

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 27, 2015

Findings Date: March 27, 2015

Project Analyst: Celia C. Inman

Assistant Chief: Martha J. Frisone

Project ID #: F-10369-15

Facility: FMC Regal Oaks

FID #: 150024

County: Mecklenburg

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Develop a new 12-station dialysis facility by relocating eight dialysis stations from FMC Matthews and four dialysis stations from BMA East Charlotte

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 Fresenius Medical Care (FMC) Regal Oaks (“the applicant”) proposes to develop a new 12-station dialysis facility in Charlotte by relocating eight dialysis stations from FMC Matthews and four dialysis stations from BMA East Charlotte. All three facilities are located in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant is proposing to relocate dialysis stations within Mecklenburg County; therefore, the county and facility need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) are not applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 38 of the 2015 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2015 SMFP is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 32 of the 2015 SMFP 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 to contiguous counties shall:

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 12-station dialysis facility, FMC Regal Oaks, in Mecklenburg County, by relocating existing Mecklenburg County dialysis stations: eight from FMC Matthews and four from BMA East Charlotte. Because all three facilities are located in Mecklenburg County, there is no change in dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policy in the 2015 SMFP.

Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to establish a new 12-station dialysis facility in Charlotte, Mecklenburg County, by relocating existing dialysis stations: eight from FMC Matthews and four from BMA East Charlotte.

Population to be Served

In Section IV.1, page 51, the applicant identifies the population of in-center and home dialysis patients served at FMC Matthews and BMA East Charlotte, as of December 31, 2014, as shown in the tables below:

FMC Matthews Patient Origin

County of Residence	In-Center Patients	Home Patients
Mecklenburg	85	0
Other - Union	11	0
Total	96	0

BMA East Charlotte Patient Origin

County of Residence	In-Center Patients	Home Patients
Mecklenburg	79	0
Rutherford	1	0
South Carolina	2	0
Other States	2	0
Total	84	0

In Section III.7, page 47, the applicant provides a table showing the projected patient origin of the patients to be served at FMC Regal Oaks for the first two years of operation following completion of the project, as shown below. The following table includes in-

center dialysis patients, home peritoneal dialysis (PD) patients and home hemodialysis (home hemo) patients.

Projected FMC Regal Oaks Patient Origin

County	Operating Year 1			Operating Year 2			County Patients as a Percent of Total	
	In-Center	Home PD	Home Hemo	In-Center	Home PD	Home Hemo	Year 1	Year 2
Mecklenburg	39	2	2	40	3	3	100.0%	100.0%
Total	39	2	2	40	3	3	100.0%	100.0%

In Section III.3, page 37, the applicant states that it proposes to relocate eight stations and transfer 15 patients from FMC Matthews to FMC Regal Oaks. On page 39, the applicant states that it proposes to relocate four dialysis stations and expects eight dialysis patients to transfer from BMA East Charlotte to FMC Regal Oaks.

Exhibit 22 includes letters of support from 39 Mecklenburg County BMA in-center patients and two home therapy patients (15 FMC Matthews in-center dialysis patients, eight BMA East Charlotte in-center patients, eight BMA Charlotte in-center patients, seven BMA North Charlotte in-center patients, one BMA Nations Ford in-center patient, and two BMA Charlotte home therapy patients) indicating that they live closer to the proposed facility or that they would be willing to consider transferring their care to FMC Regal Oaks since the location would be more convenient. Thus as stated on page 46, BMA projects that upon completion of this project, 39 in-center dialysis patients, and two home patients (one PD and one home hemo) will transfer their care to the new FMC Regal Oaks dialysis facility.

The applicant states on pages 44-45 that the patient support letters refer to a 14-station facility named FMC North East Charlotte. The applicant explains that after contact with the patients to secure the support letters, the scope of the project changed from 14 to 12 stations and the name of the facility changed to FMC Regal Oaks, however the proposed Northeast Charlotte, Albemarle Road location remains the same. The applicant further states, "... the letters were always intended to support the same project."

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.3, page 34, the applicant discusses the necessity to relocate stations to a new facility, stating:

"The intent of this application is to bring dialysis care closer to the patient residence location of patients currently dialyzing with BMA at a facility in Mecklenburg County, and to ease travel burden associated with high volumes of traffic for those patients residing north of US 74, east of BMA East Charlotte

and south of BMA North Charlotte dialysis facilities. Thus, this application should be viewed within the context of geographic accessibility.

Charlotte and Mecklenburg County are the most populous areas of our State. Mecklenburg County has the largest ESRD patient population of any county in North Carolina. There are currently 17 dialysis facilities in the County (includes two under development). While not every BMA facility exceeds 80% utilization in the current SDR, all BMA facilities are highly utilized. On the whole, utilization at BMA facilities increased from 91.92% on June 30, 2014 to 93.34% on December 31, 2014.

...

The high utilization rates at BMA facilities necessarily cause BMA to continuously evaluate need for additional stations and facilities. BMA considers overall utilization as well as seeking to determine if a more convenient setting for delivery of care is appropriate. ... BMA has determined that another facility on the east side of the city, north of US 74 would be appropriate.”

The applicant provides a map on page 35 of the application which depicts the residence location of dialysis patients currently served by BMA facilities in Mecklenburg County. The applicant states that the map demonstrates a significant number of patients dialyzing at BMA facilities, and residing in the area of the proposed facility. On page 36, the applicant provides a map depicting that approximately 50 dialysis patients, dialyzing at BMA facilities, reside within 2.5 miles of the proposed facility.

