

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 4, 2016

Findings Date: November 4, 2016

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11207-16

Facility: Fresenius Kidney Care Southeast Mecklenburg County

FID #: 160337

County: Mecklenburg

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

Project: Develop a new 10-station dialysis facility by relocating five stations from BMA Nations Ford and five stations from FMC Matthews, and offer home training and support for home hemodialysis and home peritoneal dialysis patients

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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) proposes to develop a new 10-station dialysis facility, Fresenius Kidney Care Southeast Mecklenburg County (FKC Southeast Mecklenburg) by relocating five existing certified dialysis stations from BMA Nations Ford and five existing certified dialysis stations from FMC Matthews. In addition, the proposed facility will offer home training and support for home hemodialysis (HH) and home peritoneal dialysis (PD). 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. Upon completion of the project, FKC Southeast Mecklenburg will be certified for 10 dialysis stations, BMA Nations Ford will be certified for 23 stations (28-5), and FMC Matthews will be certified for 16 stations (21-5).

Need Determination

The applicant proposes to relocate existing dialysis stations within Mecklenburg County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 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 2016 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 33 of the 2016 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. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous [sic] county is currently serving residents of that contiguous [sic] county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing 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*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing 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 10-station dialysis facility, FKC Southeast Mecklenburg, in Mecklenburg County, by relocating 10 existing Mecklenburg County dialysis stations: five from BMA Nations Ford and five from FMC Matthews. Because all three facilities are located in Mecklenburg County, there is no change in the total 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 Policy ESRD-2 in the 2016 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, BMA, proposes to develop FKC Southeast Mecklenburg, a new 10-station Mecklenburg County dialysis facility, by relocating five existing certified dialysis stations from BMA Nations Ford and five existing certified dialysis stations from FMC Matthews. In addition, the proposed facility will offer home training and support for home hemodialysis (HH) and home peritoneal dialysis (PD). All three facilities are located in Mecklenburg County.

Patient Origin

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

FKC Southeast Mecklenburg will be a new facility in Mecklenburg County, therefore it has no existing patient origin.

In supplemental information, the applicant provides the projected patient origin for FKC Southeast Mecklenburg for in-center (IC), HH and PD patients for the first two years of operation following completion of the project, Calendar Year (CY) 2019 and CY2020, as follows:

**FKC Southeastern Mecklenburg
 Projected Patient Origin**

County	Operating Year 1 (OY1) CY2019			Operating Year 2 (OY2) CY2020			County Patients as Percent of Total**	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Mecklenburg	11.9	2.0	4.0	12.5	2.1	4.2	46.3%	46.3%
Union	16.7	0.0	0.0	17.9	0.0	0.0	43.3%	43.3% [44.0%]
South Carolina	4.0	0.0	0.0	4.0	0.0	0.0	10.4%	10.4% [9.8%]
Total*	32.6	2.0	4.0	34.4	2.1	4.2	100.0%	100.0%

*"Rounded down to the whole patient."

**Totals may not foot due to rounding.

In supplemental information, the applicant provides the assumptions and data utilized to project patient origin, including a summary of the patient support letters found in Exhibit C-1.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.4, pages 13, 15-17, the applicant discusses the need to develop a new 10-station dialysis facility, FKC Southeast Mecklenburg, by relocating five stations from BMA Nations Ford and five stations from FMC Matthews. The applicant states, in Section B.4, page 13,

"This development will promote safety and quality by delivering needed dialysis care and treatment to the patient population of Southeast Mecklenburg County and areas of southeast Mecklenburg County in a very convenient, easily accessible location....Patient quality of life will be enhanced with time returned to the patient rather than time spent in transit to and from dialysis treatment."

In addition, the applicant states, in Section C.1, page 20, that the proposed project will include home therapies since the nearest home training facility, FMC Charlotte, is more than 15 miles away from the proposed facility and would result in patients traveling in "Charlotte traffic."

In Section C.2., pages 23-24, the applicant states that it identified a number of IC, HH, and PD dialysis patients receiving care at BMA dialysis facilities who reside in southeast Mecklenburg County and who would be closer to the site of the proposed facility. The applicant further states that the BMA dialysis facilities where these patients are currently receiving dialysis are not the most convenient locations for the patients, requiring more travel time and more travel expense. The applicant states, in Section C.1, page 21, and in supplemental information, that it received 27 letters of support from IC patients residing in close proximity to the proposed facility who are currently receiving dialysis care and treatment at BMA dialysis facilities in Mecklenburg and Union counties, and at its FMC Fort Mill, South Carolina facility. In addition, six letters of support were received from HH and PD patients residing in close proximity to the proposed facility. Each of these patients' letters

state their willingness to consider transferring their care to the proposed facility because it would be more convenient, resulting in less travel time. Moreover, the applicant states that there are no other dialysis facilities located in the area proposed for the new facility.

