

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 25, 2015
Findings Date: February 25, 2015

Project Analyst: Gregory F. Yakaboski
Assistant Chief: Martha J. Frisone

Project ID #: M-10340-14
Facility: Fayetteville Kidney Center
FID #: 944475
County: Cumberland
Applicant(s): Bio-Medical Applications of Fayetteville, Inc.
Project: Add three dialysis stations for a total of 45 stations upon completion of this project and Project ID# M-10191-13 (add 3 stations)

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 Fayetteville, Inc, d/b/a Fayetteville Kidney Center (“Fayetteville Kidney Center or BMA Fayetteville”), whose parent company is Fresenius Medical Care Holdings Inc. (FMC), proposes to add three dialysis stations to its existing facility for a total of 45 certified dialysis stations upon completion of the proposed project and Project ID # M-10191-13 (add three stations).

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need

methodology shows there is a surplus of 3 dialysis stations in Cumberland County. The applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for the Fayetteville Kidney Center in the July 2014 SDR is 3.6154 patients per station. This utilization rate was calculated based on 141 in-center dialysis patients and 39 certified dialysis stations (141 patients / 39 stations = 3.6154 patients per station). Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

| | | |
|--|---|-----------|
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 12/31/13 | | 90.4% |
| Certified Stations | | 39 |
| Pending Stations | | 3 |
| Total Existing and Pending Stations | | 42 |
| In-Center Patients as of 12/31/13 (July 2014 SDR) (SDR2) | | 141 |
| In-Center Patients as of 6/30/13 (January 2014 SDR) (SDR1) | | 140 |
| Step | Description | Result |
| (i) | Difference (SDR2 - SDR1) | 1 |
| | Multiply the difference by 2 for the projected net in-center change | 2 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13 | 0.0143 |
| (ii) | Divide the result of step (i) by 12 | 0.0012 |
| (iii) | Multiply the result of step (ii) by 12 (the number of months from 12/31/12 until 12/31/13) | 0.0143 |
| (iv) | Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2 | 143.0143 |
| (v) | Divide the result of step (iv) by 3.2 patients per station | 44.6920 |
| | and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed | 3 |

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

Policies

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2014 SMFP is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical

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

The applicant addresses Policy GEN-3 beginning on page 5 of the application.

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section I.13, pages 5-9, Section II.1, page 21, Section II.3, pages 28-30, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 22-23, Section VI.1, page 48, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section II.1, page 23. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

Bio-Medical Applications of Fayetteville, Inc. d/b/a Fayetteville Kidney Center (“Fayetteville Kidney Center or BMA Fayetteville”), whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), proposes to add three dialysis stations to its existing facility for a total of 45 certified dialysis stations upon completion of the proposed project and Project ID # M-10191-13 (add three stations).

Population to be Served

In Section IV.1, page 40, the applicant identifies the population it served in-center, as of June 30, 2014, as illustrated in the table below.

| Fayetteville Kidney Center Current Patient Origin | | |
|--|---------------------------|-----------------------------------|
| COUNTY | In-center Patients | Patients dialyzing at home |
| Cumberland | 136 | 74 |
| Harnett | 0 | 2 |
| Hoke | 5 | 4 |
| Robeson | 1 | 1 |
| Sampson | 0 | 2 |
| Total | 142 | 83 |

In Section III.7, page 34, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

| County | Operating Year 1 | | | Operating Year 2 | | | County Patients Percent of Total | |
|------------|------------------|------|------|------------------|------|------|----------------------------------|--------|
| | In-Center | PD | HH | In-Center | PD | HH | Year 1 | Year 2 |
| Cumberland | 152.2 | 60.4 | 22.4 | 159.2 | 63.2 | 23.4 | 94.00% | 94.25% |
| Harnett | 0 | 2 | 0 | 0 | 2 | 0 | 0.80% | 0.77% |
| Hoke | 5 | 2 | 2 | 5 | 2 | 2 | 3.60% | 3.45% |
| Robeson | 1 | 1 | 0 | 1 | 1 | 0 | 0.80% | 0.77% |
| Sampson | 0 | 2 | 0 | 0 | 2 | 0 | 0.80% | 0.77% |
| TOTAL | 158.2 | 67.4 | 24.4 | 165.2 | 70.2 | 25.4 | 100.0% | 100.0% |