In Section II, pages 14-17, and Section III.7, pages 44-47, the applicant provides the assumptions and methodology it uses to determine the need for an additional dialysis facility in Mecklenburg County and to project FMC Regal Oak’s patient utilization. The assumptions and methodology are summarized below:

- The applicant polled its BMA Mecklenburg County patients and determined that a significant number of BMA dialysis patients residing in eastern Charlotte and Mecklenburg County could be better served by a dialysis center located north of US 74. Exhibit 22 contains support letters from 39 of these patients, agreeing to transfer to the proposed facility to reduce travel time and thereby enhance quality of life. On page 16, the applicant identifies these patients, where they currently dialyze and the zip code of their residence, as follows:

BMA Patients Willing To Transfer

	28105	28205	28212	28215	28227	Totals
BMA Nations Ford			1			1
BMA North Charlotte		1	3	2	1	7
BMA Charlotte		2	4	1	1	8
BMA East Charlotte		3	4		1	8
FMC Matthews	4			1	10	15
BMA Charlotte Home Therapy	1				1	2
Totals	5	6	12	4	14	41

Exhibit 29 includes maps of the above zip codes and shows their proximity to the proposed facility. Based upon this information, the applicant projects that upon completion of this project, 39 in-center dialysis patients and two home therapy patients (one PD and one hemodialysis) will transfer their care to the new FMC Regal Oaks dialysis facility.

- The applicant assumes that the Mecklenburg County patient population dialyzing at the proposed FMC Regal Oaks facility will increase at the 7.1% Mecklenburg County Five Year Average Annual Change Rate published in the January 2015 Semiannual Dialysis Report (SDR).
- The project is scheduled to be completed June 30, 2016. Operating Year One is July 1, 2016 – June 30, 2017. Operating Year Two is July 1, 2017 – June 30, 2018.

Projected Utilization

In Section II, pages 16-17 and Section III, pages 46-47, the applicant provides the calculations used to arrive at the projected patient census for Operating Year One, as of June 30, 2017 and Operating Year Two, as of June 30, 2018, as shown below. The first table projects the number of in-center patients and the second projects home dialysis patients.

FMC Regal Oaks	In-Center Dialysis
<i>BMA begins with the 39 in-center patients projected to transfer their care to the new facility upon certification of the project. This is June 30, 2016.</i>	39
<i>BMA projects growth of the census by the Mecklenburg County Five Year Average Annual Change Rate for one year to June 30, 2017.</i>	$(39 \times .071) + 39 = 41.8$
<i>BMA subtracts two patients projected to change to home dialysis. This is the projected ending census for Operating Year 1, June 30, 2017.</i>	$41.8 - 2 = 39.8$
<i>BMA again projects growth of the patients by the Mecklenburg County Five Year Average Annual Change Rate for one year.</i>	$(39.8 \times .071) + 39.8 = 42.6$
<i>BMA subtracts two patients projected to change to home dialysis. This is the projected ending census for Operating Year 2, June 30, 2018.</i>	$42.6 - 2 = 40.6$

FMC Regal Oaks	Home Dialysis
<i>BMA begins with the two home dialysis patients projected to transfer their care to the new facility upon certification of the project. This is June 30, 2016.</i>	2
<i>BMA projects growth of the census by the Mecklenburg County Five Year Average Annual Change Rate for one year to June 30, 2017</i>	$(2 \times .071) + 2 = 2.14$
<i>BMA adds two patients projected to change to home dialysis. This is the projected ending census for Operating Year 1, June 30, 2017.</i>	$2.14 + 2 = 4.14$
<i>BMA again projects growth of patients by the Mecklenburg County Five Year Average Annual Change Rate for one year.</i>	$(4.14 \times .071) + 4.14 = 4.44$
<i>BMA adds two patients projected to change to home dialysis. This is the projected ending census for Operating Year 2, June 30, 2018.</i>	$4.44 + 2 = 6.44$

As shown in the previous tables, at the end of Operating Year One, FMC Regal Oaks is projecting an in-center patient census of 39 patients for a utilization rate of 81.25% or 3.25 patients per station (39 patients / 12 stations = 3.25 / 4 = .8125). At the end of Operating Year Two, the applicant is projecting an in-center patient census of 40, for a utilization rate of 83.33% or 3.3 patients per station (40 / 12 = 3.33 / 4 = .8333). The projected utilization of 3.25 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

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

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

On page 60, the applicant states that the patient population of the FMC Regal Oaks facility is expected to be comprised of the following, based upon a weighted average of the facilities contributing stations to the new dialysis facility:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC Regal Oaks	15.8%	48.9%	64.0%	45.5%	62.3%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 64.0% of the facility treatment reimbursement is from Medicare.

On page 61, the applicant projects that approximately 86% of its in-center patients and approximately 68% of its home dialysis patients will be covered by some form of Medicare or Medicaid, including Medicare/Commercial insurance. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

BMA proposes to relocate eight existing certified dialysis stations from its FMC Matthews facility and four existing certified dialysis stations from its BMA East Charlotte facility, both in Mecklenburg County, to develop a new, 12-station dialysis facility, FMC Regal Oaks, also in Mecklenburg County.

In Section III.3(c), on pages 36-41, the applicant discusses how the needs of dialysis patients at FMC Matthews and BMA East Charlotte will continue to be met after the relocation of stations to the proposed FMC Regal Oaks dialysis facility. The applicant states that the development of the proposed facility results in the following changes to the existing facilities named above.

	Current Stations	Stations to be Relocated	Stations Remaining	Transferring Patients
FMC Matthews	21	8	13	15
BMA East Charlotte	25	4	21	8

The applicant states the relocation of stations and transfer of patients is projected to occur on June 30, 2016. Thus the applicant states it is appropriate to consider the projected patient population of the facilities as of July 1, 2016, the day after the relocation and transfer.

