

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 3, 2012

PROJECT ANALYST: Jane Rhoe-Jones

SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8776-12 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC West Fayetteville/ Relocate three dialysis stations from BMA Fayetteville to FMC West Fayetteville for a total of 40 stations at FMC West Fayetteville / Cumberland County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC West Fayetteville, whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), proposes to relocate three existing dialysis stations from BMA Fayetteville to FMC West Fayetteville for a total of 40 dialysis stations at FMC West Fayetteville upon completion of the project. FMC West Fayetteville is located at 6959 Nexus Court, Fayetteville, North Carolina. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. Therefore, neither of the two need methodologies in the 2012 State Medical Facilities Plan (SMFP) is applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a new institutional health service for which there is a need determination in the 2012 SMFP. However, Policy ESRD-2 is applicable to this review.

Policy ESRD-2: Relocation of Dialysis Stations states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations 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 North Carolina Semiannual 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 North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate three existing dialysis stations within Cumberland County. Consequently, there is no change in the inventory of dialysis stations in Cumberland County, thus, the application is consistent with Policy ESRD-2 and 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 North Carolina, Inc. (BMA) d/b/a FMC West Fayetteville, proposes to relocate three existing dialysis stations from BMA Fayetteville to FMC West Fayetteville for a total of 40 dialysis stations at FMC West Fayetteville upon completion of the project. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section III.7, page 38, the applicant projects the number of in-center dialysis patients to be served in the first two years of operation following project completion, as illustrated in the following table:

County	Operating Year 1 Census	Operating Year 2 Census	County Patients as a Percent of TOTAL	
			Year 1	Year 2
Cumberland	122.6	127.3	94.60%	94.79%
Hoke	5.0	5.0	3.86%	3.72%
Scotland	1.0	1.0	0.77%	0.74%
Sampson	1.0	1.0	0.77%	0.74%
TOTAL	129.6	134.3	100.00%	100.00%

On page 33, the applicant states that this project will provide greater geographic accessibility for patients living closer to this facility - FMC West Fayetteville. On page 12, the applicant states:

“BMA will not project any increase in the patient population of patients residing in other counties. FMC West Fayetteville currently has a total of seven patients from Hoke, Scotland and Sampson Counties. Each of these counties has at least one operational dialysis facility. BMA assumes that patients from Hoke, Scotland, and Sampson Counties are dialyzing at FMC West Fayetteville as a function of patient choice.”

The applicant adequately identifies the population to be served.

Need Analysis

In Section 111.3, page 33, the applicant states that the BMA Fayetteville facility is at capacity. Exhibit 22 of the application contains 10 support letters from patients indicating that FMC West Fayetteville is closer to their residence. The applicant projects that five of ten BMA Fayetteville patients having written letters of support for this project will transfer to FMC West Fayetteville facility.

The letters of support state in part:

“Patients on dialysis have many hardships, especially arranging transportation three days per week. The location of the FMC West Fayetteville facility is much more convenient for me and is closer to my home. Dialyzing at FMC West Fayetteville would mean less time involved in transportation and more time for me, and my needs.”

In Section II.7, page 12, the applicant states:

“BMA assumes that the patient population of FMC West Fayetteville will increase at a rate commensurate with the Cumberland County Five Year Average Annual Change Rate as published in the January 2012 SDR. That rate is 3.8%.”

The following table from page 14 illustrates the applicant’s assumptions and methodology used to project the utilization at FMC West Fayetteville.