*On page 16, the applicant states that it recognizes that the CON Section, has previously indicated that patients are not partial patients, but rather whole. In financial projections and utilization projections for this application, BMA has rounded down to the nearest whole number.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III, page 32, the applicant states the application is filed pursuant to the Facility Need Methodology. The applicant utilizes data from the July 2014 SDR and proposes to add three dialysis stations to the Fayetteville Kidney Center for a total of 45 stations upon completion of this project and Project ID #M-10191-13 (add 3 stations).

In Section III.7, pages 34-35, the applicant provides the following assumptions used to project utilization:

- As of June 30, 2013 the utilization rate at BMA Fayetteville was 90.38% or 3.6154 patients per station per week based on 141 patients utilizing 39 existing certified stations.
- The applicant projected growth for the patients residing in Cumberland County at 4.6% per year, which is the Cumberland County Five Year Average Annual Change Rate as published in the July 2014 SDR.
- The project is scheduled to be completed in December 2015. (See page 82 of the application.) Operating Year 1 is projected to be CY 2016 and Operating Year 2 is projected to be CY 2017.
- There are currently six in-center patients utilizing BMA Fayetteville who are not residents of Cumberland County. These patients are utilizing the BMA Fayetteville facility as a matter of patient choice but the applicant assumes no growth for this portion of the population currently being served.

In Section III.7, pages 35-36, the applicant provides the following methodology used to project utilization:

| | <i>In-Center</i> |
|--|--|
| <i>BMA begins with facility census of Cumberland County patients as of June 30, 2014.</i> | 136 |
| <i>The census is increased by the one half of the Cumberland County Five Year Average Annual Change Rate to December 31, 2014.</i> | $[136 \times (.046/12 \times 6)] + 136 = 139.1$ |
| <i>The census is increased by the Five Year Change Rate for one year to December 31, 2015.</i> | $(139.1 \times .046) + 139.1 = 145.5$ |
| <i>BMA adds the six in-center patients from Hoke and Robeson Counties. This is the beginning In-Center census for this project.</i> | $145.5 + 6 = 151.5$ |
| <i>The census of Cumberland County patients is increased by the Five Year Change Rate for one year to December 31, 2016.</i> | $(145.5 \times .046) + 145.5 = 152.2$ |
| <i>BMA adds the six in-center patients from Hoke and Robeson Counties. This is the ending In-Center census for Operating Year 1.</i> | $152.2 + 6 = 158.2$ |
| <i>The census of Cumberland County patients is increased by the Five Year Change Rate for one year to December 31, 2017.</i> | $(152.2 \times .046) + 152.2 = 159.2$ |
| <i>BMA adds the six in-center patients from Hoke and Robeson Counties. This is the ending In-Center census for Operating Year 2.</i> | $159.2 + 6 = 159.2$ [sic- correct calculation is 165.2.] |

The applicant projects to serve 158 in-center patients or 3.51 patients per station per week ($158 / 45 = 3.51$) by the end of Year 1 (December 31, 2016) and 165 in-center patients or 3.67 patients per station per week ($165 / 45 = 3.67$) by the end of Year 2 (December 31, 2017). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access to Services

In Section VI, page 48, the applicant states that the parent company to BMA, Fresenius Medical Care Holdings, Inc., currently operates 100 facilities in 42 North Carolina Counties which patient populations include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 94.73% of its in-center patients and 86.43% of its HH patients will be covered by either Medicare, Medicaid or the VA. (See application p. 49) 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, demonstrates the need the population has for three additional stations 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.