Projected Utilization for IC Patients

In Section C.1, pages 20-23, and in supplemental information, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

1. Thirty-three letters of support were received from dialysis patients residing in close proximity to the site of the proposed facility who indicated their willingness to consider transferring their care to FKC of Southeast Mecklenburg. Twenty-seven of the letters of support were from IC patients. The applicant projects that all 27 IC patients will transfer to the proposed facility based on their expressed support. See Exhibit C-1 for letters of support.
2. Growth of the projected population begins July 1, 2016. The project is scheduled for occupancy December 31, 2018. Operating Year 1 is CY2019 and Operating Year 2 is CY2020.
3. Ten of the 27 IC patients reside in Mecklenburg County. The applicant assumes the Mecklenburg County in-center dialysis patients transferring to the proposed FKC Southeast Mecklenburg facility are a part of the Mecklenburg County ESRD patient population as a whole, and that this population will increase at the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 5.0%, as published in the July 2016 SDR.
4. Thirteen of the 27 IC patients reside in Union County. The applicant assumes the in-center dialysis patients receiving dialysis care in Mecklenburg County BMA facilities, but who live in Union County, will increase at the Union County Five Year AACR of 7.4%.
5. Four of the 27 IC patients reside in South Carolina. No growth is assumed for in-center dialysis patients in Mecklenburg County BMA facilities who reside in South Carolina.

In supplemental information, the applicant provides the calculations used to project in-center patient census for FKC Southeast Mecklenburg for Operating Years 1 and 2, as follows:

FKC Southeast Mecklenburg	In-Center Patients	
Begin the facility census on July 1, 2016 with 10 IC patients from Mecklenburg County and 13 IC patients from Union County who indicated their willingness to consider transferring.	Mecklenburg County Patients 10	Union County Patients 13
Project growth of the census of Mecklenburg County patients by applying the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 5% and project growth of the census of Union County patients by applying the Union County Five Year AACR of 7.4% for six months to December 31, 2016.	$\{10 \times (0.05/12 \times 6)\} + 10 = 10.3$	$\{13 \times (.074/12 \times 6)\} + 13 = 13.5$
Project these populations forward 12 months to December 31, 2017 by applying the appropriate Five Year AACRs.	$(10.3 \times .050) + 10.3 = 10.8$	$(13.5 \times .074) + 13.5 = 14.5$
Project these populations forward 12 months to December 31, 2018 by applying the appropriate Five Year AACRs.	$(10.8 \times .050) + 10.8 = 11.3$	$(14.5 \times .074) + 14.5 = 15.6$
Add the South Carolina patients to the combined Mecklenburg and Union County patients. This is the starting census for CY2019.	$11.3 + 15.6 + 4 = 30.9$	
Project growth of the Mecklenburg and Union county patients for one year to December 31, 2019 by applying the appropriate Five Year AACRs.	$(11.3 \times .050) + 11.3 = 11.9$	$(15.6 \times .074) + 15.6 = 16.7$
Add the South Carolina patients to the combined Mecklenburg and Union County patients. This is the ending census for OY1, December 31, 2019.	$11.9 + 16.7 + 4 = 32.6$	
Project growth of the Mecklenburg and Union county patients for one year to December 31, 2020 by applying the appropriate Five Year AACRs.	$(11.9 \times .050) + 11.9 = 12.5$	$(16.7 \times .074) + 16.7 = 17.9$
Add the South Carolina patients to the combined Mecklenburg and Union County patients. This is the ending census for OY2, December 31, 2020.	$12.5 + 17.9 + 4 = 34.4$	

In supplemental information, the applicant rounds down its projected in-center patients to 32 for OY1 (CY2019) and 34 to OY2 (CY2020), respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.2 patients per station per week, or 80.0% (32 patients/ 10 stations = 3.2/4 = .80 or 80%)
- OY2: 3.4 patients per station per week, or 85% (34 patients/ 10 stations = 3.4/4 = .85 or 85%)

The projected utilization of 3.2 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

Projected utilization of in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Projected Utilization for Home PD Patients

In Section C.1, page 20, the applicant states that home dialysis will be provided at FKC Southeast Mecklenburg. Six letters of support were provided from home dialysis patients indicating their willingness to transfer their care to the proposed facility's home training program. All of the home dialysis patients, two HH patients and four PD patients, indicated in their letters that the proposed facility would be more convenient because it would be closer to their homes. See Exhibit C-1 for home dialysis patients' letters of support.