FMC WEST FAYETTEVILLE	
Cumberland County	In-Center

<i>BMA begins with Cumberland County patients utilizing the FMC West Fayetteville dialysis facility as of December 31, 2011.</i>	109
<i>BMA projects growth of this patient population forward for 12 months using the Cumberland County Five Year Average Annual Change Rate for 12 months to December 31, 2012.</i>	$(109 \times .038) + 109 = 113.1$
<i>BMA adds the five patients projected to transfer to the facility upon completion of the project. This is the beginning census for the project.</i>	$113.1 + 5 = 118.1$
<i>BMA projects the patient population for 12 months at 3.8%. This is the projected Cumberland County patient population for December 31, 2013. This is the end of Operating Year 1.</i>	$(118.1 \times .038) + 118.1 = 122.6$
<i>BMA adds the seven patients from the other counties. This is the ending census for Operating Year 1.</i>	$122.6 + 7 = 129.6$
<i>BMA projects the patient population forward for 12 months at 3.8%. This is the projected Cumberland County patient population for December 31, 2014. This is the end of Operating Year 2.</i>	$(122.6 \times .038) + 122.6 = 127.3$
<i>BMA adds the seven patients from other counties. This is the ending census for Operating Year 2.</i>	$127.3 + 7 = 134.3$

The applicant projects to serve 129 in-center patients by the end of Year One or 3.2 patients per station [$129 / 40 = 3.23$]; and 134 in-center patients by the end of Year Two or 3.4 patients per station [$134 / 40 = 3.35$]. The projected utilization rate is 81% at the end of Year One [$129/160 = 0.806$] and 84% in Year Two [$134 / 160 = 0.838$]. Projected utilization at FMC West Fayetteville is based on reasonable and supported assumptions.

In summary, the applicant adequately identifies the population proposed to be served and demonstrates the need to relocate three existing dialysis stations from BMA Fayetteville to FMC West Fayetteville. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to transfer three existing dialysis stations from BMA Fayetteville to FMC West Fayetteville. In Section III, pages 35-36, the applicant discusses how the needs of dialysis patients at BMA Fayetteville will continue to be met after the transfer of stations. BMA Fayetteville is certified for 38 dialysis stations.

The applicant reports 127 patients at BMA Fayetteville as of December 31, 2011 and as reported in the January 2012 SDR. The patient origin is comprised of Cumberland County patients (121), Hoke County patients (4), Harnett County patients and Sampson County patients (1 each). The applicant discusses projections for the in-center patient population on pages 35-36. With 35 dialysis stations and 127 dialysis patients after the transfer, the

applicant projects the utilization will be 3.63 in-center patients per dialysis station (127 patients / 35 dialysis stations = 3.63).

The applicant also discusses the impact of transferring stations on the third dialysis shift at BMA Fayetteville. Even so, the utilization per station is projected to be 3.26 patients per dialysis station (127 total patients – 13 third shift patients = 114 patients / 35 dialysis stations = 3.26).

Further, the applicant provides ten letters of support of which five indicated they will transfer to the FMC West Fayetteville facility. Relocating three stations will add service capacity to FMC West Fayetteville and improve access for dialysis patients in the service area.

The applicant states,

“Relocation of these three stations will not adversely affect the patient population of BMA Fayetteville, and the facility will continue to be available for new dialysis patients.”

The applicant demonstrates that the needs of the population presently served at BMA Fayetteville will continue to be adequately met following relocation of three stations to FMC West Fayetteville. 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 40, the applicant discusses alternatives to the proposed project that include: not relocating the three dialysis stations and transferring fewer dialysis stations. The applicant concludes that transferring three dialysis stations to FMC West Fayetteville is the most effective and least costly alternative. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (13), (14), (18a) (20); and the Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200. Therefore, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC West Fayetteville shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC West Fayetteville shall be certified for no more than 40 dialysis stations, which shall include any home hemodialysis or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC West**

Fayetteville shall install plumbing and electrical wiring through the walls for no more than 40 dialysis stations which shall include any isolation stations.

- 4. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC West Fayetteville shall not develop or offer home dialysis services as a part of this project and will provide back-up hemodialysis treatments to home patients in temporary hemodialysis.**
 - 5. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC West Fayetteville shall provide a letter from the Medical Director affirming his/her willingness to serve as Medical Director of the facility, prior to issuance of the certificate of need.**
 - 6. After certification of the three stations relocated from BMA Fayetteville to FMC West Fayetteville with this project, BMA Fayetteville shall take the steps necessary to decertify three dialysis stations for a total of no more than 35 stations at BMA Fayetteville.**
 - 7. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC West 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, the applicant projects no capital costs associated with this project. The applicant states that the project will be financed through accumulated reserves, however, the project analyst concludes that it is reasonable to assume statements regarding financing the project are in error; since the project requires no capital costs. Exhibit 24 contains a letter from the VP of Fresenius Medical Care Holdings, Inc., which confirms no capital costs for the project and states in part:

“BMA is submitting a Certificate of Need Application to transfer three dialysis from BMA Fayetteville to FMC West Fayetteville in Cumberland County. The project does not require any capital expenditures on behalf of BMA.”

