

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 1, 2014

PROJECT ANALYST: F. Gene DePorter
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: M-10304-14 / Bio-Medical Applications of Fayetteville, Inc., d/b/a BMA Fayetteville / Relocate the 42 station facility (39 existing stations plus 3 previously approved) within Cumberland County/ Cumberland

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 BMA Fayetteville (“Fayetteville Kidney Center or BMA Fayetteville”) whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to relocate BMA Fayetteville to 2610 Legion Road, Fayetteville, 2.1 miles from its current site in Cumberland County. BMA Fayetteville consists of 39 existing stations plus 3 stations previously approved in Project I.D.# M-10191-13, for a total of 42 stations upon project completion.

The applicant is proposing to relocate dialysis stations within Cumberland County; therefore, neither the county need nor facility need methodologies in the 2014 State Medical Facilities Plan (SMFP) apply to this review. Additionally, Policy GEN-3; BASIC PRINCIPLES is not applicable because neither need methodology is applicable to the review. Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS is applicable to this review. Policy ESRD-2 states:

“Relocation 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 shall:

- (A) 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 Dialysis Report, and*
- (B) 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 Dialysis Report.”*

In summary, the applicant is proposing to relocate dialysis stations within Cumberland County. Consequently there is no change in the dialysis station inventory for Cumberland County, thus the application is consistent with Policy ESRD-2 of the 2014 SMFP. Therefore the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.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

C

Bio-Medical Applications of Fayetteville, Inc., d/b/a BMA Fayetteville proposes to relocate its current facility, which includes 39 existing stations plus 3 stations previously approved in Project I.D.# M-10191-13, from its current location at 1319 Avon Street to 2610 Legion Road, Fayetteville. The applicant states that the proposed location is 2.1 miles from the current location and will easily serve the same patient population as currently served by BMA Fayetteville.

In Section III, page 34, the applicant states:

“The BMA Fayetteville facility has been operating in the same building for more than 35 years. Over the years the facility has been expanded, contracted, changed, realigned and used extensively. The physical structure for the facility is in need of replacement. ... the age of the building coupled with its extensive utilization over the years has resulted in increasing costs of maintenance on the structure.

In the early years of BMA Fayetteville, it was necessary to move the home training department to a separate building, but contiguous to the facility. This separation has required extra staff for maintenance, extra maintenance costs, and has not been

conducive to patient education efforts when in-center patients inquired about home dialysis.

The new facility will provide immediate relief to all of the above issues.”

Population to be Served

In Section IV.1, page 40, the applicant identifies the current patient origin, as illustrated in the table below.

Fayetteville Kidney Center Patient Origin as of 4/30/2014		
County	In-Center Patients	Home Patients
Cumberland	138	66
Hoke	3	4
Lee	0	1
Robeson	0	1
Total	141	72

In Section III.7, page 37, 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 2016		Operating Year 2017		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Cumberland	148.6	71.7	152.7	73.7	96.07%	96.18%
Hoke	3.0	4.0	3.0	4.0	3.05%	2.97%
Lee	0.0	1.0	0.0	1.0	0.44%	0.42%
Robeson	0.0	1.0	0.0	1.0	0.44%	0.42%
Total	151.6	77.7	155.7	79.7	100.00%	100.00%

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.7, page 35-36, the applicant provides the following assumptions for the proposed project:

- The January 2014 Semiannual Dialysis Report (SDR) indicates that as of June 30, 2013 utilization at BMA Fayetteville was 89.74% based on 140 patients dialyzing on 39 stations for a rate of 3.58 patients per station per week.
- The project is scheduled to be completed December 31, 2015
 Operating year 1 is the period from January 1, 2016 to December 31, 2016
 Operating year 2 is the period from January 1, 2017 to December 31, 2017

- The applicant projects population growth at BMA Fayetteville for the patients residing in Cumberland County at 2.8%, the Cumberland County Five Year Average Annual Change Rate as published in the January 2014 SDR.
- As of April 30, 2014 BMA Fayetteville was serving dialysis patients residing in Cumberland, Hoke, Lee and Robeson Counties. BMA typically does not demonstrate an increase in patient population residing in counties other than the host county- Cumberland. Hoke, Lee and Robeson all have operational dialysis facilities. Therefore, BMA assumes that patients from these counties are dialyzing at BMA Fayetteville by choice.

