

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 29, 2013
PROJECT ANALYST: Fatimah Wilson
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-10052-12 / Bio-Medical Applications of North Carolina d/b/a FMC Southwest Charlotte / Develop a new 10-station dialysis facility in Charlotte by relocating four existing dialysis stations from BMA Charlotte and six existing dialysis stations from BMA Nations Ford / Mecklenburg 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 Southwest Charlotte, whose parent company is Fresenius Medicare Holdings Inc., (FMC), proposes to establish a new 10-station dialysis facility to provide in-center hemodialysis and home training for peritoneal dialysis, to be located at 10000 South Tryon Street in Charlotte, Mecklenburg County. The applicant proposes to relocate the following existing dialysis stations from existing dialysis facilities in Mecklenburg County:

- ◆ Four dialysis stations from the BMA Charlotte facility; and
- ◆ Six stations from the BMA Nations Ford facility.

Bio-Medical Applications of North Carolina, Inc. is a subsidiary of Fresenius Medical Care Holdings, Inc. BMA will own the dialysis stations proposed in this application, and an unaffiliated property developer will purchase the land and develop the building. BMA will lease the building from the developer. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. BMA proposes this in-

county relocation of dialysis stations in order to enhance geographical accessibility of dialysis services in Southwestern Charlotte. This project is scheduled for completion on July 1, 2015. In this application, the applicant proposes to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2012 *State Medical Facilities Plan* (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because neither need methodology is applicable to the review. However, Policy ESRD-2 is applicable to this review. Policy ESRD-2 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 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 proposes to relocate 10 certified dialysis stations within Mecklenburg County in order to develop a new 10-station dialysis facility. Consequently, there is no change in inventory in Mecklenburg County, so the application is consistent with Policy ESRD-2 of the 2012 SMFP and is therefore conforming to this criterion.

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Southwest Charlotte proposes to relocate four (4) dialysis stations from BMA Charlotte and six (6) dialysis stations from BMA Nations Ford to establish a new 10-station dialysis facility to provide in-center dialysis and home training for peritoneal dialysis in Mecklenburg County.

In Section III.3(b), page 41, the applicant is expected to provide treatment for 36 dialysis patients at the end of the first year of operations. This project is scheduled for completion on July 1, 2015. 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 49, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

FMC SOUTHWEST CHARLOTTE	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Mecklenburg	33.1	3.0	35.0	6.0	92%	93%
South Carolina	3.0	0.0	3.0	0.0	8%	7%
Total	36.1	3.0	38.0	6.0	92%	93%

On page 49, the applicant states that Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole and that financial projections and utilization are rounded down to the whole number.

The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant proposes to relocate 10 certified dialysis stations from existing facilities in Mecklenburg County to develop a new facility in the same county and projects that the stations will be utilized at 90% by the end of the first year of operation [36 patients / 10 stations = 3.60; 36 / (4 X 10) = 90 or 90%].

In Section II, page 14, the applicant states that BMA is proposing development of this facility to enhance geographic access for the ESRD patient population of southwestern Charlotte and southern Mecklenburg County. The applicant states that the location of the facility will be very convenient for patients from South Carolina who choose to dialyze at a BMA facility in Mecklenburg County. In Section II, page 15 and Section III, page 47, the applicant also states there is a need to offer a second location for home dialysis patients in the Charlotte area due to the increasing home patient population far surpassing the Mecklenburg County Five Year Average Annual Change Rate.

In Section III.7, pages 46 - 48, the applicant presents a more detailed methodology along with its assumptions for projecting to serve 36 in-center patients by the end of the second year of operation. The applicant states:

“Assumptions

1. *“BMA assumes that patients signing letters of support for this project will transfer to the new facility upon certification. BMA has included 30 patients letters of support in Exhibit 22.*
2. *BMA assumes that the patient population supporting this project will increase at a rate commensurate with the Mecklenburg County Five year*

Average Annual Change Rate as published in the July 2012 SDR. That rate is 5.6%. BMA will project this patient population to increase starting October 1, 2012. This is the first day of the review period associated with this project.