In Section X, page 61, the applicant provides the allowable charge per treatment by each payor source for FMC West Fayetteville, as follows:

FMC WEST FAYETTEVILLE	
Payor	In-Center

Commercial Insurance	\$1375.00
Private Pay	\$1375.00
Medicare	\$234.00
VA	\$146.79
Medicaid	\$137.29

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X, pages 62 and 65, the applicant projects that revenue will exceed operating expenses in each of the first two operating years.

FMC WEST FAYETTEVILLE		
	Year 1	Year 2
Revenue	\$6,254,990	\$6,451,997
Operating Costs	\$5,332,616	\$5,527,079
Total Revenue	\$922,374	\$924,918

The assumptions used in preparation of the pro formas, including the number of projected treatments are reasonable. See Section X, pages 62-65, for the applicant's assumptions. In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable 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.

C

BMA proposes to relocate three existing dialysis stations from BMA Fayetteville to FMC West Fayetteville for a total of 40 stations at FMC West Fayetteville upon project completion. FMC West Fayetteville is currently operating at 109 patients per station. The applicant does not propose to add new dialysis stations to an existing facility or to establish a new dialysis facility. The applicant adequately demonstrates that that BMA Fayetteville patients are willing to transfer to FMC West Fayetteville based on letters of support; thus creating a need to relocate stations to that facility. The applicant discusses projections for the in-center patient population on pages 35-36. With 35 dialysis stations and 127 dialysis patients after the transfer, the applicant projects the utilization will be 3.63 in-center patients per station (127 patients / 35 dialysis stations = 3.63). Therefore, the applicant adequately demonstrates that the proposed project would not result in 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.

CA

In Section VII, page 53, the applicant provides projected staffing for FMC West Fayetteville upon project completion, as illustrated in the following table:

FMC WEST FAYETTEVILLE	
Full-Time Equivalent (FTE) Positions	
RN	8.00
Tech	18.00
Clinical Mgr.	1.00
Area Mgr.	.25
Dietician	1.00
Social Worker	1.00
Chief Tech	.10
Equip Tech	.90
In-Service	.25
Clerical	2.00
Total FTEs	32.50

The applicant projects a total of 32.5 FTE positions upon project completion and states on page 55 that there is no difficulty expected in recruiting staff. In Section V.4, page 46, the applicant identifies the current Medical Director. The applicant failed to provide a letter from the Medical Director indicating his willingness to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided with the exception of a letter from the Medical Director. Therefore, the application is conforming to this criterion as conditioned in Criterion (4).

- (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, page 43, the applicant lists the providers of the necessary ancillary and support services. On pages 46, the applicant discusses relationships with other local healthcare and social service providers. Exhibit 21 contains a letter of support from an area physician. The applicant adequately demonstrates that 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 provides the payor mix for services currently provided at the facility. The applicant states:

“... 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 applicant states that 79.3% of dialysis services were provided to Medicare and/or Medicaid patients in the year prior to submitting this application. An additional 10.5% of services were provided by VA sponsorship. See the following table, from page 49:

FMC WEST FAYETTEVILLE	
PAYOR	% OF TOTAL PATIENTS
Medicare	74.7%
VA	10.5%
Commercial Insurance	10.1%
Medicaid	4.6%
Self/Indigent	0.1%
TOTAL	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2008-2009, respectively. The data in the table were obtained on April 12, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Cumberland County	18.0%	7.4%	20.3%
Statewide	17.0%	6.7%	19.7%

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 FMC West Fayetteville of Cumberland County.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those

actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of April 12, 2012, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' 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.