FMC Matthews

On page 37 of the application, the applicant provides the assumptions used to project FMC Matthews' utilization on June 30, 2016. The assumptions are summarized below:

- FMC Matthews is presently at physical plant capacity with 21 dialysis stations. The facility cannot be further expanded.
- The January 2015 SDR reports the FMC Matthews' census was 84 patients on June 30, 2014.
- On December 31, 2014, FMC Matthews' census was comprised of 85 Mecklenburg County patients and 11 Union County patients for a total of 96 patients.
- The applicant projects growth of the Mecklenburg County patient population using the 7.1% Mecklenburg County Five Year Average Annual Change Rate as published in the January 2015 SDR.
- The applicant assumes the 11 Union County patients are dialyzing at FMC Matthews as a function of patient choice and does not project an increase in the patient population.
- FMC Matthews is currently operating at greater than 100% capacity using the third, or evening shift for 18 patients.

- The applicant states that FMC Matthews qualifies for additional stations by way of the Facility Need Methodology. BMA filed a CON application on March 16, 2015 seeking to add eight dialysis stations at FMC Matthews.

Based on the above assumptions, the applicant projects utilization at FMC Matthews as follows:

BMA begins with the 85 Mecklenburg County dialysis patients at FMC Matthews as of December 31, 2014. (21 stations)	85
BMA projects this population forward for 12 months to December 31, 2015, using the 7.1% rate.	$(85 \times 0.071) + 85 = 91$
BMA projects this population forward for 6 months to June 30, 2016, the projected date of certification of this project.	$[91 \times (.071 / 12 \times 6)] + 91 = 94$
BMA subtracts 15 patients expected to transfer their care to the new FMC Regal Oaks facility upon certification.	$94 - 15 = 79$
BMA adds the 11 Union County patients. This is the projected patient census for FMC Matthews at the date the project is planned for certification. (13 stations)	$79 + 11 = 90$

Thus, as of June 30, 2016, following the relocation of stations and transfer of patients, FMC Matthews is projected to have 90 patients and 13 stations, which is a utilization rate of 173% ($90 \text{ patients} / 13 \text{ stations} = 6.92 / 4 = 1.73$).

On page 38, the applicant utilizes the Facility Need Methodology to demonstrate that FMC Matthews should qualify to apply for up to eight additional stations in the April 1, 2015 Review Cycle.

April 1 Review – January SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		100.0%
Certified Stations		21
Pending Stations		0
Total Existing and Pending Stations		21
In-Center Patients as of 6/30/14 (SDR2)		84
In-Center Patients as of 12/31/13 (SDR1)		75
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.2400
(ii)	Divide the result of step (i) by 12	0.0200
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.1200
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	94.0800
(v)	Divide the result of step (iv) by 3.2 patients per station	29.4000
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed (21 stations)	8

The applicant states that the facility is at physical capacity at 21 stations. The addition of eight stations is not physically possible at the FMC Matthews facility. However, following the relocation of the eight stations and transfer of patients to FMC Regal Oaks, FMC Matthews will have the physical capacity to accommodate eight additional stations.

The applicant demonstrates that the needs of the population presently served at FMC Matthews will continue to be adequately met following the proposed relocation of eight dialysis stations from FMC Matthews to FMC Regal Oaks and that access for medically underserved groups will not be negatively impacted.

BMA East Charlotte

On pages 39-40 of the application, the applicant provides the assumptions used to project BMA East Charlotte’s utilization on June 30, 2016. The assumptions are summarized below:

- BMA East Charlotte is presently at physical plant capacity with 25 dialysis stations in its current configuration.
- The January 2015 SDR reports the BMA East Charlotte’s census was 67 patients on June 30, 2014.

- On December 31, 2014, BMA East Charlotte’s census was 84 patients (79 Mecklenburg County patients and five patients residing outside of Mecklenburg County).
- The applicant projects growth of the Mecklenburg County patient population using the 7.1% Mecklenburg County Five Year Average Annual Change Rate as published in the January 2015 SDR.
- The applicant assumes the patients from other counties are dialyzing at BMA East Charlotte as a function of patient choice and does not project an increase in that patient population.
- The applicant states that BMA East Charlotte operates at a high utilization rate and the facility will qualify for additional stations by way of Facility Need Methodology in the July 2015 SDR, and October 1 ESRD Review Cycle. BMA will file a September 15, 2015 CON application seeking to add four dialysis stations at BMA East Charlotte. (Note that on page 40, the applicant erroneously states that BMA will seek to add six dialysis stations at BMA East Charlotte.)

Based on the above assumptions, the applicant projects utilization at BMA East Charlotte as follows:

BMA begins with the 79 Mecklenburg County dialysis patients at BMA East Charlotte as of December 31, 2014. (25 stations)	79
BMA projects this population forward for 12 months to December 31, 2015, using the 7.1% rate.	$(79 \times 0.071) + 79 = 84.6$
BMA projects this population forward for 6 months to June 30, 2016, the projected date of certification of this project.	$[84.6 \times (.071 / 12 \times 6)] + 84.6 = 87.6$
BMA subtracts 8 patients expected to transfer their care to the new FMC Regal Oaks facility upon certification.	$87.6 - 8 = 79.6$
BMA adds the 5 patients from other counties. This is the projected patient census for BMA East Charlotte at the date the project is planned for certification. (21 stations)	$79.6 + 5 = 84.6$

Thus, as of June 30, 2016, following the relocation of stations and transfer of patients, BMA East Charlotte is projected to have 84 patients and 21 stations, which is a utilization rate of 100% ($84 / 21 = 4 / 4 = 1.00$).