- 3. BMA assumes that some home dialysis patients residing on the south side of Charlotte will transfer their care to the new FMC Southwest Charlotte home training program. BMA will offer very conservative estimates of the number of patients to be served by the home therapies section of FMC Southwest Charlotte. This is not to suggest that BMA will restrict the number of home dialysis patients. Rather, for purposes of this application BMA does not intent to overstate projections.*
- 4. The patient letters of support for this project include three South Carolina residents currently dialyzing at BMA Nations Ford. BMA assumes that these patients will transfer their care to the new facility as is indicated by their support for this project. BMA will not project any increase in this segment of the patient population. These three patients are added to the projected population to be served at appropriate points in time.*
- 5. BMA also notes that the performance rules for dialysis facilities do not require all patients to be residents of the State. Rather, 10A NCAC 14C .2203(a) only requires that BMA project to serve 3.2 patients per station as of the end of the first operating year. As will be demonstrated within this application, BMA projects to serve 3.2 patients per station as of the end of the first operating year.”*

Methodology In-Center

<i>BMA begins with the 27 Mecklenburg County hemodialysis patients who have signed letters of support for this project.</i>	27
<i>BMA projects this patient population forward for 3 months from October 1, 2012 to December 31, 2012.</i>	$[27 \times (.056 / 12 \times 3)] + 27 = 27.4$
<i>BMA projects this population forward for 12 months to December 31, 2013.</i>	$(27.3 \times .056) + 27.3 = 28.9$
<i>BMA projects this population forward for 12 months to December 31, 2014.</i>	$(28.9 \times .056) + 28.9 = 30.5$
<i>BMA projects this population forward for 6 months to June 30, 2015.</i>	$[30.5 \times (.056 / 12 \times 6)] + 30.5 = 31.4$
<i>BMA will assume that the census on June 30, 2015 is the same as the census on July 1, 2015. BMA adds the 3 South Carolina patients. This is the beginning census for this project, July 1, 2015.</i>	$31.4 + 3 = 34.4$
<i>BMA projects the Mecklenburg patient population forward to June 30, 2016.</i>	$(31.4 \times .056) + 31.4 = 33.1$
<i>BMA adds the 3 South Carolina patients to determine the projected patient population for the end of Operating Year 1.</i>	$33.1 + 3 = 36.1$
<i>BMA projects the Mecklenburg patient population forward to June 30, 2017.</i>	$(33.1 \times .056) + 33.1 = 35.0$
<i>BMA adds the 3 South Carolina patients. This is the projected patient population for the end of Operating Year 2.</i>	$35.0 + 3 = 38.0$

Methodology Home Patients

It has been BMA experience that, generally speaking, dialysis patients desire to dialyze at a facility close to their residence location. Home patients likewise prefer to have their monthly clinic visits at a facility in close proximity to their residence location. Home patients will generally only require one visit per month to the home training facility.

In this case, BMA is proposing to offer a second location for home dialysis patients in the Charlotte area. BMA has [sic] traditionally offered only a single location for home training—this was at the BMA Charlotte facility. However, the home patient population is increasing at a rate far surpassing the Mecklenburg County Five Year Average Annual Change Rate for the ESRD patient population. The following Table includes information extracted from the respective SDR reports for dates indicated. BMA has calculated an average annual change rate for the home patient population of Mecklenburg County using the methodology which DHSR/Medical Facilities Planning Section employs to determine the Five Year Average Annual Change Rate for each County in NC.

SDR	Jul-08	Jul-09	Jul-10	Jul-11	Jul-12
-----	--------	--------	--------	--------	--------

<i>Census</i>	<i>12/31/2007</i>	<i>12/31/2008</i>	<i>12/31/2009</i>	<i>12/31/2010</i>	<i>12/31/2011</i>
<i>Home Pts</i>	<i>84</i>	<i>84</i>	<i>95</i>	<i>129</i>	<i>139</i>
<i>Change</i>		<i>0</i>	<i>11</i>	<i>34</i>	<i>10</i>
<i>% Change</i>		<i>0</i>	<i>0.131</i>	<i>0.358</i>	<i>0.142</i>

The above demonstrates that the home patient population of Mecklenburg County is increasing at a rate more than double the ESRD patient population of Mecklenburg County as a whole. Based upon this growth, and the residence location of existing home patients, BMA expects home dialysis patients to choose the new FMC Southwest Charlotte facility.”

The applicant projects to serve 36 in-center patients or 3.6 patients per station by the end of Year 1 and 38 in-center patients or 3.8 patients per station by the end of Year 2 for the proposed 10-station facility. This exceeds the minimum 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

The applicant states on pages 15 and 47 that 27 Mecklenburg County hemodialysis patients who have signed letters of support for this project will transfer their treatment to the proposed FMC Southwest Charlotte facility when it is operational. In Section II, page 14, and Section III, page 46, the applicant states:

“BMA assumes that patients signing letters of support for this project will transfer to the new facility upon certification. BMA has included 30 patient letters of support in Exhibit 22.”