In Section III.7, page 36, the applicant provides the following methodology for the proposed project:

<i>BMA Fayetteville</i>	<i>In-Center</i>
<i>BMA begins with facility census of Cumberland County patients as of April 30, 2014.</i>	138
<i>The census is increased by 8/12 of the Cumberland County Five Year Average Annual Change Rate to December 31, 2014.</i>	$[138 \times (.028 / 12 \times 8)]$ $+138=140.6$
<i>The census is increased by the Five Year Change Rate for one year to December 31, 2015.</i>	$(140.6 \times .028) + 140.6 = 144.5$
<i>BMA adds the three in-center patients from Hoke County. This is the beginning in-center census for this project.</i>	$144.5 + 3 = 147.5$
<i>The census of Cumberland County patients is increased by the Five Year Change Rate for one year to December 31, 2016.</i>	$(144.5 \times .028) + 144.5 = 148.6$
<i>BMA adds the three in-center patients from Hoke County. This is the ending In-Center census for Operating Year 1.</i>	$148.6 + 3 = 151.6$
<i>The census of Cumberland County patients is created by the Five Year Average Annual Change Rate for one year to December 31, 2017.</i>	$(148.6 \times .028) + 148.6 = 152.7$
<i>BMA adds the three in-center patients from Hoke County. This is the ending In-Center census for Operating Year 2.</i>	$152.7 + 3 = 155.7$

In Section III. 7, page 38 BMA states that the projected year end census is rounded down to the whole number. Operating Year 1 is projected to be:

151 patients dialyzing on 42 stations = 3.6 patients per station.
 $151 / (4 \times 42) = .8988$, or 89.88%

The applicant projects to serve 151 in-center patients or 3.6 patients per station ($151 / 42 = 3.595$) by the end of Year 1 (December 31, 2016) and 155 in-center patients or 3.7 patients per station ($155 / 42 = 3.69$) by the end of Year 2 (December 31, 2017) for the proposed 42

station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Furthermore, the applicant states on page 36 that as of April 30, 2014 BMA Fayetteville was serving 138 in-center patients. The project analyst notes that if no growth was projected and the patient census held constant at 138 as of the end of project Year 1 (December 31, 2016), and the proposed three dialysis stations were added, utilization of the BMA Fayetteville facility would be 3.29 patients per station ($138 / 42 = 3.286$) which would exceed the minimum of 3.2 patients per station required by the performance standard.

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

Access to Services

In Section VI, 1(a), page 48, the applicant states:

“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. Low income and medically underinsured persons will continue to have access to all services provided by BMA.”

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed project and the extent to which all residents of the area 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.

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The applicant proposes to relocate its existing facility 2.1 miles from the current location in Fayetteville and states that the new location *“will easily serve the same patient population as currently served by BMA Fayetteville.”* The applicant demonstrates that the needs of the population presently served at BMA Fayetteville will continue to be adequately met following the proposed relocation. 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, page 39, the applicant states the following alternatives were considered prior to the submission of its application:

1) BMA could have chosen to remain within the existing structure. However, the landlord had determined that the building incurs excessive costs for maintenance. BMA lease on the property has been extended to allow development of the new facility. However, continued presence in the current location was not an option.

2) BMA considered splitting the BMA Fayetteville facility by development of two smaller dialysis facilities to serve the same patient population. However, this alternative was a much more costly proposal. Two facilities would have resulted in increased operational expenses such as utilities. Two facilities would also result in slightly higher personnel costs for clerical and receptionists. Two facilities would have resulted in higher development costs; a single structure, while larger, does afford some development cost containment.