NA

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

CA

In Section III.9, pages 38-39, the applicant discusses the alternatives considered, which include:

1. Maintain the Status Quo –the applicant dismissed this alternative based on the fact that with the continued growth at the facility and in Cumberland County there is a need for three additional stations. Therefore, doing nothing would not be in the best interest of the patients.
2. Apply for Less Than 3 Stations- The facility projects continued high utilization rates. Applying for less than 3 stations would not be in the best interest of the patients.
3. Relocate Dialysis Stations from its other facilities in Cumberland County – BMA has three other facilities in Cumberland County. Of the three facilities, only the FMC South Ramsey facility had a utilization rate less than 80.0% as of December 31, 2013. However, BMA has traditionally utilized FMC South Ramsey to host transient patient populations visiting the Fayetteville/Cumberland County area with its vast military complex. Therefore, relocating stations from the FMC South Ramsey facility was not deemed to be in the best interest of the patients.

Thus, the applicant concluded that the project as proposed was the most effective alternative to meet the need.

The applicant adequately demonstrates the need for three additional stations based on the continued growth of the ESRD patient population in Cumberland County and the facility's

projected utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

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

- 1. Bio-Medical Applications of Fayetteville, Inc. d/b/a Fayetteville Kidney Center shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of Fayetteville, Inc. d/b/a Fayetteville Kidney Center shall develop no more than three additional stations for a total of no more than 45 certified stations upon completion of this project and Project I.D. #M-10191-13 (develop 3 new stations), which shall include any home hemodialysis or isolation stations.**
 - 3. Bio-Medical Applications of Fayetteville, Inc. d/b/a Fayetteville Kidney Center shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 45 dialysis stations upon completion of this project and Project ID #F-10191-13 (develop 3 new stations), which shall include any home hemodialysis or isolation stations**
 - 4. Bio-Medical Applications of Fayetteville, Inc. d/b/a Fayetteville Kidney Center 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

In Sections VIII, page 57, the applicant projects the total capital cost for the project will be \$8,250, including \$1,500 for water treatment equipment, \$2,250 for medical equipment and \$4,500 for patient TV's.

In Section IX, page 61, the applicant projects no initial start-up costs or initial operating expenses because this is an existing facility.

In Section VIII, pages 58-59, BMA states it will fund the capital needs of the proposed project from accumulated reserves. Exhibit 24 contains a letter, dated September 15, 2014, from the Vice President of Fresenius Medical Care Holdings, Inc., which states

“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of Fayetteville, Inc.

BMA is submitting a Certificate of Need Application to add three dialysis stations for a total of 45 dialysis stations. The project calls for the following capital expenditure:

Capital Expense \$8,250

As Vice President, I am authorized and do hereby authorize addition of three dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$8,250 as may be needed for this project.”

Exhibit 4, contains the Consolidated Financial Statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for December 31, 2013 and 2012. As of December 31, 2013, FMC had \$275,719,000 in cash and cash equivalents, \$16,597,314,000 in total assets and \$8,521,824,000 in nets assets. (See page 3 of Exhibit 4) The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, pages 62-63, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

| Payor | In-center Treatment | Home PD | Home Hemo |
|----------------------|----------------------------|----------------|------------------|
| Private Pay | \$1,425.00 | \$1,425.00 | \$1,425.00 |
| Commercial Insurance | \$1,425.00 | \$1,425.00 | \$1,425.00 |
| Medicare | \$239.00 | \$239.00 | \$239.00 |
| Medicaid | \$140.23 | \$140.23 | \$120.18 |
| VA | \$231.12 | \$231.12 | \$196.90 |
| Medicare/Medicaid | \$239.00 | \$239.00 | \$239.00 |
| Medicare/Commercial | \$239.00 | \$239.00 | \$239.00 |
| State Kidney Program | \$100.00 | \$100.00 | \$100.00 |
| Other: Self/Indigent | \$1,425.00 | \$1,425.00 | \$1,425.00 |

The applicant states that the commercial charge listed does not reflect actual reimbursement. In addition, the applicant states that Medicare utilized a “bundling” reimbursement program, which resulted in the basic Medicare fee per dialysis treatment of \$240.