Exhibit 22 contains 30 letters signed by existing BMA patients as evidence of those patients’ willingness to transfer their care to FMC Southwest Charlotte when the facility is certified. Each letter includes the patient name, the name of the dialysis facility in which the patient currently receives treatment, and the county and ZIP code of the patient residence as illustrated in the following table:

PATIENT’S	PATIENT’S	CITY	CURRENT DIALYSIS	# LETTERS
-----------	-----------	------	------------------	-----------

ZIP CODE	COUNTY OF RESIDENCE		FACILITY/COUNTY	SIGNED
29710	York	Clover, SC	BMA Charlotte	1
29715	York	Fort Mill, SC	BMA Nations Ford	1
29715	Lancaster	Fort Mill, SC	BMA Nations Ford	1
29707	Lancaster	Fort Mill, SC	BMA Nations Ford	1
28278	Mecklenburg	Charlotte	BMA Nations Ford	1
28273	Mecklenburg	Charlotte	BMA Nations Ford	12
28278	Mecklenburg	Charlotte	BMA Beatties Ford	1
28270	Mecklenburg	Charlotte	BMA Charlotte	1
28273	Mecklenburg	Charlotte	BMA Charlotte	2
28278	Mecklenburg	Charlotte	BMA Charlotte	2
28210	Mecklenburg	Charlotte	BMA Charlotte	1
28277	Mecklenburg	Charlotte	BMA Charlotte	1
28214	Mecklenburg	Charlotte	BMA Nations Ford	1
28217	Mecklenburg	Charlotte	BMA Nations Ford	3
28269	Mecklenburg	Charlotte	BMA Nations Ford	1
Total Letters				30
Total Letters from Out of County Residents				4

Zip Codes researched using the United States Postal Service website www.usps.com

The applicant previously stated that the facility will begin with a census of 27 in-center patients. The table above is reflective of support letters found in Exhibit 22 and demonstrates that at least 30 patients have expressed interest in transferring their treatment to the new facility; therefore, a beginning census of 27 patients is reasonable and has been demonstrated.

Access to Services

In Section IV, page 59, the applicant states that BMA currently operates 93 facilities in 40 North Carolina Counties, which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 84.7% of its patients will be covered by Medicare, Medicaid or VA. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has to develop a new 10-station dialysis facility 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.

C

The applicant proposes to establish a new 10-station dialysis facility in Charlotte by relocating existing dialysis stations from two existing facilities in the same county. In Section III.3, page 39, the applicant states:

“This relocation of dialysis stations is necessary and appropriate in order to enhance geographical accessibility of dialysis services in southwestern Charlotte.

BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence. Mecklenburg County has the largest ESRD patient population of any county in North Carolina. Currently there are 15 dialysis facilities (14 operational and one under development – DaVita Mint Hill) within Mecklenburg County. These facilities are comprised of 377 dialysis stations (source: July 2012 SDR). However, there is not a dialysis facility located within southwest Charlotte. ...”

In Section III.3(c), pages 42 – 45, the applicant describes the impact of the proposed relocation of stations from each facility that will donate stations to the proposed FMC Southwest Charlotte facility. On pages 42 – 43, with regard to the BMA Charlotte facility, the applicant states:

“BMA Charlotte

BMA Charlotte was providing dialysis treatment to 123 in-center dialysis patients as of June 30, 2012. Each of these was a Mecklenburg County resident. The following table will demonstrate growth of this patient population through June 30, 2015, the day prior to projected certification of the project. BMA expects that six patients will transfer their care upon completion of the project.”

In projecting utilization of the BMA Charlotte facility following the station relocation and patient transfer, the applicant states that all 123 in-center dialysis patients at the facility were residents of Mecklenburg County. See the following table from page 42 of the application:

BMA begins with the 123 Mecklenburg County hemo-dialysis patients.	123
BMA projects this patient population forward for 3 months from October 1, 2012 to December 31, 2012.	$[123 \times (.056 / 12 \times 3)] + 123 = 124.7$
BMA projects this population forward for 12 months to December 31, 2013.	$(124.7 \times .056) + 124.7 = 131.7$
BMA projects this population forward for 12 months to December 31, 2014.	$(131.7 \times .056) + 131.7 = 139.1$
BMA projects this population forward for 6 months to June 30, 2015.	$[139.1 \times (.056 / 12 \times 6)] + 139.1 = 143$
BMA subtracts the six patients projected to transfer to the new center.	$143 - 6 = 137$

As shown in the table above, the applicant projects to serve 137 dialysis patients on 36 dialysis stations, a utilization rate of 3.81 patients per station at the BMA Charlotte facility upon project completion ($137 / 36 = 3.8055$); $137 / (4 \times 36) = 0.951$, or 95.1%. On pages 42 the applicant states that BMA Charlotte operates a third, or evening dialysis shift. Assuming that these patients would continue to dialyze on the evening shift, the resultant utilization for traditional shifts is reduced as following:

$$137 - 15 \text{ evening shift patients} = 122$$

$$122 \text{ patients dialyzing on 36 stations} = 3.38 \text{ patients per station}$$

$$122 / (4 \times 36) = 0.847, \text{ or } 84.7\%$$

The applicant demonstrates that the remaining dialysis stations at the BMA Charlotte facility will continue to be adequately utilized following the proposed relocation.