In supplemental information, projected utilization for both HH and PD patients at FKC Southeast Mecklenburg is provided as follows:

FKC Southeast Mecklenburg	HH	PD
Begin the facility census with two HH patients and four PD patients from Mecklenburg County, beginning July 1, 2016.	2	4
Project growth of the census by the Mecklenburg County Five Year AACR of 5.0% for six months to December 31, 2016.	$\{2 \times (.050/12 \times 6)\} + 2 = 2.1$	$\{4 \times (.050/12 \times 6)\} + 4 = 4.1$
Project growth of the census by the Mecklenburg County Five Year AACR for 12 months to December 31, 2017.	$(2.1 \times .050) + 2.1 = 2.2$	$(4.1 \times .050) + 4.1 = 4.3$
Project growth of the census by the Mecklenburg County Five Year AACR for 12 months to December 31, 2018.	$(2.2 \times .050) + 2.2 = 2.3$	$(4.3 \times .050) + 4.3 = 4.5$
Project growth of the census by the Mecklenburg County Five Year AACR for 12 months to December 31, 2019, the ending census for OY1.	$(2.3 \times .050) + 2.4$	$(4.5 \times .050) + 4.5 = 4.7$
Project growth of the census by the Mecklenburg County Five Year AACR for 12 months to December 31, 2020, the ending census for OY2.	$(2.4 \times .050) + 2.4 = 2.5$	$(4.7 \times .050) + 4.7 = 5.0$

The applicant states, in supplemental information, that it will serve two HH patients and four PD patients in OY1, and two HH patients and five PD patients in OY2, therefore, the applicant rounds down to the nearest whole.

The applicant provides the assumptions and methodology used to project utilization for HH and PD patients in supplemental information. Projected utilization of HH and PD patients is based on reasonable and adequately supported assumptions regarding continued growth.

The applicant adequately identifies the population to be served and adequately demonstrates the need for a new, 10-station dialysis facility.

Access to Services

In Section C.3, page 24, the applicant states that Fresenius Medical Care Holdings, Inc., the parent company to BMA, serves patients with low incomes, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons in its 100+ dialysis facilities in the state. On page 25, the applicant states that underserved persons will continue to have access to all Fresenius-related services. In Section L.1, page 76, and supplemental information, the applicant states that the projected payor mix for FKC Southeast Mecklenburg County is based on the historical average of the in-center patient payor mix at BMA Nations Ford and FMC Matthews, and a conservative projection of the historical home therapy payor mix at one of the BMA facilities in Mecklenburg County.

The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed 10-station facility, and demonstrates the extent to which all residents, 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 develop a new 10-station dialysis facility, FKC Southeast Mecklenburg, by relocating five existing certified dialysis stations from BMA Nations Ford and five existing certified dialysis stations from FMC Matthews. In addition, the proposed facility will offer home training and support for HH and PD patients. 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.

Upon completion of this project, BMA Nations Ford will be certified for 23 dialysis stations ($28-5 = 23$) and FMC Matthews will be certified for 16 dialysis stations ($21-5 = 16$).

In Section D.1, pages 37-42, the applicant discusses how the needs of dialysis patients at BMA Nations Ford and FMC Matthews will continue to be met after the relocation of stations to the proposed FKC Southeast Mecklenburg dialysis facility.

BMA Nations Ford

In Section D.1, pages 37-38, and in supplemental information, the applicant provides the assumptions used to project utilization for BMA Nations Ford for December 31, 2018, the date when FKC Southeast Mecklenburg is to be operational. The assumptions are summarized as follows:

- BMA Nations Ford is certified for 28 dialysis stations as reported in the January 2016 SDR. Two other CON projects will affect the number of stations as follows: Project I.D. #F-10052-12 will relocate six stations to the new FMC Southwest Charlotte facility and Project I.D. #F-10092-13 will add six stations back to BMA Nations Ford. Therefore, the number of stations at BMA Nations Ford will remain the same until the proposed project is completed.
- In Project I.D. #F-10052-12, the applicant projects that 22 patients will transfer from BMA Nations Ford to FMC Southwest Charlotte upon certification of FMC Southwest Charlotte. BMA reflects the transfer of the 22 patients as of December 31, 2016.
- The applicant projects that five patients from BMA Nations Ford will transfer their care to FKC Southeast Mecklenburg. These transfers are expected to take place December 31, 2018.
- The patient population of BMA Nations Ford is projected forward three years from December 31, 2015.
- As of December 31, 2015 there were 115 patients dialyzing at BMA Nations Ford and 112 of them were from Mecklenburg County. BMA projects the Mecklenburg County population forward 12 months by applying the Mecklenburg County Five Year AACR of 5.0%.
- The three remaining patients from outside Mecklenburg County are added at the end of the calculations.