BMA has chosen the most effective and least costly alternative for meeting the needs of the patients choosing to receive treatment at the BMA Fayetteville facility. Considering the alternatives, BMA has only one viable option: apply to relocate the entire facility.”

The applicant adequately demonstrates that the proposed alternative is its least costly or most effective alternative.

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

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

- 1. Bio-Medical Applications of Fayetteville, Inc. d/b/a BMA Fayetteville shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of Fayetteville, Inc. d/b/a BMA Fayetteville shall relocate and operate no more than forty-two (42) dialysis stations, which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of Fayetteville, Inc. d/b/a BMA Fayetteville shall install plumbing and electrical wiring through the walls for no more than forty-two (42) dialysis stations which shall include any home hemodialysis training or isolation stations.**

4. Bio-Medical Applications of Fayetteville, Inc. d/b/a BMA Fayetteville 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, page 58 the applicant states that the total capital costs of the proposed project will be \$801,333. The capital costs include \$380,000 for water treatment equipment (RO), \$302,704 for equipment and furniture and \$118,629 for other. On page 59, the applicant states that the source of the financing for the project is accumulated reserves. Exhibit 24 contains a letter dated June 16, 2014, from the Vice President of Fresenius Medical Care North America, which states:

“As Vice President, I am authorized and do hereby authorize the relocation of the entire BMA Fayetteville dialysis facility for capital costs of \$801,333. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$801,333 as may be needed for this project. I am also authorized and authorize any additional funds as may be necessary for start-up costs in the new location.”

In Section IX, page 62, the applicant projects no initial start-up costs or initial operating expenses because *“the facility will simply cease operation at the current location on one day, and open at the new location the next day.”* The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Exhibit 4, the applicant provides a copy of the most recent audited financial reports for FMC, Inc. and Subsidiaries. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$275,719,000 with \$16,597,314,000 in total assets and \$8,852,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 63, the applicant lists the following charges per treatment for each payment source:

Allowable Charges	
Payor	In-Center Charge
Private Pay	\$1,425.00

Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
VA	\$231.12
Private Pay	\$1,425.00

In Section X.1 the applicant states:

“The commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. It is industry standard for providers to have contractual relationships with various payors, resulting in less reimbursement than the stated charge.

The majority of dialysis treatments are reimbursed through Medicare or Medicaid. As noted in this application, it is expected that 91.4% of the treatments will be Medicare (includes Medicare Advantage) reimbursement rates. These rates are fixed by the payor.

BMA also notes that Medicare began the “Bundling” reimbursement program in 2010. The Bundling program provides one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As a consequence of this, the basic rate for Medicare reimbursement has been approximately \$240 per treatment.

...

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

*Table X.1-2
 Anticipated Medicare Reimbursement by Year.*

<i>Year</i>	<i>Medicare Rate</i>
<i>2014</i>	<i>\$ 239.02</i>
<i>2015</i>	<i>\$ 239.02</i>
<i>2016</i>	<i>\$229.46</i>
<i>2017</i>	<i>\$220.28</i>
<i>2018</i>	<i>\$211.47</i>
<i>2019</i>	<i>\$211.47</i>

In Sections X.2-X.4, pages 64-71, the applicant projects revenues and operating expenses for BMA Fayetteville, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$9,987,654	\$10,008,365

Total Operating Costs	\$8,380,192	\$8,489,660
Net Profit	\$1,607,462	\$1,518,705

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.

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating costs. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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Bio-Medical Applications of Fayetteville, Inc., d/b/a BMA Fayetteville proposes to relocate its entire facility of 42 stations (39 existing stations plus 3 previously approved in Project I.D.# M-10191-13) from 1319 Avon Street, Fayetteville to 2610 Legion Road, Fayetteville, a distance of 2.1 miles.