In Section III.3(c), pages 43 – 45, the applicant describes the impact of the proposed relocation of stations from the BMA Nations Ford facility:

“BMA Nations Ford

BMA Nations Ford was providing dialysis treatment to 96 in-center dialysis patients as of June 30, 2012. Each of these was a Mecklenburg County resident. The following table will demonstrate growth of this patient population through June 30, 2015, the day prior to projected certification of the project. BMA expects that six [sic] patients will transfer their care upon completion of the project.”

In projecting utilization of the BMA Nations Ford facility following the station relocation and patient transfer, the applicant states that all 96 in-center dialysis patients at the facility were residents of Mecklenburg County. See the following table from page 42 of the application:

BMA begins with the 96 Mecklenburg County hemo-dialysis patients.	96
BMA projects this patient population forward for 3 months from October 1, 2012 to December 31, 2012.	$[96 \times (.056 / 12 \times 3)] + 96 = 97.3$
BMA projects this population forward for 12 months to December 31, 2013.	$(97.3 \times .056) + 97.3 = 102.8$
BMA projects this population forward for 12 months to December 31, 2014.	$(102.8 \times .056) + 102.8 = 108.6$
BMA projects this population forward for 6 months to June 30, 2015.	$[108.6 \times (.056 / 12 \times 6)] + 108.6 = 111.6$
BMA subtracts the six patients projected to transfer to the new center.	$111.6 - 22 = 89.6$, rounded to 90

As shown in the table above, the applicant projects to serve 90 dialysis patients on 18 dialysis stations, a utilization rate of 3.81 patients per station at the BMA Nations Ford facility upon project completion ($90 / 18 = 5$); $90 / (4 \times 18) = 1.25$, or 125%. On pages 43 the applicant states that BMA Nations Ford operates a third, or evening dialysis shift. Assuming that these patients would continue to dialyze on the evening shift, the resultant utilization for traditional shifts is reduced as following:

$$90 - 12 \text{ evening shift patients} = 78$$

$$78 \text{ patients dialyzing on 18 stations} = 4.3 \text{ patients per station}$$

$$78 / (4 \times 18) = 1.08, \text{ or } 108.3\%$$

The applicant demonstrates that the remaining dialysis stations at the BMA Nations Ford facility will continue to be adequately utilized following the proposed relocation.

The applicant proposes to develop a new 10-station dialysis facility in Charlotte in Mecklenburg County by relocating existing stations within the county. The applicant adequately demonstrates that the two facilities from which dialysis stations would be transferred would be adequately utilized following the station relocation. Thus, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed dialysis station relocation, including services to the medically underserved. 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.

C

In Section III.9, page 50, the applicant states the alternatives it considered prior to submitting this application:

- 1) BMA considered asking patients to transfer to other facilities in the Mecklenburg County area. This option removes patient choice and is the least likely option short of a major catastrophe which would remove the facility from operation.

- 2) BMA could not apply for fewer expansion stations. This option seems to ignore the growing patient census at FMC Southwest Charlotte. It will also eventually remove choice from the patient options. Patients choose a dialysis facility for a variety of reasons, such as access to transportation, shift schedules which are compatible with the patient lifestyle, staff, or even the physical appearance of the facility. The growth rate for the facility seems likely to continue. Failure to recognize this growth and expand the facility will result in utilization rates continuing to exceed 100%.

After considering those alternatives, the applicant states the alternative represented in the application is the best alternative.

The applicant adequately demonstrated the need to develop a new 10-station dialysis facility by relocating stations from existing BMA facilities in Mecklenburg County based on the continued growth of the ESRD patient population in Mecklenburg County and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, 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. d/b/a FMC Southwest Charlotte shall materially comply with all representations made in the certificate of need application and supplemental responses. In those instances where representations conflict, FMC Southwest Charlotte shall materially comply with the last-made representation.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Southwest Charlotte shall develop and operate no more than 10 dialysis stations at FMC Southwest Charlotte, which shall include any isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Southwest Charlotte shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Southwest Charlotte shall take the necessary steps to decertify four dialysis stations at BMA Charlotte for a total of no more than 36 dialysis stations at BMA Charlotte and six dialysis stations at BMA Nations Ford for a total of no more than 18 dialysis stations at BMA Nations Ford.**
- 5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Southwest Charlotte shall acknowledge acceptance of and agree to comply with all**