On page 41, the applicant utilizes the Facility Need Methodology to demonstrate that BMA East Charlotte should qualify to apply for up to 10 additional stations in the October 1, 2015 Review Cycle.

October 1 Review – July SDR		
Required SDR Utilization		80%
Center Utilization Rate (projected as of July 2015)		84.0%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		25
In-Center Patients as of 12/31/14 (SDR2)		84
In-Center Patients as of 6/30/2014 (SDR1)		67
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	17
	Multiply the difference by 2 for the projected net in-center change	34
	Divide the projected net in-center change for 1 year by the number of in-center patients	0.5075
(ii)	Divide the result of step (i) by 12	0.0423
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.5075
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	126.6269
(v)	Divide the result of step (iv) by 3.2 patients per station	39.5709
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed (25 stations)	15
	Maximum added stations allowed under the Facility Need Methodology	10

Based on the calculations above, BMA East Charlotte would qualify for as many as 10 additional stations in the October 1, 2015 Review.

The applicant demonstrates that the needs of the population presently served at BMA East Charlotte will continue to be adequately met following the proposed relocation of four dialysis stations from BMA East Charlotte to FMC Regal Oaks and that access for medically underserved groups will not be negatively impacted.

The applicant adequately demonstrates that the needs of the population presently served will continue to be adequately met following the proposed relocation of four dialysis stations from BMA East Charlotte to FMC Regal Oaks.

Therefore, the application is conforming to this criterion.

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

CA

In Section III.9, pages 48-50, the applicant discusses the purpose of the proposed new facility as providing patient choice and community based delivery of healthcare. The applicant states the alternatives considered prior to submitting this application include:

- 1) Relocation of the entire BMA East Charlotte facility to another area in east Charlotte. This alternative was not considered viable because it would ultimately force some patients to travel further for their three weekly dialysis treatments.
- 2) Development of the new facility (using relocated stations from BMA East Charlotte and FMC Matthews) in other areas of Mecklenburg County. The applicant determined it would be inappropriate to relocate stations developed to support patients from BMA East Charlotte and FMC Matthews area to areas in northern or western Mecklenburg County which are further from their homes.
- 3) The development of a larger or smaller facility with more or fewer dialysis stations. BMA determined the proposed facility size is optimal for the need demonstrated at this time.
- 4) Relocation of stations from other BMA facilities in Mecklenburg County. The applicant states that each of the BMA facilities in Mecklenburg County are highly utilized and the applicant focuses on patient convenience and community based delivery of care. BMA is currently seeking to add stations at BMA Beatties Ford and considering filing another application for more stations at BMA Beatties Ford. BMA was recently awarded a CON to add stations at BMA North Charlotte. BMA is currently developing the FMC Southwest Charlotte dialysis facility and has CONs to add stations at BMA Charlotte and BMA Nations Ford. BMA determined that relocation of stations from these facilities is not viable at this time.
- 5) Maintain the Status Quo - the applicant states that failure to develop the proposed facility will eventually remove choice from the patient.

After considering the above alternatives, the applicant states that the alternative represented in the application, to develop the new FMC Regal Oaks facility, is the most effective alternative.

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall relocate no more than 8 dialysis stations from FMC Matthews and no more than 4 dialysis stations from BMA East Charlotte.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 8 dialysis stations at FMC Matthews for a total of no more than 13 dialysis stations at FMC Matthews upon project completion.**
- 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 dialysis stations at BMA East Charlotte for a total of no more than 21 dialysis stations at BMA East Charlotte upon project completion.**
- 6. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with a letter of intent to sign a written agreement with a transplantation center describing the relationship with the facility and the specific services that will be provided by the transplantation center.**
- 7. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with documentation to demonstrate the availability of power at the proposed primary FMC Regal Oaks site.**
- 8. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with documentation that the primary site is owned or under option by the applicant or provide documentation to demonstrate the availability of power and water at the proposed secondary site.**
- 9. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In the table in Section VIII, page 69, the applicant shows the capital cost of the project as summarized in the following table.

Construction Contract	\$ 1,296,673
Water Treatment Equipment	\$ 225,000
Equipment/Furniture	\$ 147,365
Architect & Engineering Fees	\$ 116,701
Other Miscellaneous	\$ 76,285
Contingency Fund	\$ 70,669
Total Capital Cost	\$ 1,932,692

Totals may not sum due to rounding.

In Section IX, pages 73-74, the applicant discusses FMC Regal Oaks' working capital needs. The applicant states that startup expenses are estimated at \$164,216, comprised of two weeks of clinical supplies at \$4,957 and salaries of \$159,259. The applicant further states that BMA typically operates with a two week clinical supply on hand and estimated the amount based on the annual supply amount divided by 26. A table detailing the projected staffing start-up expenses appears on page 73. Because the applicant expects clinical staff to transfer from existing BMA facilities, staff training should be minimal; however, to be conservative, BMA projects startup expenses as if the clinical positions are new positions. The clerical position is expected to be a new hire, but will require only a two-week training period. The applicant also allows an additional expense for PRN staff during the transition.

On page 74, the applicant estimates the initial operating period at eight months and the initial operating expenses at \$1,474,843 for a total working capital need of \$1,639,059.

In Section VIII.5, page 71, the applicant states, "BMA is utilizing accumulated reserves to finance this project." The applicant further states:

"Please refer to Exhibit 24 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project."

Exhibit 24 contains a January 15, 2015 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

“BMA is submitting a Certificate of Need Application to develop a new 12 station dialysis facility, Fresenius Medical Care Regal Oaks, by relocation of eight dialysis stations from FMC Matthews and four dialysis stations from BMA East Charlotte dialysis facility in Mecklenburg County. The project calls for the following capital expenditure:

Capital Expenditure \$ 1,932,692

As Vice President, I am authorized and do hereby authorize the development of this new Fresenius Medical Care Regal Oaks, and relocation of dialysis stations from FMC Matthews and BMA East Charlotte for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$1,932,692 as may be needed for this project. I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location.”