Based on the above assumptions, the applicant projects utilization at BMA Nations Ford as follows:

BMA Nations Ford

BMA begins with the Mecklenburg County ESRD patient population of BMA Nations Ford as of December 31, 2015.	112
BMA projects this population forward 12 months to December 31, 2016, applying the Mecklenburg County Five Year AACR of 5%.	$(112 \times 0.05) + 112 = 117.6$
BMA subtracts 22 patients transferring to FMC Southwest Charlotte.	$117.6 - 22 = 95.6$
BMA projects the population forward 12 months to December 31, 2017, applying the Mecklenburg County Five Year AACR of 5%.	$(95.6 \times 0.05) + 95.6 = 100.4$
BMA projects the population forward 12 months to December 31, 2018, applying the Mecklenburg County Five Year AACR of 5%.	$(100.4 \times 0.05) + 100.4 = 105.4$
BMA subtracts five patients projected to transfer to FKC Southeast Mecklenburg.	$105.4 - 5 = 100.4$
BMA adds the three patients from counties outside of Mecklenburg County for the ending census for December 31, 2018, the date FKC Southeast Mecklenburg is projected to be certified.	$100.4 + 3 = 103.4$

Thus, the applicant states, in supplemental information, as of December 31, 2018 BMA Nations Ford is projected to have 103.4 in-center dialysis patients dialyzing on 23 stations for a utilization rate of 4.47 [4.5] patients per station per week, or 111.96% [112.5%] ($103.4/23 = 4.5$; $4.5/4 = 1.125$ or 112.5%).

The applicant states, in supplemental information, that 19 patients were dialyzing on a third shift at BMA Nations Ford as of June 30, 2016, thereby reducing the utilization rate to 91.3% ($103 - 19 = 84$; $84 \text{ patients} / 23 \text{ stations} = 3.65 \text{ patients per station per week}$; $3.65/4 = 91.3\%$). The applicant states that patients will continue to dialyze on a third shift through the certification of FKC Southeast Mecklenburg. In addition, the applicant states that BMA Nations Ford qualifies for an additional three stations. The applicant uses the Facility Need Methodology to demonstrate the need for three additional stations in supplemental information. The applicant states, on pages 39-40 and in supplemental information, that it intends to file a CON application on September 15, 2016 to add three dialysis stations to BMA Nations Ford upon completion of this project. The applicant submitted an application to add three dialysis stations to BMA Nations Ford for the Certificate of Need (CON) review period beginning October 1, 2016.

The applicant demonstrates that the needs of the population presently served at BMA Nations Ford will continue to be adequately met following the proposed relocation of five dialysis stations from BMA Nations Ford to FKC Southeast Mecklenburg.

FMC Matthews

In Section D.1, pages 40-42, and in supplemental information, the applicant provides the assumptions used to project utilization for FMC Matthews for December 31, 2018, the date which FKC Southeast Mecklenburg is projected to be operational. The assumptions are summarized as follows:

- FMC Matthews is certified for 21 dialysis stations as reported in the January 2016 SDR. Two other CON projects will affect its number of stations as follows: Project I.D. #F-10369-15 will relocate eight stations to FMC Regal Oaks by September 30, 2016 and Project I.D. #F-11012-15 will add eight stations back to FMC Matthews. Therefore, the number of stations at FMC Matthews will remain the same until the proposed project is completed.
- Fifteen patients will be transferred from FMC Matthews to FMC Regal Oaks on December 31, 2016.
- BMA projects two patients from FMC Matthews to transfer their care to the new FKC Southeast Mecklenburg dialysis facility upon completion of the proposed project.
- On December 31, 2015 there were 99 patients dialyzing at FMC Matthews and 90 of those were Mecklenburg County residents.
- The applicant projects growth of the Mecklenburg County patient population for three years, beginning on December 31, 2015, applying the Mecklenburg County Five Year AACR of 5.0%, as published in the January 2016 SDR, for each year.
- BMA adds the nine patients from outside of Mecklenburg County at the end of its calculations.

Based on the above assumptions, the applicant calculates the in-center patient census for FMC Matthews starting December 31, 2015 through December 31, 2018, illustrated as follows from supplemental information:

FMC Matthews

BMA begins with the 90 Mecklenburg County ESRD patients receiving dialysis care at FMC Matthews as of December 31, 2015.	90
BMA projects this population forward for 12 months to December 31, 2016, applying the Mecklenburg County Five Year AACR of 5.0%.	$(90 \times 0.05) + 90 = 94.5$
BMA subtracts 15 patients projected to transfer to the new FMC Regal Oaks facility.	$94.5 - 15 = 79.5$
BMA projects this population forward for 12 months to December 31, 2017, applying the Mecklenburg County Five Year AACR of 5.0%.	$(79.5 \times 0.05) + 79.5 = 83.48$
BMA projects this population forward for 12 months to December 31, 2018, applying the Mecklenburg County Five Year AACR of 5.0%.	$(83.48 \times .050) + 83.48 = 87.65$
BMA subtracts the two patients projected to transfer to the proposed FKC Southeast Mecklenburg.	$87.65 - 2 = 85.65$
BMA adds the nine patients from outside Mecklenburg County. This is the projected census for December 31, 2017 [2018].	$85.65 + 9 = 94.65$