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

	In-Center	Home PD	Home Hemo
Commercial Insurance	\$1,375.00	\$1,375.00	\$1,375.00
Medicare	\$234.00	\$234.00	\$234.00
Medicaid	\$137.29	\$137.29	\$137.29
VA	\$193.29	\$193.29	\$193.29
Private Pay	\$1,375.00	\$1,375.00	\$1,375.00

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application, pages 81 - 82. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	PY1	PY 2
Net Revenue	\$2,117,699	\$2,364,565
Operating Expenses	\$2,031,867	\$2,249,129
Profit	\$85,832	\$115,436

Assumptions:

1. Average number of patients for the current year is increased by the county growth rate for the first two operating years;
2. Average of 3 treatments per week per patient for 52 weeks reduced by a 6.5% allowance for missed treatment; and
3. Ancillary revenues: treatment numbers = In-center treatments less Medicare treatments; Average reimbursement per treatment is based upon the applicant historical experience and expected future reimbursement.

In Section VIII.9, page 71, the applicant states, “*Machine Leases are executed as the machines are needed. FMC works with a capital leasing firm to ensure the best possible rates, which are competitive with regard to financial terms, at the time the lease is executed.*” Exhibit 26 contains a sample dialysis machine lease. The applicant further states that all FMC leases are “arms length” negotiations.

In Section VII.1, page 63 and Section X pages 81 and 83, the applicant provides projected staffing and salaries. On page 65, the applicant states that FMC Southwest Charlotte will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 67. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Charlotte by relocating existing stations from two BMA facilities in Mecklenburg County. The July 2012 SDR shows there is a deficit of 15 dialysis stations in Mecklenburg County; however, in this application, the applicant is not applying for additional stations due to a facility or county need methodology; but to relocate existing stations from two existing facilities, BMA Charlotte and BMA Nations Ford so that ESRD patients' will be closer to home. According to the July 2012 SDR, BMA Charlotte and BMA Nations Ford are two of 14 dialysis facilities currently in operation in Mecklenburg County with utilization rates ranging from 38.89% to 121.43%. The applicant adequately demonstrates the need to develop a new dialysis facility based on the number of in-center patients it proposes to serve. Per the July 2012 SDR, as of June 25, 2012, the 40 station BMA Charlotte facility was operating at 75.63% capacity ($121 / 40 = 3.025$; $3.025 / 4 = .75625$ or 75.63%). The BMA Nations Ford facility was operating at 104.55% capacity ($92 / 22 = 4.1818$; $4.1818 / 4 = 1.0455$ or 104.55%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. The applicant projects utilization rates for BMA Charlotte as follows upon completion of the proposed project:

137 patients dialyzing on 36 stations = 3.81 patients per station;
 $137 / (4 \times 36) = 0.951$, or 95.1%
137 – 15 evening shift patients = 122
122 patients dialyzing on 36 stations = 3.39 patients per station;
 $122 / (4 \times 36) = 0.847$, or 84.7%

The applicant states utilization rates upon project completion for BMA Nations Ford as follows upon completion of the proposed project:

90 patients dialyzing on 18 stations = 5.0 patients per station;
 $90 / (4 \times 18) = 1.25$, or 125%
90 – 12 evening shift patients = 78
78 patients dialyzing on 18 stations = 4.33 patients per station;
 $78 / (4 \times 18) = 1.08$, or 108.3%

Upon completion of the proposed project, the FMC Southwest Charlotte facility will have 10 stations serving 36 patients (end of year 1) which is a utilization rate of 90% ($36 / 10 = 3.60$; $3.60 / 4 = 0.90$ or 90%). Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 3, the applicant provides the current and projected number of full-time equivalent (FTE) positions following completion of the proposed project, as illustrated in the table below:

POSITION	PROJECTED # OF FTEs
RN	2.25
Tech	4.00
Nurse Assist.	0.75
Clinical Manager	1.00
Medical Director	
Administration	0.20
Dietitian	0.40
Social Worker	0.40
Home Training Nurse	1.00
Chief Tech	0.20
Equipment Tech	0.50
In-Service	0.30
Clerical	1.00
Total	12.00

In Section VII.10, page 67, the applicant provides the direct care staff for each shift offered in the facility as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	3	3	3	3	3	3
Afternoon	11am to 4pm	3	3	3	3	3	3
Evening	4pm to 8am	2		2		2	

In Section V.4(c), page 56, the applicant states Dr. Nancy Gritter will be the Medical Director for FMC Southwest Charlotte. In Exhibit 21, the applicant provides a September 12, 2012 letter signed by Dr. Gritter that confirms her commitment to serve as Medical Director. In Section VII.4, page 65, the applicant states it anticipates no difficulty in hiring the necessary staff for the FMC Southwest Charlotte dialysis facility, and describes the experience it has in recruiting and hiring staff necessary to operate dialysis facilities. The additional information provided in Application Sections V and VII is reasonable and credible and supports a finding of conformity to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and

support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 53, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, beginning on page 23 of the application. Diagnostic and evaluation services, x-ray services, blood bank services, acute dialysis in an acute care setting services and transplantation services will be provided by Carolina's Medical Center (CMC). The applicant provided a copy of a hospital affiliation agreement request submitted to Carolinas Medical Center between the dialysis facility and CMC. The other services will be provided at the individually stated facility.