The applicant states that in November 2013, Medicare announced further cuts to reimbursement for dialysis treatment which amount to a 12% reduction in revenues to be phased in over several years. The following table illustrates projected Medicare reimbursement rates BMA used to project revenues:

Anticipated Medicare Reimbursement by Year

| Year | Medicare Rate |
|-------------|----------------------|
| 2014 | \$239.02 |
| 2015 | \$239.02 |
| 2016 | \$229.46 |
| 2017 | \$220.28 |
| 2018 | \$211.47 |
| 2019 | \$211.47 |

In Sections X.2-X.4, pages 64-73, the applicant projects revenues and operating expenses for the Fayetteville Kidney Center, as illustrated in the table below:

| | Operating Year 1 | Operating Year 2 |
|-----------------------|-------------------------|-------------------------|
| Total Net Revenue | \$11,804,764 | \$12,036,652 |
| Total Operating Costs | \$9,755,623 | \$10,005,665 |
| Net Profit | \$2,049,140 | \$2,030,988 |

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 62-74, for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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

Bio-Medical Applications of Fayetteville, Inc., d/b/a Fayetteville Kidney Center ("Fayetteville Kidney Center or BMA Fayetteville"), whose parent company is Fresenius Medical Care Holdings Inc. (FMC), proposes to add three dialysis stations to its existing facility for a total of 45 certified dialysis stations upon completion of the proposed project and Project ID # M-10191-13 (add three stations).

According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of three dialysis stations in Cumberland County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. Although the July 2014 SDR shows there is a deficit of three dialysis stations in Cumberland County, in this application, the applicant is applying for additional stations based on the facility need methodology.

According to the July 2014 SDR, BMA Fayetteville is one of four dialysis facilities in Cumberland County with utilization rates ranging from 62.25% to 90.38%. The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it currently serves and proposes to serve. The growth projections are based on Cumberland County's projected five-year average annual growth rate in the number of dialysis patients. As of December 31, 2013, facility was operating at 90.38% capacity with 39 stations ($141 / 39 = 3.6154 / 4 = 0.9038$ or 90.38%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Upon completion of the proposed project and Project ID #M-10191-13 (develop 3 new stations), the facility will have 45 stations serving 158 in-center patients at the end of year 1, which is a utilization rate of 88.0% or 3.51 patients per station [$158 / 45 = 3.51 / 4.0 = 0.88$ or 88.0%]. Thus, the facility is expected to serve more than the 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

According to the July 2014 North Carolina Semiannual Dialysis Report, including Fayetteville Kidney Center, there are four ESRD facilities in Cumberland County. All of the facilities are operational and operating a total of 170 available stations. All four of the facilities have a Fayetteville address, including Fayetteville Kidney Center. All four of the facilities are ultimately operated and controlled by Fresenius Medical Care Holdings, Inc. (FMC). The following table illustrates the utilization rate as of December 31, 2013:

| Name of facility | # of Certified dialysis stations as of 12/31/13 | # of Stations approved per CON conditional approval* | # of In-center Patients | Utilization by % as of 12/31/13 |
|---|--|---|--------------------------------|--|
| Fayetteville Kidney Center (BMA Fayetteville) | 39 | 3 | 141 | 90.38% |
| FMC Dialysis Services North Ramsey | 40 | 0 | 135 | 84.38% |
| FMC Dialysis Services South Ramsey | 51 | 0 | 127 | 62.25% |
| FMC Services of West Fayetteville | 40 | 0 | 130 | 81.25% |
| Total | 170 | 3 | 533 | 79.57% |

In Section III.9, page 38, the applicant explains why it did not propose to relocate existing stations from the FMC South Ramsey facility, which has a utilization rate below 80.0%, to

the satisfy the facility need at the Fayetteville Kidney Center by stating “*Only the FMC South Ramsey facility was utilized at less than 80%. However, this facility has traditionally been utilized by BMA as the facility to host transient patient populations visiting the Fayetteville/Cumberland County area. As the CON Analyst will know, Fayetteville and Cumberland County are home to the US Army Fort Bragg military installation. This is a vast military complex with a tremendous active duty army population. Coupled with the families of those active duty soldiers, this area is frequented by visitors on a regular basis. FMC South Ramsey dialysis has become the BMA facility hosting transient patient populations and many of those visiting Fort Bragg.*”

