ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: December 18, 2018
Findings Date: December 18, 2018

Project Analyst: Gloria C. Hale
Team Leader: Fatimah Wilson

Project ID #: F-11392-17
Facility: FMC Charlotte
FID #: 955947
County: Mecklenburg
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add 3 dialysis stations for a total of 44 stations upon completion of this project, Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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. d/b/a FMC Charlotte proposes to add three dialysis stations to its existing facility for a total of 44 certified dialysis stations upon completion of this project, Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte).

Need Determination

The 2017 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there

is no county need determination for Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Charlotte in the July 2017 SDR is 3.63 patients per station per week. This utilization rate was calculated based on 156 in-center dialysis patients and 43 certified dialysis stations as of December 31, 2016 (156 patients /43 stations = 3.63 patients per station per week). Application of the facility need methodology indicates that three additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		90.7%
Certified Stations		43
Pending Stations		7
Total Existing and Pending Stations		**50**
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		156
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		150
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0800
(ii)	Divide the result of Step (i) by 12	0.0067
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0800
(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	168.4800
(v)	Divide the result of Step (iv) by 3.2 patients per station	52.6500
	and subtract the number of certified and pending stations to determine the number of stations needed	2.6500

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2017 SDR. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. *Policy GEN-3*, on page 33, states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and*

quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 60-62, and Exhibit O-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 9, Section L, pages 52-55, and Exhibit L-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 10-12, Section C, pages 13-20, and Section N, pages 58-59. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant.

Conclusion

The information in the application is reasonable and adequately supported for the following reasons:

- The proposed project meets the facility need determination for dialysis stations and application of the facility need methodology indicates there is a need for three additional dialysis stations.
- The applicant adequately demonstrates how the proposed project would meet each component of *Policy GEN-3: Basic Principles.* Specifically, the applicant adequately demonstrates how the proposed project would promote safety and quality, promote equitable access, and maximize healthcare value.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

(2) Repealed effective January 1, 1987.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add three dialysis stations to its existing facility for a total of 44 certified dialysis stations upon completion of this project, Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte).

Patient Origin

On page 373, the 2017 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.

In Section C.8, page 20, the applicant provides the historical in-center, home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for FMC Charlotte as of June 30, 2017, which is summarized in the following table:

FMC Charlotte
Historical Patient Origin
June 30, 2017

County	In-Center Patients	HH Patients	PD Patients
Mecklenburg	149	17	62
Cabarrus	0	1	1
Gaston	0	0	3
Iredell	1	0	0
Pender	0	1	0
Rowan	0	0	1
Union	2	4	3
South Carolina	0	3	3
Other States	2	0	0
TOTALS	**154**	**26**	**73**

In Section C.1, page 13, and in supplemental information, the applicant provides the projected patient origin for FMC Charlotte for operating year one (OY1), Calendar Year (CY) 2019, and OY2, CY2020, following completion of the project, as follows:

FMC Charlotte
Projected Patient Origin

	OY1 (CY2019)			OY2 (CY2020)			County Patients as a Percent of Total*	
County	In-Center Patients	HH Patients	PD Patients	In-Center Patients	HH Patients	PD Patients	OY1 CY2019	OY2 CY2020
Mecklenburg	152.72	19.25	70.23	160.50	20.24	73.81	91.3%	91.7%
Cabarrus	0.00	1.00	1.00	0.00	1.00	1.00	0.8%	0.8%
Gaston	0.00	0.00	3.00	0.00	0.00	3.00	1.1%	1.1%
Iredell	1.00	0.00	0.00	1.00	0.00	0.00	0.4%	0.4%
Pender	0.00	1.00	0.00	0.00	1.00	0.00	0.4%	0.4%
Rowan	0.00	0.00	1.00	0.00	0.00	1.00	0.4%	0.4%
Union	2.00	4.00	3.00	2.00	4.00	3.00	3.4%	3.2%
South Carolina	0.00	3.00	3.00	0.00	3.00	3.00	2.3%	2.2%
TOTAL	**155.72**	**28.25**	**81.23**	**163.50**	**29.24**	**84.81**	**100.0%****	**100.0%****

*Calculated by Project Analyst based on supplemental information provided by the applicant.
**Total may not foot due to rounding.