In Section VIII.7, page 71, the applicant refers to Exhibit 4 for a copy of the most recent audited FMC Holdings, Inc, financial statements (years ended December 31, 2013 and 2012). However, Exhibit 4 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries’ audited financial reports for the years ended December 31, 2012 and 2011. Fresenius Medical Care Holdings, Inc. and Subsidiaries’ most recent audited financial reports for the years ended December 31, 2013 and 2012, were submitted to the Agency in another recently filed CON application. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 75, the applicant provides its allowable charges per treatment for each payment source, as illustrated below:

Allowable Charge Per Treatment

Payment Source	In-Center	Home PD	Home Hemo
Private Pay	\$ 1,425.00	\$ 1,425.00	\$ 1,425.00
Commercial Insurance	\$ 1,425.00	\$ 1,425.00	\$ 1,425.00
Medicare	\$ 239.02	\$ 239.02	\$ 239.02
Medicaid	\$ 140.23	\$ 120.18	\$ 140.23
Medicare/Medicaid	\$ 239.02	\$ 239.02	\$ 239.02
Medicare/Commercial	\$ 239.02	\$ 239.02	\$ 239.02
State Kidney Program	\$ 100.00	\$ 100.00	\$ 100.00
VA	\$ 231.12	\$ 196.90	\$ 231.12
Other: Self/Indigent	\$ 1,425.00	\$ 1,425.00	\$ 1,425.00

The applicant provides the following explanations for the costs and charges on pages 75-76,

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

...

BMA also notes that Medicare began the “Bundling” reimbursement program in 2010. The Bundling program provides one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As a consequence of this, the basic rate for Medicare reimbursement has been approximately \$240 per treatment. Medicare will provide additional reimbursement for some co-morbid conditions. BMA has reflected a Medicare rate of \$239 in the above table.”

The applicant projects revenues in Section X.2-4, pages 76-83, and operating expenses in Section X.4, page 83, as summarized in the table below:

FMC Regal Oaks	Operating Year 1 7/1/16-6/30/17	Operating Year 2 7/1/17-6/30/18
Total Net Revenue	\$ 2,243,511	\$ 2,562,071
Total Operating Expenses	\$ 2,212,265	\$ 2,400,924
Net Profit	\$ 31,247	\$ 161,147

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 77-78 for the applicant’s assumptions, including number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments) for in-center patients. The applicant’s projections of treatments and revenues

are reasonable based on the number of in-center patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 65, the applicant provides projected staffing and salaries. The financials in Sections X.4 and X.5, pages 82-84, show budgeted operating costs adequate to cover the projected staffing.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion

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

C

The applicant proposes to develop a new 12-station dialysis facility, FMC Regal Oaks, in Charlotte, by relocating eight existing dialysis stations from FMC Matthews and four existing dialysis stations from BMA East Charlotte. All three facilities are located in Mecklenburg County. The January 2015 SDR indicates there are 17 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
BMA Beatties Ford (BMA)	32	96.09%	3.84
BMA Nations Ford (BMA)	24	113.54%	4.54
BMA East Charlotte (BMA)	24	69.79%	2.79
BMA North Charlotte (BMA)	28	110.71%	4.42
BMA West Charlotte (BMA)	29	70.69%	2.82
Carolinas Medical Center (CMC)	9	47.22%	1.88
Charlotte Dialysis (DaVita)	35	80.00%	3.20
Charlotte East Dialysis (DaVita)	24	84.38%	3.37
DSI Charlotte Latrobe (TRC)	24	67.71%	2.70
DSI Glenwater (TRC)	42	73.21%	2.92
FMC Charlotte (BMA)	40	86.88%	3.47
FMC Matthews (BMA)	21	100.00%	4.00
FMC Southwest Charlotte (BMA)*	0	0.00%	0.00
Huntersville Dialysis (DaVita)*	0	0.00%	0.00
Mint Hill Dialysis (DaVita)	10	87.50%	3.50
North Charlotte Dialysis (DaVita)	35	88.57%	3.54
South Charlotte Dialysis (DaVita)	20	73.75%	2.95

Source: January 2015 SDR, Table A.

*New Site, no data reported

The applicant operates eight of the 17 dialysis facilities in Mecklenburg County. DaVita, Total Renal Care (TRC) and Carolinas Medical Center (CMC) are the other providers of dialysis services in Mecklenburg County, as shown in the table above. Nine of the seventeen Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), two of the seventeen facilities are operating at or above 70% utilization, three of the seventeen facilities are operating below 70% utilization and two of the seventeen facilities were not operational at the time of the report.

In Section III.3, page 36, the applicant provides a map depicting that approximately 50 dialysis patients, dialyzing at BMA facilities reside within 2.5 miles of the proposed facility. In Exhibit 22, the applicant provides letters from 39 dialysis patients currently receiving care at BMA dialysis facilities in Mecklenburg County who have indicated that the proposed FMC Regal Oaks facility would be more convenient for them.

BMA is not adding dialysis stations in Mecklenburg County, rather it is relocating stations from two existing Mecklenburg County facilities, FMC Matthews and BMA East Charlotte. As shown in the Mecklenburg County Dialysis Facility Data table above, FMC Matthews and BMA East Charlotte are operating at 100% and 69.79% of capacity, respectively, as of June 30, 2014. The applicant provides data demonstrating that, as of December 31, 2014, FMC Matthews and BMA East Charlotte were operating at 114% (operating a third shift) and 84% of capacity, respectively. The applicant projects

applying for additional stations at both facilities in the upcoming semi-annual ESRD review cycles.