The applicant adequately demonstrates the need to add three dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 53, the applicant states that Fayetteville Kidney Center currently employs 31.58 full time equivalent (FTE) positions. The applicant further states on page 53, that Fayetteville Kidney Center proposes to hire 13.17 additional FTEs upon project completion, which are illustrated in the table below.

| Fayetteville Kidney Center Proposed New FTE Positions | |
|--|--------------|
| RN | 3.00 |
| Technician | 6.00 |
| Dietitian | 0.50 |
| Social Worker | 0.50 |
| Home Training Nurse | 2.50 |
| Chief Tech | 0.17 |
| Equipment Tech | 0.50 |
| Total Proposed FTEs | 13.17 |

The applicant projects a total of 44.75 FTE positions upon project completion and states on page 54 that there is no difficulty expected in recruiting staff. In Section VII.10, page 56, the applicant provides a chart showing a third shift being offered Monday, Wednesday and Friday. In Section V.4(c), page 45, and Exhibit 21 the applicant identifies the Medical Director for Fayetteville Kidney Center as Dr. Maureen Achuko. In Exhibit 21, the applicant provides a letter from Dr. Achuko indicating her willingness to continue to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 V.1, page 42, the applicant lists the providers of the necessary ancillary and support services. See Exhibits 15 and 25-26 for service agreements documentation. Also see the applicant's response to 10A NCAC 14C .2204, Section II, pages 18-20 and the "Description of Services" in Section II, pages 25-26. The applicant adequately demonstrates the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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

C

In Section VI.1, page 48 the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... The patient population of the BMA Fayetteville facility is 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>BMA Fayetteville</i> | <i>21.8%</i> | <i>22.2%</i> | <i>74.7%</i> | <i>27.1%</i> | <i>50.2%</i> |

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 74.7% of the facility treatment reimbursement is from Medicare.

In Section, VI.1, page 49, the applicant provides the current and projected in-center payor mix for the Fayetteville Kidney Center. The current payor mix is illustrated in the table below.

Historical Payor Source

| Payor Source | Percentage | |
|-----------------------|---------------|---------------|
| | In-Center | Home |
| Commercial Insurance | 5.24% | 13.57% |
| Medicare | 74.66% | 78.79% |
| Medicaid | 5.03% | 0.05% |
| VA | 3.38% | 1.14% |
| Medicare/Commercial | 11.66% | 6.45% |
| Other:: Self/Indigent | 0.03% | 0.00% |
| Total | 100.0% | 100.0% |

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 Cumberland and Hoke counties and statewide.

| | 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) * |
|-------------------|--|---|--|
| Cumberland County | 18.0% | 7.0% | 20.3% |
| Hoke County | 19.0% | 7.0% | 21.9% |
| Statewide | 16.5% | 6.7% | 19.7% |

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

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

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

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

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

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

The 2013 *USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

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

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

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

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

³<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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

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

C

In Section VI.6(a), page 51, the applicant states there have been no patient civil rights access complaints filed against BMA's North Carolina facilities in the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 49, the applicant provides the projected payor mix for the proposed services at the Fayetteville Kidney Center as shown in the table below.

Projected Payor Mix

| Payor Source | Percentage | |
|----------------------|--------------------|---------------|
| | In-Center Patients | HH Patients |
| Commercial Insurance | 5.24% | 13.57% |
| Medicare | 74.66% | 78.79% |
| Medicaid | 5.03% | 0.05% |
| VA | 3.38% | 1.14% |
| Medicare/ Commercial | 11.66% | 6.45% |
| Other: Self/Indigent | 0.03% | 0.00% |
| Total | 100.0% | 100.0% |

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 51, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Fayetteville will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that the Fayetteville Kidney Center will provide a range of means by which a person can access its 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 44, the applicant states that Exhibit 19 includes a letter from the applicant requesting that the Methodist University Nursing program include the Fayetteville Kidney Center dialysis facility *“in your list of facilities for clinical rotation of your nursing students.”* The application is conforming 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

Bio-Medical Applications of Fayetteville, Inc., d/b/a Fayetteville Kidney Center (“Fayetteville Kidney Center or BMA Fayetteville”) whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add three dialysis stations to its existing facility for a total of 45 certified dialysis stations upon completion of the proposed project and Project ID # M-10191-13 (add three stations).