According to the January 2014 SDR, there are four ESRD facilities in Cumberland County, operating a total of 170 available stations. FMC is the parent company of all four and all four have a Fayetteville address. The table below shows the number of in-center patients as of June 30, 2013.

Name of Facility	# Certified Dialysis Stations	# In-Center Patients	Utilization by %
BMA Fayetteville	39*	140	89.74%
FMC North Ramsey	40	142	88.75%
FMC South Ramsey	51	131	64.22%
FMC West Fayetteville	40	130	81.25%
Total	170	543	79.85%

*plus 3 stations previously approved in Project I.D. # M-10191-13 for a total of 42 stations upon project completion.

The applicant adequately demonstrates the need to relocate the facility within Cumberland County. 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 nonconforming to this criterion.

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

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In Section VII.1, page 54, the applicant states that BMA Fayetteville currently employs 30.58 full time equivalent staff (FTEs). The applicant further states on page 54, that BMA Fayetteville proposes to hire 3.0 additional FTEs upon project completion. The current and proposed FTEs are illustrated in the table below.

Positions	Current FTEs	# FTEs to be Added	Total FTEs
RN	5.00	1.00	6.00
LPN			
Tech.	14.00	2.00	16.00
Nurse Assistant			
Clinical Manager	1.00		1.00
Med. Dir.			
Admin.	0.25		0.25
Dietitian	1.00		1.00
Social Worker	1.00		1.00
Home Training Nurse	4.00		4.00
Other (Specify)			
Medical Records	1.00		1.00
Chief Tech	0.33		0.33
Equipment Tech	1.50		1.50
In-Service	0.50		0.50
Clerical	1.00		1.00
Total	30.58	3.00	33.58

The applicant projects a total of 33.58 FTEs upon project completion and states on page 55 that it expects no difficulty in recruiting staff. In Section VII.10, page 57, the applicant provides a chart showing a third shift being offered Monday, Wednesday and Friday from 5:00 PM to 10:00 PM, in addition to two shifts Monday – Saturday 7 AM – 5 PM.

The following table shows the projected number of direct care staff for each shift to be offered after relocation of BMA Fayetteville.

	Times	Mon	Tue	Wed	Thur	Fri	Sat
Morning	7 AM-12 PM	10	10	10	10	10	10
Afternoon	12 PM – 5 PM	10	10	10	10	10	10
Evening	5 PM – 10 PM	3		3		3	

In Section V.4(c), page 45, and Exhibit 21 the applicant identifies the Medical Director for BMA Fayetteville 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.

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In Section V.1, page 42, the applicant lists the providers of the necessary ancillary and support services indicating whether they are provided on the premises or off site, and if off site, by whom. Cape Fear Valley Hospital will provide acute dialysis services when needed, diagnostic evaluation services, x-ray services, blood bank services, and psychological counseling. The applicant indicates that UNC Hospital will provide transplantation services and pediatric nephrology services. Vascular surgical services will be provided by Carolina Kidney Care Vascular Access Center, Village Surgical, Dr. Husain, Dr. Morfesis, Dr. Leke, Dr. Chang or Dr. Ross. Isolation for hepatitis, dialysis/maintenance, nutritional counseling, social work services and self-care training for hemodialysis, intermittent peritoneal dialysis, CAPD, and CCPD will be provided on site. All laboratory services will be provided on site by Spectra Laboratories. All other ancillary services will be provided by stated providers. The applicant states, on page 46, that it has existing professional relationships with local physicians for referrals and that it does not expect referral patterns to change. In addition, the applicant states, in Section V.6(a), page 46,

“As an active facility in Cumberland County, BMA Fayetteville enjoys the support of the medical community and community leadership. The applicant keeps the medical community apprised of developments through the relationship with Nephrology physicians who refer patients to the facility.”