The applicant states, in supplemental information, that as of December 31, 2017 [2018] FMC Matthews will have 95 patients, rounded up, dialyzing on 16 stations for a utilization rate of 5.93 [5.94] patients per station per week, or 148.44% [148.25%]. The applicant states, in supplemental information, that 14 patients were dialyzing on a third shift at BMA Nations Ford as of June 30, 2016, thereby reducing the utilization rate to 126.50% ($95 - 14 = 81$; $81 \text{ patients} / 16 \text{ stations} = 5.06 \text{ patients per station per week}$; $5.06/4 = 126.50\%$). The applicant states that FMC Matthews will continue to operate a third shift. In addition, the applicant states, in supplemental information, that FMC Matthews qualifies for an additional two dialysis stations based on the Facility Need Methodology which it illustrates in a table provided in supplemental information. The applicant states, in supplemental information, that BMA will file a CON application on September 15, 2016 to add two dialysis stations to FMC Matthews upon completion of this project. The applicant submitted a CON application to add two dialysis stations to FMC Matthews for the CON review period beginning October 1, 2016.

The applicant states, in supplemental information,

“No patients will be adversely affected by this relocation of stations. Relocation of the 10 stations from these facilities will not create any undue hardship or impair admissions to BMA facilities. BMA has a long history of applying to relocate stations from one facility followed by subsequent CON applications to add stations at the facility which has transferred (lost) stations.

...

The relocation of stations from BMA Nations Ford and BMA Charlotte [sic] will not alter or affect the ability of low income persons, racial and ethnic minorities,

women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”

Conclusion

The applicant demonstrates that the needs of the population presently served at BMA Nations Ford and FMC Matthews will continue to be adequately met following the proposed relocation of five dialysis stations from BMA Nations Ford and five dialysis stations from FMC Matthews to FKC Southeast Mecklenburg and that access for medically underserved groups will not be negatively impacted.

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 E, pages 44-45, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintaining the status quo – the applicant states that five of its seven existing dialysis facilities cannot be expanded due to physical capacity constraints and that it has limited options for expanding service to the growing ESRD population in Mecklenburg County. Therefore, this is not an effective alternative.
- Develop a facility in another area of Mecklenburg County - the applicant states that it evaluated existing and projected populations served by BMA and that the population in southeast Mecklenburg County would be better served by a new facility. Therefore, this is not an effective alternative.
- Develop a larger facility – the applicant states that it considered applying for more stations at the proposed BMA Southeast Mecklenburg facility but concluded that the 10-station facility will meet the needs of the projected patients who will transfer their care to the proposed facility upon certification, and will also meet the performance standards of 10A NCAC 14C .2203. Therefore, this is not an effective alternative.
- Relocate stations into an existing BMA facility with capacity for additional stations - the applicant states that this alternative was rejected because moving stations into another facility would not address the needs of the specific patient population to be served and would only shift the finite space issue to another facility. Therefore, this was not an effective alternative.
- Relocate stations to one of BMA’s three facilities under development – the applicant states that this would not be an effective alternative because these facilities are

projected to serve a different population and are not located in the general area of the proposed facility.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served and the limitations in the capacity of the physical plants of existing BMA facilities in the county, the proposed project is the most effective alternative to meet the identified need.

Furthermore, the application is 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 the 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 Fresenius Kidney Care Southeast Mecklenburg County shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, Fresenius Kidney Care Southeast Mecklenburg County shall materially comply with the last made representation.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Southeast Mecklenburg County shall relocate no more than five dialysis stations from BMA Nations Ford and no more than five dialysis stations from FMC Matthews.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Southeast Mecklenburg County shall install plumbing and electrical wiring through the walls for no more than 10 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 five dialysis stations at BMA Nations Ford for a total of no more than 23 dialysis stations at BMA Nations Ford upon completion of this project and all of the following projects: Project I.D. #F-10092-13 (add 6 stations) and Project I.D. #F-10052-12 (delete 6 stations).**
- 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify five dialysis stations at FMC Matthews for a total of no more than 16 dialysis stations at FMC Matthews upon completion of this project and all of the following projects: Project I.D. #F-11012-15 (add 8 stations) and Project I.D. #F-10369-15 (delete 8 stations).**
- 6. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Southeast Mecklenburg County 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

The applicant proposes to develop a new 10-station dialysis facility in Mecklenburg County, FKC Southeast Mecklenburg, by relocating five stations from BMA Nations Ford and five stations from FMC Matthews. In addition, the applicant proposes to offer home training and support services for HH and PD patients at the proposed facility.

Capital and Working Capital Costs

In Section F.1, page 47, the applicant projects \$1,718,552 in capital costs to develop the proposed project, summarized as follows:

**FKC Southeast Mecklenburg
Capital Costs**

Category	Cost
Construction	\$1,131,638
Miscellaneous Project Costs	
(RO) Water Equipment	\$200,000
Other Equipment and Furniture	\$223,393
Architect/Engineering Fees	\$101,847
Contingency	\$61,674
Subtotal Miscellaneous	\$586,914
Total Project Capital Costs	\$1,718,552

In Section F.10, page 50, the applicant states that it will have \$125,737 in start-up expenses and in Section F.11, page 51, it states it will have eight months of initial operating expenses of \$1,767,471. The total estimated working capital for the project will be \$1,893,207.