The July 2014 SDR shows there is a deficit of three dialysis stations in Cumberland County. In this proposal the applicant is applying for additional stations based on the facility need methodology. According to the July 2014 SDR there are four ESRD facilities (including

Fayetteville Kidney Center) which are currently operational in Cumberland County. The July 2014 SDR states that, as of December 31, 2013, the Fayetteville Kidney Center was operating at 90.38% capacity with 39 stations ($141 / 39 = 3.6154 / 4 = 0.9038$ or 90.38%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility.

In Section V.7, pages 46-47, the applicant discusses how any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA does not expect this proposal to have effect on competition in Cumberland County. According to the January 2014 SDR there were four dialysis facilities operating within Cumberland County, all operated by Fresenius Medical Care.

This facility also has added value stemming from the strength of our relationship with Carolina Kidney Care. Carolina Kidney Care is a premier group of nephrologists practicing across south central North Carolina. As evidence by the physician letter of support, the practice brings together the collaborative efforts of 12 very qualified nephrologists to provide care for the patients choosing to dialyze at BMA Fayetteville.

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ... In this application, BMA projects that 94.7% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.

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

This proposal will ... enhance the quality of the ESRD patients' lives.”

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

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will continue to provide quality services. The discussions regarding quality found in Criterion (1) and (20), are incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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.

Fayetteville Kidney Center is an existing facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Fayetteville Kidney Center has 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant states the utilization rate was 90.38% or 3.62 patients per station ($141 / 39 = 3.62$) as reported in the July 2014 SDR.

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant states the mortality rates were 8.7%, 10.0% and 9.8% for 2011, 2012 and 2013, respectively.

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

-C- In Section II.1, page 11, the applicant states, that Fayetteville Kidney Center has 83 patients dialyzing at home. In 2013, the facility provided home dialysis training to 58 patients and had trained 22 patients as of June 30, 2014.

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

-C- In Section II.1, page 11, the applicant states the Fayetteville Kidney Center referred 6 transplants in 2012 and 11 in 2013. Five transplants were performed in 2012 and 4 in 2013.

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

-C- In Section II.1, page 11, the applicant states, “*BMA Fayetteville has 31 patients on the transplant waiting list.*”

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

-C- In Section II.1, page 12, the applicant states that there were 335 hospital admissions in 2013, of which 40 were dialysis related and 295 that were non-dialysis related.

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

-C- In Section II.1, page 12, the applicant states that there were no patients at the facility in 2012 or 2013 with an infectious disease.

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

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

-NA- Fayetteville Kidney Center is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with 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- Fayetteville Kidney Center is an existing facility.

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

-NA- Fayetteville Kidney Center is an existing facility.

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

-C- See Exhibit 12 for a copy of the Emergency/Disaster Manual (which has policies and procedures for back-up electrical service in the event of a power outage) for the Fayetteville Kidney Center.

(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- Fayetteville Kidney Center is an existing facility.

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

-C- In Section II.1, page 13, the applicant states, “BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at BMA Fayetteville.”

(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, pages 13-16, and Section III.7, pages 33-37, the applicant provides the methodology and assumptions used to project patient origin, as illustrated in table below:

| County | Operating Year 1 | | | Operating Year 2 | | | County Patients Percent of Total | |
|--------------|------------------|-------------|-------------|------------------|-------------|-------------|----------------------------------|---------------|
| | In-Center | PD | HH | In-Center | PD | HH | Year 1 | Year 2 |
| Cumberland | 152.2 | 60.4 | 22.4 | 159.2 | 63.2 | 23.4 | 94.00% | 94.25% |
| Harnett | 0 | 2 | 0 | 0 | 2 | 0 | 0.80% | 0.77% |
| Hoke | 5 | 2 | 2 | 5 | 2 | 2 | 3.60% | 3.45% |
| Robeson | 1 | 1 | 0 | 1 | 1 | 0 | 0.80% | 0.77% |
| Sampson | 0 | 2 | 0 | 0 | 2 | 0 | 0.80% | 0.77% |
| TOTAL | 158.2 | 67.4 | 24.4 | 165.2 | 70.2 | 25.4 | 100.0% | 100.0% |

*On page 16, the applicant states that it recognizes that the CON Section, has previously indicated that patients are not partial patients, but rather whole. In financial projections and utilization projections for this application, BMA has rounded down to the whole number.