Exhibits 16-20 contain documentation on service agreements to include: Hospital Affiliation Agreement, Transplantation Agreement, Spectra Lab Agreement, Health Professional Educational Facility Agreement and a Home Training Agreement.

The information regarding coordination of services in Section V of the application and referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

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

proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to construct a 9,973 square foot dialysis facility. In Section VIII.1, page 68, the applicant provides a cost breakdown to include \$1,125,184 in construction cost, \$101,267 in architect and engineering fees and a \$122,645 contingency. In Section XI.6(d), pages 87-88, the applicant states the methods which BMA of North Carolina dialysis facilities utilize to maintain efficient energy operations and therefore contain utility costs as follows:

HVAC SYSTEM

1. If a new unit is required, its operating efficiency will equal current industry standards for high seasonal efficiency;
2. Systems are controlled via 7 day, 24 hour set back time clock; and
3. Systems are maintained and serviced quarterly along with air filter replacement.

ENERGY CONSERVATION MEASURES

1. Energy efficient exit signs;
2. Water flow restrictors at sink faucets;
3. Water conserving flush toilets;
4. Optical sensor water switches; and
5. External insulation wrap for hot water heaters

WATER TREATMENT EQUIPMENT

1. A percentage of the concentrate water is re-circulated into supply feed water, therefore, lowering the quantity of water discharged in the drain; and
2. Water treatment equipment electric motors are three phase, which run cooler and draw less amperage.

The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

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

C

In Section VI.1(a), page 59, the applicant discusses BMA's history of providing dialysis services to the underserved populations of North Carolina. The applicant states:

"...Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the FMC Southwest Charlotte facility is expected to be comprised of the follow:

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC Southwest Charlotte	9.0%	20.3%	68.7%	44.1%	73.2%

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

The FMC Southwest Charlotte facility is not an existing facility; therefore, there is no historical payor mix to report.

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 Mecklenburg County and Statewide:

	TOTAL # OF MEDICAID ELIGIBLES AS % OF TOTAL POPULATION	TOTAL # OF MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION	% UNINSURED CY 2008 (ESTIMATE BY CECIL G. SHEPS CENTER)
Mecklenburg	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

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 FMC Southwest Charlotte. In fact,

only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender 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 Centers for Medicare & Medicaid Services (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."¹

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..."

The report validates the statistical constancy reported by CMS above. 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 in ten prevalent hemodialysis patients had some type of Medicare coverage in 2009, with 40 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 2009 reaching 10.8 and 10.2 percent for hemodialysis and peritoneal dialysis patients, respectfully."

The report provides 2010 ESRD spending, by payor as follows:

¹ www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf

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 demonstrating the following:

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

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

C

In Section VI.1(f), page 61, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6(a), page 59, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 60, the applicant states:

“...Projections are a function of the historical performance at BMA Nations Ford and BMA Charlotte.”

Projected Payor Source

PAYOR SOURCE	IN-CENTER	Home
Commercial Insurance	15.3%	41.6%
Medicare	68.3%	55.1%
Medicaid	13.1%	3.3%
VA	3.3%	0.0%
Total	100.0%	100.0%

As shown in the table above, the applicant projects that 81.4% of all in-center patients would continue to have some or all of their services paid for by Medicare or Medicaid with VA covering another 3.3%.

In Section VI.1(d), page 60, 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.”* [emphasis in original]

In Section VI.2, page 61, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act

(ADA) requirements. On page 62, the applicant states patients will be accepted for treatment based on medical criteria, not age or other factors.

The applicant demonstrates it will provide adequate access to the elderly and medically underserved populations. 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(a), pages 61-62, 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 Southwest Charlotte 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 demonstrated that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 55, the applicant states that all health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. The facility has requested to establish a formal relationship with Central Piedmont Community College. See Exhibit 19 for a copy of a letter to the Department Head of Nursing for Central Piedmont Community College from the Director of Market Development for Fresenius Medical Care offering FMC Southwest Charlotte as a clinical training site. The applicant adequately demonstrated that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is 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 develop a new 10-station dialysis facility in Charlotte by relocating four existing dialysis stations from BMA Charlotte and six existing dialysis stations from BMA Nations Ford. According to the July 2012 SDR, BMA Charlotte and BMA Nations Ford are two of 14 dialysis facilities currently in operation in Mecklenburg County with utilization rates ranging from 38.89% to 121.43%.