Availability of Funds

In Section F.2, page 48, and Section F.13, page 52, the applicant states it will finance the capital costs and working capital costs with owner's equity/accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMC). Exhibit F-1 contains a letter dated July 15, 2016, from the Senior Vice President & Treasurer of FMC, authorizing and committing \$1,718,522 in capital costs for the project. In addition, the letter from the Senior Vice President & Treasurer of FMC in Exhibit F-1 states, "I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location."

Exhibit F-2 contains the Consolidated Financial Statements for FMC and Subsidiaries for the years ending December 31, 2015 and December 31, 2014. These statements indicate that as of December 31, 2015, FMC and Subsidiaries had \$249.3 million in cash and cash equivalents, \$19,332,539 in total assets and \$10,144,288 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In supplemental information, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

**FKC Southeast Mecklenburg
Projected Revenues and Operating Expenses**

	Operating Year 1 CY2019	Operating Year 2 CY2020
Gross Patient Revenue	\$20,091,544	\$23,042,664
Deductions from Gross Patient Revenue	\$16,236,136	\$18,842,899
Net Patient Revenue	\$3,855,408	\$4,199,765
Total Operating Expenses	\$2,557,995	\$2,771,843
Net Income	\$1,297,413	\$1,427,922

In supplemental information, the applicant states in its assumptions for Form C of the pro formas that it uses the average number of HH and PD patients for OY1 and OY2 to calculate revenues. The assumptions used by the applicant in preparation of the pro forma financial statements, including projected utilization, costs and charges, are reasonable and adequately supported. See supplemental information for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In supplemental information, the applicant provides projected staffing and salaries. Form A of the pro formas, in supplemental information, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

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 costs and charges. Therefore, the application is conforming to this criterion.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately

demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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, BMA, proposes to develop a new 10-station dialysis facility in Mecklenburg County, FKC Southeast Mecklenburg, by relocating five stations from BMA Nations Ford and five stations from FMC Matthews. In addition, the applicant proposes to offer home training and support services for HH and PD patients at the proposed facility.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County. Of these, 16 are operational, four are under development, and one has certified stations but is not yet operational. The applicant or its parent company owns and operates 10 of the 21 dialysis facilities in Mecklenburg County. DVA Healthcare Renal Care, Inc. (DaVita) owns and operates eight facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (DMC) operates one facility, as shown in the table below.

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2015**

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA Nations Ford	BMA	Charlotte	28	102.68%
BMA of East Charlotte	BMA	Charlotte	25	85.00%
BMA of North Charlotte	BMA	Charlotte	28	103.57%
BMA West Charlotte	BMA	Charlotte	29	87.07%
Brookshire Dialysis	DaVita	Charlotte	10	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	88.89%
Charlotte East Dialysis	DaVita	Charlotte	26	108.65%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	55.21%
DSI Glenwater Dialysis	DSI	Charlotte	41	81.71%
FMC Charlotte	BMA	Charlotte	43	82.56%
FMC Matthews	BMA	Matthews	21	117.86%
FMC of Southwest Charlotte*	BMA	Charlotte	10	0.00%
FMC Regal Oaks*	BMA	Charlotte	12	0.00%
FMC Aldersgate*	BMA	Charlotte	10	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	12	93.75%
North Charlotte Dialysis Center	DaVita	Charlotte	41	92.68%
South Charlotte Dialysis	DaVita	Charlotte	22	80.68%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.

**Facility has certified stations but is not yet operational.

As shown in the table above, all seven of BMA’s operational dialysis facilities are operating above 80% utilization (3.2 patients per station). Three of BMA’s dialysis facilities are under development. Only two of the 16 operational dialysis facilities in the county are operating below 80% utilization, a DSI facility and a CMC facility. The applicant provides 33 letters in Exhibit C-1 from in-center and home trained dialysis patients at BMA facilities in Mecklenburg and Union counties, and at one BMA facility in South Carolina, indicating that the proposed facility, in the southeastern portion of Mecklenburg County, would be closer to their homes, and therefore, more convenient.

The applicant is not increasing the number of dialysis stations in Mecklenburg County, rather it is relocating 10 of them to develop a new facility that is closer to patients living in or near the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

The applicant adequately demonstrates the need to relocate stations to develop a new dialysis facility in Mecklenburg County. The discussion on analysis of need found in Criterion (3) is

incorporated herein by reference. The discussion on the needs of the population presently served at BMA Nations Ford and FMC Matthews, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Consequently, the application is not 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 supplemental information, the applicant provides the proposed staffing for the new facility, which includes 9.78 full-time equivalent (FTE) employee positions, summarized as follows:

Position	Projected # of FTE Positions
Medical Director*	
RN	1.50
Patient Care Technician	4.00
Clinical Manager	1.00
Director of Operations	0.15
Dietary Consultant	0.33
Social Services	0.33
Home Training RN	0.67
Chief Technician	0.15
Equipment Technician	0.50
In-Service	0.15
Clerical	1.00
Total FTE Positions	9.78

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

In Section H.3, page 60, the applicant describes its experience and process for recruiting and retaining staff.