The discussion regarding population to be served and analysis of need found in Criterion (3) is incorporated herein by reference.

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

-NA- Fayetteville Kidney Center is an existing facility.

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

-C- In Section II.1, page 17, 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.”*

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Fayetteville Kidney Center does not propose to establish a new End Stage Renal Disease facility.

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

-C- Fayetteville Kidney Center projects to serve 158 in-center patients or 3.51 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 13-16, and Section III.7, pages 33-37. The discussion regarding analysis of need found in Criteria (3) is incorporated herein by reference

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 13-16, and Section III.7, pages 33-37. The discussion regarding analysis of need found in Criteria (3) is incorporated herein by reference.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- In Section II.1, page 18, the applicant states, *“Patients will be referred to Cape Fear Valley Hospital.”*

(2) *maintenance dialysis;*

-C- In Section II.1, page 18, the applicant states, *“The facility will provide in-center dialysis, home training for patients choosing to dialyze at home and training for patients who desire to do dialysis self care at the facility.”*

(3) *accessible self-care training;*

C- In Section II.1, page 19, the applicant states, *“Patients who are candidates for self-care will be referred to the facility home training department. The facility will provide space and nursing staff supervision for patients desiring to do dialysis self care.”*

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

C- In Section II.1, page 19, the applicant states, *“Patients who are candidates for self-care will be referred to the facility home training department. ”*

(5) *x-ray services;*

C- In Section II.1, page 19, the applicant states, *“Patients will be referred to Cape Fear Valley Hospital.”*

(6) *laboratory services;*

-C- In Section II.1, page 19, the applicant states, *“BMA provides on site laboratory services through contract with Spectra Labs.”* See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.

(7) *blood bank services;*

-C- In Section II.1, page 19, the applicant states, *“Patients will be referred to Cape Fear Valley Hospital.”*

(8) *emergency care;*

-C- In Section II.1, page 19, the applicant states, *“Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.”*

(9) *acute dialysis in an acute care setting;*

-C- In Section II.1, page 19, the applicant states, *“Patients will be referred to Cape Fear Valley Hospital.”*

(10) *vascular surgery for dialysis treatment patients;*

-C- In Section II.1, page 19, the applicant states, *“Patients will be referred to Carolina Kidney Care Access Center; Village Surgical or one of the following surgeons: Dr. Hussain, Dr. Morfesis, Dr. Leke, Dr. Chang, or Dr. Ross. The surgeons of these locations will coordinate with the patient and schedule vascular surgery.”*

(11) *transplantation services;*

-C- In Section II.1, page 19, the applicant states, *“BMA Fayetteville has a transplant agreement with UNC Hospital.”* See Exhibit 26 for a copy of the transplant agreement.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section II.1, page 19, the applicant states, *“Patients in need of vocational rehabilitation services will be referred to the local NC Division of Vocational Rehabilitation.”*

(13) *transportation.*

-C- In Section II.1, page 20, the applicant states, *“Transportation services are provided by Cumberland County Department of Social Services or Fayetteville Area System Transit, FAST.”*

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

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

-C- In Section II., page 20, the applicant states that sufficient staffing for each shift is provided. In Section VII.10, page 56, the applicant states BMA offers a third shift on Mondays, Wednesdays and Fridays. In Section VII.2, page 54, BMA states

that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(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 II.1, page 20 and Section VII.5, page 54, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten week training program. Exhibit 9 contains an outline of the training program and Exhibit 10 contains the outline of continuing education information.