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at FMC West Fayetteville of Cumberland County. 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 civil rights access complaints filed against FMC West Fayetteville within the last 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 dialysis services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. 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 32, the applicant states:

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

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, page 45, the applicant states:

“Exhibit 19 contains a letter from Sam Long, Area Manager, requesting to establish a Health Occupations Agreement with Fayetteville Technical Community College. ...”

However, the letter in Exhibit 19 is actually addressed to Methodist University in Fayetteville stating the request to establish a clinical rotation for student nurses at the FMC West Fayetteville dialysis facility.

The information provided in Section V3. and Exhibit 19 is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

See Sections II, III, V, VI, and VII. of the FMC West Fayetteville application. In particular, see Section V.7, pages 46-47 in which FMC West Fayetteville discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness,

quality and access to dialysis services in Cumberland County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to relocate three existing dialysis stations from BMA Fayetteville to FMC West Fayetteville and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations. The proposed project improved geographic access to patients who wish to transfer their care to a closer facility. The patient population of FMC West Fayetteville is shown below.

FMC West Fayetteville					
	Racial Minorities	Medicare	Women	Elderly	Medicaid/ Low Income
FMC West Fayetteville	82.8%	75.9%	47.6%	39.7%	22.4%

*The Medicare percentage indicates patients who receive some category of Medicare benefit only, not that 75% of the facility reimbursement is from Medicare.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMC West Fayetteville operated in compliance with all Medicare conditions of participation within the 18 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- See Section IV, pages 41-42, and Exhibit 2 (copy of the January 2012 SDR, Tables A and B).

.2202(a)(2) Mortality rates;

-C- See Section IV, page 41.

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

-C- See Section IV, page 41.

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

-C- See Section IV, page 41.

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

-C- See Section IV, page 41.

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

-C- See Section IV, page 41.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- See Section IV, page 42.

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

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

- NA-
.2202(b)(2) FMC West Fayetteville is an existing facility.
For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA-
.2202(b)(3) FMC West Fayetteville is an existing facility.
For new or replacement facilities, documentation that power and water will be available at the proposed site.
- NA-
.2202(b)(4) FMC West Fayetteville is an existing facility.
Copies of written policies and procedures for back up for electrical service in the event of a power outage.
- C-
.2202(b)(5) See Exhibit 12.
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-
.2202(b)(6) FMC West Fayetteville is an existing facility.
Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.
- C-
See Section II, page 12; Section VII, page 54; Section XI.6(g), page 69; and Exhibits 11 and 12.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C-
See Section III.7, pages 37-39.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA-
.2202(b)(9) FMC West Fayetteville is an existing facility.
A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.
- C-
In Section II, page 15, the applicant states: “BMA will admit and provide

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC West Fayetteville is an existing facility.

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

-C- In Section II, pages 12-14 and 15-18, and Section III, pages 33-39, the applicant documents the need for the additional stations.

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

-C- In Section II, pages 12-14 and 15-18, and Section III, pages 33-39, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*

- C- See Section V, page 43.
- .2204(2) *Maintenance dialysis;*
- C- See Section V, page 43.
- .2204(3) *Accessible self-care training;*
- C- See Section II, page 21 and Section V, page 43.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section II, page 21 and Section V, pages 44-45.
- .2204(5) *X-ray services;*
- C- See Section V, page 43.
- .2204(6) *Laboratory services;*
- C- See Section V, page 43.
- .2204(7) *Blood bank services;*
- C- See Section V, page 43.
- .2204(8) *Emergency care;*
- C- See Section V, page 43.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- See Section V, page 43.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V, page 43.
- .2204(11) *Transplantation services;*
- C- See Section V, page 43.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- See Section V, page 43.
- .2204(13) *Transportation*
- C- See Section V, page 43.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- See Section II, page 22. Also, in Section VII, page 53, the applicant provides the proposed staffing. The applicant states on page 54 that the facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section VII, page 54, and Exhibits 14 and 15.