | \$29.6 | 62.32% |
| Medicare Patient Obligation | \$4.7 | 9.89% |
| Medicare HMO | \$3.4 | 7.16% |
| Non-Medicare | \$9.8 | 20.63% |

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

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, gender, and race as shown below.

| Number and Percent of Dialysis Patients by Age, Gender, and Race* | | |
|--|---------------------------|---------------------------------|
| | # of ESRD Patients | % of Dialysis Population |
| Age | | |
| 0-19 | 89 | 1.0% |
| 20-34 | 451 | 4.8% |
| 35-44 | 773 | 8.3% |
| 45-54 | 1,529 | 16.4% |
| 55-64 | 2,370 | 25.4% |
| 65-74 | 2,258 | 24.2% |
| 75+ | 1,872 | 20.0% |
| Gender | | |
| Female | 4,237 | 45.4% |
| Male | 5,105 | 54.7% |
| Race | | |
| African-American | 5,096 | 54.6% |
| White | 4,027 | 43.1% |
| Other | 219 | 2.3% |
| Total | 9,342 | 100.0% |

* Source: SKC Network 6, which includes North Carolina, South Carolina, and Georgia.

The applicants demonstrate that medically underserved populations currently have adequate access to the applicants' existing services and are 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 VI.1, page 68, the applicants state:

“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 applicants 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, page 69, the applicants state, *“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, page 67, the applicants state

“Projections of future in-center reimbursement is [sic] a function of historical performance of the facilities contributing stations to this project. The facilities contributing stations to the project are operating in Wake County.”

FMC Northern Wake Projected Patient Payer Mix

| Payer Source | In-Center Dialysis | Home Hemodialysis | Home Peritoneal Dialysis |
|----------------------|-------------------------------|------------------------------|-------------------------------------|
| Commercial Insurance | 13.1% | 58.0% | 23.5% |
| Medicare | 83.2% | 33.4% | 76.0% |
| Medicaid | 3.1% | 1.0% | 0.1% |
| VA | 0.6% | 7.8% | 0.0% |
| Other: Self/Indigent | 0.1% | 0.0% | 0.4% |
| Total | 100.0% | 100.0% | 100.0% |

As shown in the table above, the applicants project that 86.3% of in-center patients will be Medicare or Medicare/Medicaid beneficiaries. The applicants demonstrate that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 69, the applicants state

“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.”

The applicants adequately demonstrated that they will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 61, the applicants state, “*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.*” Exhibit 19 contains a copy of a March 22, 2013 letter from the Director of Operations for Fresenius Medical Care to the Department Head of the Nursing Program for Wake Technical Community College offering FMC Northern Wake as a clinical training site for a CON application submission date of April 15, 2013 [sic]. The information provided in Section V.1 is reasonable and credible 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

The applicants propose to develop a new 13-station dialysis facility in Raleigh (Wake County) by transferring existing stations from two BMA facilities in Wake County. There are currently 12 dialysis facilities in Wake County, 11 dialysis facilities operated by BMA and 1 operated by DaVita.

In Section V.7, pages 64-65, the applicants state

“Approval of this application will not alter the competitive nature of dialysis facilities and providers serving Wake County. Approval of this application will not change the number of dialysis stations in the county. Approval of this application will enhance patient access to care.”

BMA has included 57 patient letters of support from existing dialysis patients who reside in Wake County. While development of “bricks and mortar” may be construed as a change within the competitive environment in the county, BMA suggests that the competition between providers has been ongoing for many years.

Indeed, BMA has been providing dialysis treatment to the overwhelming majority of the Wake County ESRD patient population as may be noted within this application. Further, the physicians of Wake Nephrology are likewise providing medical coverage for patients from Wake County. In fact, the physicians of Wake Nephrology Associates report that at the present time they are providing care for a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients residing in north Raleigh and Wake County. Thus, while approval of this application will allow introduction of a new dialysis facility into the county, the reality is that approval of this application will not significantly alter the competitive climate of Wake County. BMA is already serving dialysis patients from Wake County.

BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Wake County. BMA projections of patients to be served by the facility are a function of the existing patient population served by BMA coupled with growth of that population. BMA has not asserted that it would capture 100% of new dialysis patients in Wake County. Rather, BMA projections of future patient populations to be served focus on the existing patient population served by BMA. BMA also anticipates that the patient population of the DaVita Wake Forest dialysis clinic will increase at the same rate proposed by BMA.

This facility will have added value stemming from the strength of our relationship with the nephrology physicians at Wake Nephrology. The practice brings together a team of seven highly qualified nephrologists to serve the ESRD patient needs of the area.

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 86.2% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.”

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

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

- The applicants adequately demonstrate the need to relocate 13 dialysis stations within Wake County, and that it is a cost-effective alternative to meet that need;

- The applicants adequately demonstrated they will continue to provide quality services; and
- The applicants adequately demonstrated they will continue to provide adequate access to medically underserved populations.

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

The applicants propose to relocate stations from two Wake County facilities, BMA Wake and BMA Southwest Wake, to a new facility in Wake County, FMC Northern Wake. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, those Wake County facilities have operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, which are 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- See Section II.1, page 12, and Exhibit 2 (copy of the January 2013 SDR, Tables A and B), the applicants provide the utilization rates for BMA Wake and BMA Southwest Wake.