In Section H.7, page 62, the applicant provides the projected Direct Care Staff Hours for OY2. The number of proposed staff positions, and thus Direct Care Staff Hours, is the same in supplemental information as it is in Section H.7, page 62. The applicant's projected Direct Care Staff Hours are illustrated as follows:

Projected Direct Care Staff Hours – OY2

Direct Care Positions	# FTEs [a]	Hours / Year / FTE** [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
Nurse*	1.5	2,080	3,120	3,120	1.0
Patient Care Technician	4.0	2,080	8,320	3,120	2.67
Total	5.5	4,160 [2,080]	11,440	3,120	3.67

*The applicant states, in Section H.7, page 62, that the Nurse position does not include the Clinical Manager, who is a nurse, or the Home Training RN.

**Correction made by the Project Analyst is in brackets.

Exhibit I-6 contains a copy of a letter signed by George Hart, M.D., dated May 6, 2016, stating that he or another member of Metrolina Nephrology Associates will serve as the Medical Director for the facility.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide 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 I.1, page 63, the applicant includes a list of providers of the necessary ancillary and support services that will be provided to patients receiving dialysis services at FKC Southeast Mecklenburg. Exhibits I-3, 4 and 5 contain documentation regarding the availability of laboratory, hospital, and kidney transplant services, respectively. Exhibit I-6 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system in Section III.3, pages 65-66. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

The applicant proposes to construct a 3,264 square foot building to house the proposed services which will be located in Pineville in southeastern Mecklenburg County. In Section F.1, page 47, the applicant lists the project costs, including \$1,131,638 for construction, \$586,914 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,718,552. In Section K.1, pages 68-70, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application, on pages 95-97, 99, 101, and 103. 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 L.1, page 75, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina and that it is its policy to provide services to all patients regardless of income, racial/ethnic origin, age, or any other patient classified as underserved.

The applicant provides the historical payor mix for BMA Nation's Ford in Section L.7, page 80. Five dialysis stations will be relocated from BMA Nations Ford to the proposed facility and some patients will transfer to FKC Southeast Mecklenburg (See Exhibit C-1 for patients' letters of support.) The historical payor mix is as follows:

**BMA Nations Ford
Historical Payor Mix
CY2015**

Payor Type	Percent of In-Center Patients
Private Pay	3.38%
Commercial Insurance	8.37%
Medicare	69.28%
Medicaid	5.77%
Misc. (includes VA)	3.79%
Other Medicare Commercial	9.41%
Total	100.00%

As illustrated in the table above, 84.46% of BMA Nation Ford's patients were Medicare or Medicaid recipients.

Similarly, the applicant provides the historical payor mix for FMC Matthews in Section L.7, page 81. Five dialysis stations will be relocated from FMC Matthews to the proposed facility and some patients will transfer to FKC Southeast Mecklenburg (See Exhibit C-1 for patients' letters of support.) The historical payor mix is as follows:

**FMC Matthews
 Historical Payor Mix
 CY2015**

Payor Type	Percent of In-Center Patients
Private Pay	1.63%
Commercial Insurance	14.75%
Medicare	61.30%
Medicaid	1.44%
Misc. (includes VA)	2.04%
Other Medicare Commercial	18.84%
Total	100.00%

As illustrated in the table above, 81.58% of FMC Matthews’ patients were Medicare or Medicaid recipients.

The applicant provides a table showing the payor mix for home patients at FMC Charlotte, in Section L.1, on page 81, indicating that in CY2015, 57.84% of the facility’s home patients were Medicare or Medicaid recipients.

In addition, the applicant describes its admission and financial policies in Section L.3, pages 78-79, and provides a copy of its admission policy in Exhibit L-1 which states that patients will be “*admitted and treated without regard to race, creed or religion, color, age, sex, disability, national origin, and or sexual orientation.*”

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Mecklenburg	10%	52%	51%	15%	6%	19%
Union	11%	51%	27%	11%	6%	16%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates.

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

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 applicant;

C

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

In Section L.3, page 79, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service. However, the applicant states that it will treat all patients the same and that it is obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.