In Section V.7, page 58, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states its proposal to develop a new dialysis facility by relocating existing dialysis stations within Mecklenburg County will not adversely affect quality, but rather, enhance the quality of the ESRD patient's lives. On page 58, the applicant further states:

"...This facility has added value stemming from the strength of our relationship with Metrolina Nephrology Associates.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

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

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that relocating existing dialysis stations to develop a new facility in Mecklenburg County will have a positive impact on cost-effectives, quality and access to the proposed service because:

- ◆ The applicant adequately demonstrates need based on "Policy ESRD-2", to relocate four dialysis stations from BMA Charlotte and six dialysis stations for BMA Nations Ford to develop a new 10-station dialysis facility in Charlotte. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to patients in Mecklenburg and surrounding counties;

- ◆ The applicant has and 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 care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, pages 53-57 and 63-67 respectively, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

On page 27, the applicant states, *“Let there be no doubt: BMA is committed to providing quality care for all patients.”*

- ◆ The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 59, the applicant states:

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

The applicant provides the following table to demonstrate that the medically underserved population will have access to its services, as illustrated below:

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC Southwest Charlotte	9.0%	20.3%	68.7%	44.1%	73.2%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 68.7% of the facility treatment reimbursement is from Medicare.

The applicant states on page 30 that BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations. Therefore, the application is conforming to this criterion.

Therefore, the application is not conforming to this criterion

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

C

The applicant currently provides dialysis services at several dialysis facilities in Mecklenburg County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Charlotte and BMA Nations Ford have operated in

compliance with all Medicare Conditions of Participation within the five months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant provides the utilization rates as reported in the July 2012 SDR of 75.63% with 3.03 ($121 / 40 = 3.025$) patients per station for BMA Charlotte and 104.55% with 3.83 ($92 / 24 = 3.833$) patients per station for BMA Nations Ford.

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant provides the mortality rates as 10.1%, 10.8% and 17.9% for 2009, 2010 and 2011, respectively for BMA Charlotte and 16.2%, 7.6%, 10.7% for 2009, 2010 and 2011, respectively for BMA Nations Ford.

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

-C- In Section II.1, page 12, the applicant states, “*BMA Charlotte is currently providing care and support for 58 home trained dialysis patients. BMA Nations Ford does not offer*

home training and support. The new FMC Southwest Charlotte will offer home dialysis therapies.”

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

- C- In Section II.1, page 12, the applicant states, BMA Charlotte referred 65 transplants in 2010 and 82 in 2011. Fourteen transplants were performed in 2010 and 11 in 2011. BMA Nations Ford referred 10 transplants in 2010 and 40 in 2011. Eight transplants were performed in 2010 and three in 2011.

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

- C- In Section II.1, page 12, the applicant states, “*BMA Charlotte has 32 patients on the transplant waiting list. BMA Nations Ford has seven 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 154 hospital admissions in 2011 for BMA Charlotte, 28 of which were dialysis related and 126 non-dialysis related; there were 290 hospital admissions in 2011 for BMA Nations Ford, 92 of which were dialysis related and 188 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, the applicant states that there were no patients at BMA Charlotte or BMA Nations Ford in 2010 or 2011 with an infectious disease.

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

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

- C- In Section II.1, page 13, the applicant states, “*BMA has requested to establish a hospital affiliation agreement with Carolinas Medical Center. All of the BMA facilities in Mecklenburg County have similar arrangements with CMC. BMA expects that CMC will also sign an agreement for the FMC Southwest Charlotte facility. BMA has included a copy of the agreement between CMC and BMA Nations ford for illustrative purposes. See Exhibit 16.*”

- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- The applicant refers to Exhibit 17 for a copy of the transplantation agreement with CMC for FMC Southwest Charlotte.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- The applicant states that documentation of power and water availability is included within site specific exhibits (Primary Site, Exhibit 30; Secondary Site, Exhibit 31).
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 12, the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section II.1, page 13 and in Exhibits 30 and 31 the applicant provides information regarding the site on which the dialysis services are to be offered, as required by this rule.
- (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 14, 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 FMC Southwest Charlotte.*”

(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, page 46-49 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

County	Operating Year1		Operating Year 2		County Patients as a Percent of total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Mecklenburg	33.1	3.0	35.0	6.0	92%	93%
South Carolina	3.0	0.0	3.0	0.0	8%	7%
TOTAL	36.1	3.0	38.0	6.0	92%	93%

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

-C- In Section II.1, page 17, the applicant states that BMA anticipates that all patients to be served by the new FMC Southwest Charlotte will reside within 30 miles of the facility. The entirety of Mecklenburg County is within 30 miles of the proposed location.