.2202(a)(2) *Mortality rates;*

- C- In Section IV.2, page 56, the applicants report 2010, 2011 and 2012 facility mortality rates for BMA Wake and BMA Southwest Wake.

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

- C- In Section IV.3, page 57, the applicants state that BMA Wake has 54 home trained patients. BMA Southwest Wake is not certified to provide home dialysis and does not have any home-trained patients. Any patients needing home dialysis are referred to BMA Wake.

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

- C- In Section IV.4, page 57, the applicants reported that BMA Wake referred 29 patients for transplant evaluation in 2012, and 14 patients received transplants in 2012. BMA Southwest Wake referred 41 patients for transplant evaluation in 2012, and 1 patient received a transplant in 2012.

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

- C- In Section IV.5, page 57, the applicants state that BMA Wake has 49 patients on the transplant waiting list, and that BMA Southwest Wake has 8 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 IV.6, page 57, for BMA Wake, the applicants report a total of 316 hospital admissions in 2012; 71% were non-dialysis related and 29% were dialysis-related. For BMA Southwest Wake, the applicants report a total of 154 hospital admissions in 2012; 84% were non-dialysis related and 16% were dialysis-related.

.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 IV.7, page 57, for BMA Wake, the applicants report a total of 3 current patients with an infectious disease in 2012 and no patients converted to infectious status in 2012. For BMA Southwest Wake, the applicants report there are no patients with an infectious disease and no patients converted to infectious status in 2012.

(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).

-C- Exhibit 16 contains a copy of a “Transfer Agreement” between the applicants and WakeMed that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis 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.

-C- Exhibit 17 contains a copy of a “Transplant Center Evaluation Services Agreement” between the applicants and Duke University Medical Center that includes the information required by this rule.

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

-C- In Section II.1, page 14, the applicants state power and water are available at the proposed sites. Exhibits 30-31 contain copies of letters, from the owner of the primary site and from the Town Administrator for the Town of Raleigh for the secondary site, which state water and power are available to the proposed sites.

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

-C- Exhibit 12 contains excerpts from BMA’s Emergency Preparedness Documentation which contain a copy of written policies and procedures for back up of electrical service in the event of a power outage.

- .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.*
- C- In Section II.1, page 14, the applicants state, “... Neither BMA nor O2P owns or controls either of the sites but has included information on two sites which are available for acquisition. O2P will be responsible for site acquisition and building development.” Exhibits 30-31 contain information from the owners confirming the two sites are available.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Sections II.1, page 15; VII.2, page 72 and XI.6, pages 96-97.
- .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 II.1, page 15, FMC Northern Wake provided projected patient origin, which the applicants state is based on the patient origin of current BMA patients who have expressed an interest in transferring to the proposed facility.
- .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.*
- C- In Section II.1, page 17, the applicants state, “BMA reasonably expects that 100% of the patient population of this facility resides well within 30 miles of the facility. Thirty miles from the primary and secondary sites of FMC Northern Wake covers nearly the entirety of Wake County.”
- .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 II.1, page 18, the applicants state, “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.

- C- In Section II.1, pages 19-24, the applicants demonstrate they will serve a total of 48 in-center patients on 13 stations at the end of the first operating year, which is 3.6 patients per station per week, or a utilization rate of 92.3%. Therefore, the applicants demonstrated that the proposed Wake County facility would meet the minimum performance standard requirements in this rule.

- .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.*
- N/A- The applicants are not 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.

- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 22-24, the applicants provide the assumptions and methodology used to project utilization of the facility.

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- Provided by WakeMed or other local hospital of patient choice. See Section V.1, page 58.

- .2204(2) *Maintenance dialysis;*
 - C- Provided by the applicants. See Section V.1, page 58.

- .2204(3) *Accessible self-care training;*
 - C- Provided by the applicants. See Section V.1, page 58.

- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- Provided by the applicants and through BMA Wake. See Section V.2, page 60.

- .2204(5) *X-ray services;*
 - C- Provided by WakeMed, Raleigh Radiology or patient choice. See Section V.1, page 58

- .2204(6) *Laboratory services;*
 - C- Provided by Spectra Laboratories, Inc. See Section V.1, page 58, and Exhibit 18.

- .2204(7) *Blood bank services;*
 - C- Provided by WakeMed or Rex Raleigh. See Section V.1, page 58.

- .2204(8) *Emergency care;*
 - C- Provided by local hospital. See Section V.1, page 58.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- Provided by WakeMed. See Section V.1, page 58.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- Provided by Carolina Vascular, Wake Surgical, North Raleigh Surgical or Carolina Surgery. See Section V.1, page 58.
- .2204(11) *Transplantation services;*
 - C- Provided by Duke University Hospital. See Section V.1, page 58.
- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- Provided by Vocational Rehabilitation of Wake County. See Section V.1, page 58.
- .2204(13) *Transportation*
 - C- Provided by Tri-Star, Johnston Ambulance Services, and Wake Coordinated Transportation. See Section V.1, page 58.

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 VII.1, page 71, the applicants provide the proposed staffing. In Section VII.2, page 72, the applicants state the proposed facility will comply with all staffing requirements set forth in the Federal code. The applicants adequately demonstrate that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for additional discussion which is incorporated hereby as if set forth fully herein.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
 - C- See Section II.1, page 26, Section VII.3, page 72, and Exhibits 14 and 15.