In Section III.7, page 46, the applicant demonstrates that FMC Regal Oaks will serve a total of 39 in-center patients on 12 stations at the end of the first operating year, which is 3.25 patients per station per week, or a utilization rate of 81.25% ($39/12 = 3.25$; $3.25/4 = 0.8125$). Also, the applicant's projected utilization rates are based entirely on patients currently served at BMA dialysis facilities in Mecklenburg County who have expressed their willingness to consider transferring to the proposed FMC Regal Oaks facility because it will be more convenient for them.

The applicant adequately demonstrates the need to relocate BMA stations to develop a new dialysis facility in Mecklenburg County based on the number of and geographical location of the in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Mecklenburg County. 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

The following table illustrates the projected staffing for FMC Regal Oaks, as provided by the applicant in Section VII.1, page 65. The table provided by the applicant erroneously sums the full time equivalent (FTEs) positions at 16.00 FTEs as opposed to the sum of 15.75 calculated by the Project Analyst.

Position	Projected # of FTEs
RN	3.50
Technician	6.50
Clinical Manager	1.00
Medical Director*	
Administration – FMC Director of Operations	0.15
Dietitian	0.70
Social Worker	0.70
Home Training Nurse	1.00
Medical Records	0.25
Chief Technician	0.20
Equipment Technician	0.80
In-Service	0.20
Clerical	0.75
Total	15.75

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

The following table shows the projected number of direct care staff for each shift offered at FMC Regal Oaks at project completion.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am to 12:00 pm	5	5	5	5	5	5
Afternoon	12:00 pm to 5:00 pm	5	5	5	5	5	5
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 57, the applicant states that the Medical Director for FMC Regal Oaks will be Dr. George Hart. In Exhibit 21, the applicant provides a letter dated December 30, 2014 signed by Dr. Hart of Metrolina Nephrology Associates confirming his commitment to serve as Medical Director. In Section VII.4, page 66, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*” In Section V, page 57, the applicant lists 31 nephrologists who will have privileges to admit patients and perform rounds on dialysis patients at the proposed facility. In Section VII, page 67, the applicant states, “*One or more of the 31 physicians of MNA have hospital privileges at one or more of the following hospitals: Carolinas Medical Center, CMC-Northeast, CaroMont Regional Medical Center, CMC-Mercy and Presbyterian Hospital-Charlotte.*”

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 54, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicant discusses coordination with the existing health care system on pages 55-57. Exhibits 21 and 25 contain documents from Metrolina Nephrology and Carolinas HealthCare System, respectively, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section V.1 and Exhibits 21 and 25 is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI.6, pages 88-91 of the application, the applicant states that it will construct a 10,554 square foot facility and further states that there will be an average of 258 square feet for each dialysis station. In Section VIII.1, pages 69-70, the applicant lists its project costs, including \$1,296,673 for construction, \$565,351 in miscellaneous costs including water treatment equipment, furniture, and architect/engineering fees, and a contingency of \$70,669 for a total project cost of \$1,932,692. On pages 88-89, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, including the following:

- HVAC system operating efficiency “*will equal current industry standards for high seasonal efficiency.*” In addition, the system will be controlled via 7 day/24 hour set back time clock
- Efficient exit signs, external insulation wrap for hot water heaters, water flow restrictors at sink faucets, and water conserving flush toilets will be used for energy and water conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which use less amperage.

Costs and charges are described by the applicant in Section X of the application, pages 75-84. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans 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 60, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 102 dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). The applicant further 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 proposed patient population of the FMC Regal Oaks facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC Regal Oaks	15.8%	48.9%	64.0%	45.5%	62.3%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 64% of the facility treatment reimbursement is from Medicare.

On pages 60-61, the applicant further states:

“BMA notes that the historical performance as reported here is a function of the payor mix for FMC Matthews and BMA East Charlotte as of December 30, 2014. Neither of these facilities offer home dialysis. The historical performance does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing. In addition, not every patient beginning dialysis has commercial insurance. Thus, the payor mix should be considered dynamic and not fixed.”

In Section VI.1(b), page 61, the applicant reports that as of December 30, 2014, 87.35% and 89.57% of the patients who were receiving treatments at FMC Matthews and BMA East Charlotte, respectively, had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for those facilities.

HISTORICAL PAYOR MIX

SOURCE OF PAYMENT	FMC Matthews	BMA East Charlotte
Commercial Insurance	9.20%	2.64%
Medicare	64.05%	79.32%
Medicaid	4.02%	5.32%
Medicare / Commercial	19.28%	4.93%
VA	0.94%	7.01%
Self Pay / Indigent	2.51%	0.78%
Total	100.00%	100.00%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Mecklenburg County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Mecklenburg County	14.7%	5.1%	20.1%
Statewide	16.5%	6.7%	19.7%

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

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

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

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

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

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

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

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

The 2013 USRDS Annual Data Report (p. 332) provides 2011 ESRD spending by payor, as follows:

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

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

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

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

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

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

C

In Section VI.1(f), page 62, 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

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

federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6, page 64, 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(d), page 62, 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.”