See Exhibits 15, 25, and 26 for service agreements. 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. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 100 facilities in 42 North Carolina Counties (Includes our affiliations with RRI facilities); in addition, BMA has eight facilities under development or pending CON approval. ... The patient population of the BMA Fayetteville facility is comprised of the following:

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>BMA Fayetteville</i>	27.7%	22.1%	86.2%	28.6%	55.4%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 86.2% 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 BMA Fayetteville. The current in-center payor mix is illustrated in the table below.

In-Center Payor Mix as of April 30, 2014

Payor	Percentage
Commercial Insurance	5.24%
Medicare	74.66%
Medicaid	5.03%
Medicare/Medicaid	3.38%
State Kidney Program	11.66%
Other: Self/Indigent	0.03%
Total	100.00%

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 Cumberland County and statewide.

County	CY 2010 Total # Medicaid Eligibles as % of Total Population *	CY 2010 Total # Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Cumberland	18%	7.4%	20.3%
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 services offered by BMA Fayetteville. In fact, 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 and 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 does 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 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 (page 225) 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 2010 ESRD spending, by payor as follows:

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

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, race and gender as shown below:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicant demonstrates the medically underserved populations have adequate access to the services provided at BMA Fayetteville. 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;

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In Section VI.6(a), page 52, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facility 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 BMA Fayetteville as shown in the table below.

Projected Payor Mix

Payor Source	% In-Center Patients	% Home
Commercial Insurance	5.24%	13.57%
Medicare	74.66%	78.79%
Medicaid	5.03%	0.05%
Medicare/Medicaid	3.38%	1.14%
State Kidney Program	11.66%	6.45%
Other: Self/Indigent	0.03%	0.00%
Total	100.00%	100.00%

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

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

C

In Section VI.5, page 52, 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 BMA Fayetteville 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 to the Director of the Methodist University Nursing program encouraging the school to include BMA Fayetteville in its clinical rotations for nursing students. The applicant states on page 44: *“Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.”* The information provided in Section V.3 and Exhibit 19 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 applicant proposes to relocate its 42-station dialysis facility (39 current stations plus 3 stations previously approved in Project I.D.# M-10191-13) in Fayetteville, Cumberland County from the current site to a new site 2.1 miles away. According to the January 2014 SDR, there are four ESRD facilities in Cumberland County, operating a total of 170 available stations. FMC is the parent company of all four and all four have a Fayetteville address. The table below shows the number of in-center patients as of June 30, 2013.

Name of Facility	# Certified Dialysis Stations	# In-Center Patients	Utilization by Percent
BMA Fayetteville	39*	140	89.74%
FMC North Ramsey	40	142	88.75%
FMC South Ramsey	51	131	64.22%
FMC West Fayetteville	40	130	81.25%
Total	170	543	79.85%

*plus 3 stations previously approved in Project I.D. # M-10191-13 for a total of 42 stations upon project completion.

In Section V.7, pages 46-47, the applicant discusses the impact of the project on competition as it relates to promoting cost-effectiveness, quality and access. On page 46, the applicant states:

“BMA does not expect this proposal to have effect on the competitive climate 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. The majority of our patients rely

upon Medicare and Medicaid to cover the expense of their treatments. In this application BMA projects that 94.7% of the In-center patients will be relying upon either Medicare or Medicaid.”

See also Sections II, III, V, VI and VII. The information provided by the applicant in these sections is reasonable and credible and adequately demonstrates that the expected effects of relocating the existing dialysis facility will have a positive impact on cost-effectiveness, quality and access to the proposed service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to relocate a 42 dialysis station facility within Cumberland County and that it is a cost effective alternative to meet that need;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality of care in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination with the existing healthcare system in Sections V and VII is reasonable and credible and demonstrates the quality of care;
- The applicant has and will continue to provide adequate access to medically underserved populations. The applicant provides the following table from Section VI.1(a), page 49, to demonstrate that medically underserved populations will continue to have adequate access to BMA Fayetteville’s dialysis services, as illustrated below:

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Fayetteville	27.7%	22.1%	86.2%	28.6%	55.4%

“Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 86.2% of the facility treatment reimbursement is from Medicare.”