(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- The applicant states in Section II, page 18 of the application that “*BMA will admit and provide dialysis services to patient 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 amount for such services.*”

.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.*

-C- The applicant provides the assumptions and methodology with which it projects the need for the new 10-station dialysis facility in Mecklenburg County. BMA has demonstrated

within 10A NCAC 14C .2202(b)(7) that the new facility is projected to be serving 36 in-center patients on 10 dialysis stations at the end of Operating Year 1. Furthermore, the applicant adequately demonstrates that those patients who signed letters indicating they would transfer their care would be better served by the proposed FMC Southwest Charlotte facility. The applicant provides evidence of 30 patients who would transfer their care to the proposed facility. When the Five Year AACR for Mecklenburg County is applied to that, the projected utilization for the first year of operation is 3.6 patients per station per week, based on 36 patients dialyzing on 10 stations. Therefore, the application is conforming to this rule.

(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- FMC Southwest Charlotte projects utilization of 3.6 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 19-22 and Section III.7, pages 46-49.

.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 23, the applicant states, “*Patients will be referred to Carolina’s Medical Center.*”

(2) *maintenance dialysis;*

-C- In Section II.1, page 23, the applicant states, “*The facility will provide in-center dialysis.*”

(3) *accessible self-care training;*

-C- In Section II.1, page 23, the applicant states, “*Patients desiring self care training will be referred to the facility home training department for on site training and follow-up care.*” Exhibit 20 contains a copy of the home training center program agreement.

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

- C- In Section II.1, page 23, the applicant states, “*Patients desiring to dialyze at home will be referred to the facility home training department for on site training and follow-up care.*” Exhibit 20 contains a copy of the home training center program agreement.

- (5) *x-ray services;*

- C- In Section II.1, page 23, the applicant states, “*Patients in need of X-ray services will be referred to Carolina’s Medical Center.*” See Exhibit 18 for a copy of the hospital affiliation agreement with Carolina’s Medical Center.

- (6) *laboratory services;*

- C- In Section II.1, page 23, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs. Documentation of the agreement is included in Exhibit 18.*”

- (7) *blood bank services;*

- C- In Section II.1, page 23, the applicant states, “*Patients in need of blood transfusion will be referred to Carolina’s Medical Center.*” See Exhibit 18 for a copy of the hospital affiliation agreement with Carolina’s Medical Center.

- (8) *emergency care;*

- C- In Section II.1, page 23, 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. Patients requiring emergent care are transferred to Carolina’s Medical Center or hospital of patient choice.*”

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

- C- In Section II.1, page 23, the applicant states, “*Patients in need of hospital admission will be referred to Carolina’s Medical Center.*” See Exhibit 18 for a copy of the hospital affiliation agreement with Carolina’s Medical Center.

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

- C- In Section II.1, page 23, the applicant states, “*Patients will be referred to Metrolina Nephrology Associates Access Center, Sanger Clinic or Dilworth Surgical. The surgeons at these locations will work with the patient and*

coordinate vascular surgery.” See Exhibit 18 for a copy of the hospital affiliation agreement with Carolina’s Medical Center.

(11) *transplantation services;*

-C- In Section II.1, page 23, the applicant states, *“FMC Southwest Charlotte has a transplant agreement with Carolina’s Medical Center. A copy of an executed transplant agreement is included in Exhibit 17.”*

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

-C- In Section II.1, page 24, the applicant states, *“Patients in need of vocational rehabilitation services will be referred to the Mecklenburg County Vocational Rehabilitation Office.”*

(13) *transportation.*

-C- In Section II.1, page 24, the applicant states, *“Transportation services will be provided by the providers currently transporting patients to BMA Nations Ford and BMA Charlotte. BMA will work with Crown Cab, Prestige Cab and the Red Cross to ensure patients have transportation to the facility.”*

.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 VII.2, page 24, the applicant states that BMA will provide sufficient staffing on each dialysis shift. Table VII.1 identifies all staff for the facility. BMA plans for a third dialysis shift in the second year of operation; additional staffing is noted in response to VII.1.

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

-C- In Section II.1, page 24, the applicant states that FMC Southwest Charlotte will provide ongoing training for nurses and technicians in dialysis techniques, including training in facility and corporate policies and procedures; safety precautions, regulations, CPR, and in-service training on changes/developments in procedures, product line, equipment, Center for Disease Control and Prevention guidelines and OSHA compliance. See Section VII.5, page 65 of the application for information concerning the training and continuing education programs currently in place at FMC Southwest Charlotte. Exhibit 14 contains copies of FMC’s Dialysis Services Training Manual which outlines its training program and Exhibit 15 contains

examples of information presented as part of staff's mandatory in-service and continuing education training.