In Section L.6, page 80, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 76, the applicant provides the projected payor mix for the proposed project for the second operating year, (CY2017). In supplemental information, the applicant advances the project's timeline, moving the second operating year to CY2020. However, as stated by the applicant in Section L.1, page 76 and supplemental information, the projected payor mix for FKC Southeast Mecklenburg County is based on the historical average of the payor mix at BMA Nations Ford and FMC Matthews, and a conservative projection of historical home therapy payor mix at one of the BMA facilities in Mecklenburg County. The applicant states, in Section C.1, page 20, that the nearest facility with home training is FMC Charlotte, therefore the Project Analyst concludes that the home dialysis payor mix projection is based on historical payor mix at FMC Charlotte. Therefore, it is reasonable to assume that the projected payor mix for FKC Southeast Mecklenburg, as illustrated in the original application, in Section L.1, page 76, is reasonable and is illustrated in the following table:

**FKC Southeast Mecklenburg
 Project Year Two**

Payment Source	Percent of In-Center Patients	Percent of HH Patients	Percent of PD Patients	Percent of Total Patients
Self Pay/Indigent/Charity	2.86%	0.00%	0.00%	2.60%
Medicare	65.71%	100.00%	50.00%	65.80%
Medicaid	2.86%	0.00%	0.00%	2.60%
Commercial Insurance	11.43%	0.00%	50.00%	13.20%
Medicare/Commercial Insurance	14.29%	0.00%	0.00%	13.20%
VA	2.86%	0.00%	0.00%	2.60%
Total	100.00%	100.00%	100.00%	100.00%

As illustrated in the table above, the applicant projects that 82.86% of all of the patients receiving dialysis services through FKC Southeast Mecklenburg in the second year of operation will have some or all of their services paid for by Medicare

or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FKC Southeast Mecklenburg. 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 L.4, page 79, the applicant describes the range of means by which a person will have access to the dialysis services at FKC Southeast Mecklenburg. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from other nephrologists, other physicians, or hospital emergency rooms. In addition, the applicant states that any nephrologist who applies for and receives medical staff privileges may admit patients to the facility. In Exhibit I-6, the applicant provides a letter signed by the President of Metrolina Nephrology Associates indicating support for the project, medical coverage for many ESRD patients residing in southeast Mecklenburg, and states confidence in the practice's ability to meet the needs of ESRD patients at FKC Southeast Mecklenburg. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 M.1, page 82, the applicant states that the facility is available to all health education-related education and training programs to receive instruction and to observe operations. Exhibit M-1 contains a copy of correspondence to Central Piedmont Community College inviting the school to do clinical rotations for nursing students at its proposed facility. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new 10-station dialysis facility, FKC Southeast Mecklenburg in Mecklenburg County by relocating five stations from BMA Nations Ford and FMC Matthews. In addition, the proposed facility will offer home dialysis training and support for HH and PD patients.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2015**

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA Nations Ford	BMA	Charlotte	28	102.68%
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BMA of North Charlotte	BMA	Charlotte	28	103.57%
BMA West Charlotte	BMA	Charlotte	29	87.07%
Brookshire Dialysis	DaVita	Charlotte	10	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	88.89%
Charlotte East Dialysis	DaVita	Charlotte	26	108.65%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	55.21%
DSI Glenwater Dialysis	DSI	Charlotte	41	81.71%
FMC Charlotte	BMA	Charlotte	43	82.56%
FMC Matthews	BMA	Matthews	21	117.86%
FMC of Southwest Charlotte*	BMA	Charlotte	10	0.00%
FMC Regal Oaks*	BMA	Charlotte	12	0.00%
FMC Aldersgate*	BMA	Charlotte	10	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	12	93.75%
North Charlotte Dialysis Center	DaVita	Charlotte	41	92.68%
South Charlotte Dialysis	DaVita	Charlotte	22	80.68%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.

**Facility has certified stations but is not yet operational.

As shown in the table above, all seven of BMA’s operational dialysis facilities are operating above 80% utilization (3.2 patients per station). Three of BMA’s dialysis facilities are under development. Only two of the 16 operational dialysis facilities in the county are operating below 80% utilization, a DSI facility and a CMC facility.

In Section N.1, pages 83-84, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states,

“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 83% of the In-center treatments will be reimbursed at government payors (Medicare / Medicaid / VA) rates. The facility must capitalize upon every opportunity for efficiency.

...

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 A, B, C, D, E, G, I, K, L, N, O and supplemental information where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referred to above is reasonable 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 it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) 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

In Exhibit A-4, the applicant lists the kidney disease treatment centers located in North Carolina that are owned and operated by the applicant or an affiliated company. In Section O.3, pages 88-90, the applicant identifies three of its 100+ Fresenius affiliated North Carolina facilities, BMA Lumberton, BMA East Charlotte, and RAI West College-Warsaw, as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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.

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 supplemental information, the applicant adequately demonstrates that FKC Southeast Mecklenburg will serve at least 32 in-center patients on 10 dialysis stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80.0% ($32/10 = 3.2$; $3.2/4 = 0.80$). 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.*
- NA- The applicant is seeking to develop a new 10-station dialysis facility.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In supplemental information, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion

regarding projected utilization found in Criterion (3) is incorporated herein by reference.