On page 61, the applicant reports that it expects over 85.67% of the in-center patients who receive treatments at FMC Regal Oaks to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

**FMC Regal Oaks
Projected Payor Mix**

Payor Source	In-Center	Home PD	Home-hemo
Commercial Insurance	8.82%	28.99%	28.99%
Medicare	68.14%	62.32%	62.32%
Medicaid	6.03%	1.55%	0.00%
Medicare / Commercial	11.50%	4.10%	5.66%
VA	2.41%	0.00%	0.00%
Self Pay / Indigent	3.10%	3.04%	3.04%
TOTAL	100.00%	100.00%	100.00%

On page 61, the applicant states:

“Projections of future in-center reimbursement are reflective of BMA payor mix at the facilities where the transferring patients are currently dialyzing; the projection is not merely a weighted average of the FMC Matthews and BMA East Charlotte dialysis facilities.

The future home payor mix is reflective of the BMA Charlotte home payor mix. Of all BMA facilities in Mecklenburg County, only BMA Charlotte currently offers home dialysis training and support.”

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

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

C

In Section VI.5, page 63, 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 Regal Oaks 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.

Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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 56, the applicant states:

“Exhibit 19 contains a letter to Central Piedmont Community College encouraging the school to include the FMC Regal Oaks facility in their clinical rotations for nursing students.

...

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. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”

Exhibit 19 contains a copy of a letter from Fresenius Medical Care to the Director of Health & Human Services at Central Piedmont Community College inviting the college to include FMC Regal Oaks in the clinical rotation for its nursing students. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with 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 12-station dialysis facility in Charlotte (Mecklenburg County) by transferring existing stations from two BMA facilities in Mecklenburg County. According to the January 2015 SDR, there are 17 dialysis facilities in Mecklenburg County, listed as follows:

Mecklenburg County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization
BMA Beatties Ford (BMA)	32	96.09%
BMA Nations Ford (BMA)	24	113.54%
BMA East Charlotte (BMA)	24	69.79%
BMA North Charlotte (BMA)	28	110.71%
BMA West Charlotte (BMA)	29	70.69%
Carolinas Medical Center (CMC)	9	47.22%
Charlotte Dialysis (DaVita)	35	80.00%
Charlotte East Dialysis (DaVita)	24	84.38%
DSI Charlotte Latrobe (TRC)	24	67.71%
DSI Glenwater (TRC)	42	73.21%
FMC Charlotte (BMA)	40	86.88%
FMC Matthews (BMA)	21	100.00%
FMC Southwest Charlotte (BMA)*	0	0.00%
Huntersville Dialysis (DaVita)*	0	0.00%
Mint Hill Dialysis (DaVita)	10	87.50%
North Charlotte Dialysis (DaVita)	35	88.57%
South Charlotte Dialysis (DaVita)	20	73.75%

Source: January 2015 SDR, Table A.

*New Site, no data reported

As the table above illustrates, the eight BMA Mecklenburg facilities, on average, are highly utilized.

In Section V.7, pages 58-59, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. BMA does not project to serve dialysis patients currently being served by another provider.

...

BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 74% of the In-

center patients will be relying upon government payors (Medicare / Medicaid / VA). The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."

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

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively are incorporated herein by reference.
- The applicant adequately demonstrates BMA will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate stations from two Mecklenburg County facilities, FMC Matthews and BMA East Charlotte, to a new facility in Mecklenburg County, FMC Regal Oaks. According to the files in the Acute and Home Care Licensure and Certification

Section, DHSR, FMC Matthews and BMA East Charlotte have operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

CA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming or conditionally conforming to all applicable criteria, as discussed below, subject to Conditions (6), (7), and (8) in Criterion (4).

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- In Section II.1, page 11, and Exhibit 5 (copy of the January 2015 SDR, Tables A and B), the applicant provides the utilization rates for FMC Matthews and BMA East Charlotte.

.2202(a)(2) Mortality rates;

- C- In Section II.1, page 11, the applicant reports 2012, 2013 and 2014 facility mortality rates for FMC Matthews and BMA East Charlotte.

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

- C- In Section II.1, page 11, the applicant states that neither FMC Matthews nor BMA

East Charlotte provide home dialysis services.

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

- C- In Section II.1, page 12, the applicant reports that FMC Matthews referred 12 patients for transplant evaluation in 2014, and two patients received transplants in 2014. BMA East Charlotte referred four patients for transplant evaluation in 2014, and one patient received a transplant in 2014.

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

- C- In Section II.1, page 12, the applicant states that FMC Matthews has 12 patients on the transplant waiting list, and that BMA East Charlotte has five patients on the transplant waiting list.

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

- C- In Section II.1, page 12, for FMC Matthews, the applicant reports a total of 39 hospital admissions in 2014; 18% were dialysis related and 82% were non-dialysis related. For BMA East Charlotte, the applicant reports a total of 111 hospital admissions in 2014; 28% were dialysis related and 72% were non-dialysis related.

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

- C- In Section II.1, page 12, the applicant reports that neither FMC Matthews nor BMA East Charlotte had any Hepatitis B conversions in 2013 or 2014. BMA East Charlotte has one current patient with Hepatitis B.

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

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).

- C- Exhibit 25 contains a copy of a letter, dated January 2, 2015, and signed by the Assistant Vice President of Carolinas HealthCare System, which states the hospital's intention to enter into an agreement with FMC Regal Oaks to provide a range of services to patients receiving dialysis care at the facility. A listing of services to be provided by Carolinas HealthCare System is included in the letter.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
- (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-CA- The applicant states that a letter of intent to sign a written agreement with a transplantation center is included at Exhibit 26. However, Exhibit 26 contains a letter from Carolinas HealthCare System documenting intent to offer hospital services, not transplantation services, to FMC North East Charlotte, the name BMA initially expected to use for the proposed facility. The application is conforming to this Rule subject to Condition (6) in Criterion (4).