The applicant further states on page 48,

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

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 services. Therefore, the application is conforming to this criteria

(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

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Fayetteville 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) G.S. 131E-183(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services 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- On page 11, the applicant refers to Table A of the January 2014 SDR, which shows a utilization rate 89.74% for BMA Fayetteville (3.5 patients per station ($140 / 39 = 3.589$)).

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant provides the mortality rates as 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, 58 patients were home trained and 72 patients were on home dialysis in 2013.
- (4) *The number of transplants performed or referred;*
- C- In Section II.1, page 11, the applicant states BMA Fayetteville referred 6 transplants in 2012 and 11 in 2013. Five transplants were performed in 2012 and four 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 10 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 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 with an infectious disease in 2012 or 2013.

(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- BMA Fayetteville 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- BMA Fayetteville is an existing facility.

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

-C- On page 12, the applicant states that Exhibit 30 contains a letter from the developer indicating that power and water are available at the proposed site.

(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 BMA Fayetteville.

(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- BMA Fayetteville proposes to develop the replacement facility at 2610 Legion Road. The building will be developed by Foresight Development LLC. Exhibit 30 contains a letter of commitment to develop the facility at this location.

(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 36-39, the applicant provides the methodology and assumptions used to project patient origin, as illustrated in the table below:

County	Operating Year 1		Operating Year 2		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Cumberland	148.6	71.7	152.7	73.7	96.07%	96.18%
Hoke	3.0	4.0	3.0	4.0	3.05%	2.97%
Lee	0.0	1.0	0.0	1.0	0.44%	0.42%
Robeson	0.0	1.0	0.0	1.0	0.44%	0.42%
Total	151.6	77.7	155.7	79.7	100.00 %	100.00%

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

-C- BMA Fayetteville projects that more than 96% of the patient population to be served reside in Cumberland County.

(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.9, page 16, 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- BMA Fayetteville 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.

-NA- BMA Fayetteville is not proposing to increase the number of CON approved stations at the proposed relocation site.

(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 13-15, and Section III.7, pages 35-37. The applicant projects a 2.8% increase in its current Cumberland County patient utilization using the county Five Year Average Annual Change Rate.

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 20, the applicant states, *“Patients will be referred to Cape Fear Valley Hospital.”*

(2) maintenance dialysis;

-C- In Section II.1, page 20, 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 20, the applicant states, *“The facility will provide space and nursing staff supervision for patients desiring to do dialysis self-care training.”*

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

C- In Section II.1, page 20, the applicant states, *“Patients who are candidates for home dialysis will be referred to the facility home training department.”*

(5) x-ray services;

C- In Section II.1, page 21, the applicant states, *“Patients in need of X-ray services will be referred to Cape Fear Valley Hospital.”*

- (6) laboratory services;
 - C- In Section II.1, page 21, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 15 for the laboratory services agreement with Spectra Laboratories.
- (7) blood bank services;
 - C- In Section II.1, page 21, the applicant states, “*Patients in need of blood transfusion will be referred to Cape Fear Valley Hospital.*”
- (8) emergency care;
 - C- In Section II.1, page 21, 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 21, the applicant states, “*Patients admitted to hospital will be referred to Cape Fear Valley Hospital.*”
- (10) vascular surgery for dialysis treatment patients;
 - C- In Section II.1, page 21, the applicant states, “*Patients will be referred to Carolina Kidney Care Access Center; Village Surgical; or one of the following surgeons: Dr. Husain, Dr. Morfesis, Dr. Leke, Dr. Chang, or Dr. Ross.*”
- 11) transplantation services;
 - C- In Section II.1, page 21, 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 21, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the local Division of Vocational Rehabilitation.*”
- (13) transportation.

- C- In Section II.1, page 21, 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 22, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 55, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100).

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

- C- In Section VII.5, page 55, 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, and that staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 9 contains an outline of the training program and Exhibit 10 contains the outline of continuing education information.