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

-CA- The applicant states that power and water is available at the “*site selected*” for development (primary site) and refers to Exhibits 30 and 31 for site specific information. Exhibit 30 provides a copy of a letter from the Charlotte-Mecklenburg Utility Department documenting the availability of water and sewer for the proposed primary site on Regal Oaks Drive. The Selwyn Property Group documents that it anticipates a letter from Duke Energy verifying the availability of power at the primary site. Exhibit 31 does not contain documentation of availability of water or power for the secondary site, nor does it provide information verifying that the documentation has been requested. The application is conforming to this Rule subject to Conditions (7) and (8) in Criterion (4).

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

-C- Exhibit 12 contains excerpts from Fresenius’ Clinical Services Integrated Policy and Procedure Manual Volume II which includes Guidelines for Use of Emergency Generators Policy.

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-C- In Section II.1, page 13, the applicant states that its primary site is located on Regal Oaks Drive in Charlotte. The property is identified as PIN#133-231-04. The applicant states that upon receipt of the CON, BMA will diligently work to secure the site. Exhibit 30 contains information from the Selwyn Property Group and the owner of the parcel that confirms its availability. In Section XI.3, page 86, the applicant states that the secondary site is located at 6763 Albemarle Road in Charlotte. Exhibit 31 contains information from the Selwyn Property Group that confirms the availability of the site.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- The applicant states, in Section II, page 14, that BMA, its parent company, “will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations.” See also Sections I, pages 5-8, VII.2, page 66, and Exhibits 12 and 13.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, page 16, the applicant provides projected patient origin (by Mecklenburg County zip code) for FMC Regal Oaks, based on the patients that are expected to transfer from the existing Mecklenburg facilities. The applicant’s assumptions and methodology for its projections are provided on pages 14-17 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section II.1, page 18, the applicant states, “BMA reasonably expects that 100% of the patient population will reside within 30 miles of FMC Regal Oaks.” In addition, in Section III.3, page 36, the applicant provides the locations of 50 prospective dialysis patients residing within 2.5 miles of the proposed facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section II.1, page 18, the 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.*

-C- In Section II.1, pages 14-17, the applicant demonstrates that it will serve a total of 39 in-center patients on 12 stations at the end of the first operating year, which is 3.25 patients per station per week, or a utilization rate of 81.25%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-N/A- The applicant is not proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need. The applicant is seeking to develop a new 12-station dialysis facility.

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

-C- In Section II.1, pages 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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- The applicant states, in Section II, page 20, and Section V, page 54, that diagnostic and evaluation services will be referred to Carolinas Medical Center.

.2204(2) Maintenance dialysis;

- C- The applicant states, in Section II, page 20, and Section V, page 54, that the facility will provide in-center maintenance dialysis.

.2204(3) Accessible self-care training;

- C- The applicant states, in Section II, page 20, and Section V, page 54, that FMC Regal Oaks will provide a home training department for self-care training. In addition, on page 20, the applicant states, *“Upon completion of the training the patient will continue dialysis at FMC Regal Oaks, relying upon self-care, and monitored by the staff of the facility.”*

.2204(4) Accessible follow-up program for support of patients dialyzing at home;

- C- The applicant states, in Section II, page 20, that FMC Regal Oaks will provide follow-up services to its patients upon certification of the program.

.2204(5) X-ray services;

- C- The applicant states, in Section II, page 20 and Section V, page 54, that x-ray services will be provided by Carolinas Medical Center.

.2204(6) Laboratory services;

- C- Laboratory services will be provided on-site by the applicant through a contract with Spectra Labs, as stated by the applicant in Section II, page 20, and Section V, page 54.

.2204(7) Blood bank services;

- C- The applicant states, in Section II, page 20, and Section V, page 54, that blood bank services will be provided by Carolinas Medical Center.

.2204(8) Emergency care;

- C- The applicant states, in Section II, page 20 and Section V, page 54, that facility staff provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' is available for use at the facility. Patients in need of emergency care at a hospital are transported via emergency services.

.2204(9) Acute dialysis in an acute care setting;

- C- The applicant states, in Section II, page 20 and Section V, page 54, that acute dialysis in an acute care setting will be provided by Carolinas Medical Center.

.2204(10) Vascular surgery for dialysis treatment patients;

- C- The applicant states, in Section II, page 21, that patients needing vascular surgery will be referred to Metrolina Nephrology Associates (MNA) Access Center, Piedmont Surgical or Sanger Heart and Vascular Clinic. In Section V, page 54, the applicant lists Carolinas Medical Center, Sanger Heart and Vascular, and MNA Vascular Access Center as providing vascular surgery services.

.2204(11) Transplantation services;

- CA- In Section II, page 21, and Section V, page 54, the applicant states that candidates for transplantation services will be referred to Carolinas Medical Center. The applicant states that Exhibit 26 contains a copy of a letter of intent from Carolinas Medical Center to provide these services. However, Exhibit 26 contains a Carolinas Medical Center letter documenting the availability of other hospital services, not transplantation services. The application is conforming to this Rule subject to Condition (6) in Criterion (4).

.2204(12) Vocational rehabilitation counseling and services; and

- C- Vocational rehabilitation counseling and services will be provided by the Division of Vocational Rehabilitation of Mecklenburg County, as stated by the applicant in Section II, page 21, and Section V, page 54.

.2204(13) Transportation

- C- The applicant states, in Section II, page 21, and Section V, page 54, that transportation services will be provided by Charlotte Area Transportation (CATS), A-1 Wheelchair Transport and area taxi services.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*
- C- In Section VII.1, page 65, the applicant provides a proposed staffing chart. In Section VII.2, page 66, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.
- .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- In Section II.1, pages 21-22, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated by the In-Service Instructor and Director of Nursing. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of continuing education programs.