The applicant provides the assumptions used to project in-center, HH, and PD patient origin in Section C.1, pages 13-14. The applicant provides the methodologies used to project in-center, HH, and PD patient origin in supplemental information. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.4, page 8, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP, and utilizes data from the July 2017 SDR to apply the facility need methodology provided in Section B.2, page 6, to demonstrate how the facility qualifies for three additional stations. In Section C.1, pages 13-14, the applicant provides the following assumptions for projecting in-center patients:

1. The current patient population at FMC Charlotte and who reside in Mecklenburg County are a part of the Mecklenburg County ESRD patient population as a whole and as such will increase at the Five Year Average Annual Change Rate (AACR) for Mecklenburg County of 5.1% as published in the July 2017 SDR.

2. The two patients from other states are transient patients and therefore will not be projected to dialyze at FMC Charlotte. The remaining patients who are not from Mecklenburg County will be added, however no growth is calculated for these patients.

3. Ten patients will transfer from FMC Charlotte to FMC Aldersgate (Project I.D. #F-11099-15) upon completion of that project. Therefore, 10 patients will be subtracted from FMC Charlotte on March 31, 2018.

4. One patient is projected to transfer from FMC Charlotte to Fresenius Kidney Care (FKC) Southeast Mecklenburg County (Project I.D. #F-11207-16) upon completion of that project. Therefore, one patient will be subtracted from FMC Charlotte by December 31, 2018.

5. Four patients are projected to transfer from FMC Charlotte to FKC Mallard Creek upon completion of that project. Therefore, four patients will be subtracted from FMC Charlotte by December 31, 2018.

6. The first two operating years for the proposed project will be CY2019 and CY2020.

Projected Utilization of In-Center Patients

The applicant provides its methodology for projecting utilization for in-center patients for OY1 and OY2, in supplemental information, as follows:

	In-Center Patients
The applicant begins with the Mecklenburg County in-center patient census at the facility on June 30, 2017.	149
The Mecklenburg County in-center patient census is projected forward six months to December 31, 2017, increased by one-half the Five Year AACR for Mecklenburg County of 5.1%.	149 x 1.0255 = 152.80
The Mecklenburg County in-center patient census is projected forward three months to March 31, 2018, increased by one-fourth the Five Year AACR for Mecklenburg County of 5.1%.	152.80 x 1.0128 = 154.75
The applicant subtracts 10 in-center patients projected to transfer to FMC Aldersgate.	154.75 – 10 = 144.75
The census of Mecklenburg County in-center census is projected forward nine months to December 31, 2018, increased by three-fourths the Five Year AACR for Mecklenburg County of 5.1%.	144.75 x 1.0383 = 150.28
The applicant subtracts one patient projected to transfer to FKC Southeast Mecklenburg County.	150.28 – 1 = 149.28
The applicant subtracts four patients projected to transfer to FKC Mallard Creek.	149.28 – 4 = 145.28
The applicant adds three patients, two from Union County and one from Iredell County. This is the starting census for OY1.	145.28 + 3 = 148.28
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5.1% to December 31, 2019.	145.28 x 1.051 = 152.69
The applicant adds three patients, two from Union County and one from Iredell County. This is the ending census for OY1.	152.69 + 3 = 155.69
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5.1% to December 31, 2020.	152.69 x 1.051 = 160.48
The applicant adds the three patients from Union and Iredell counties. This is the ending census for OY2.	160.48 + 3 = 163.48

The applicant states, in supplemental information, that it projects to serve 155 in-center patients by the end of OY1 which is 3.52 patients per station per week (155 patients/ 44 dialysis stations = 3.52). Therefore, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected Utilization of HH patients

In supplemental information, the applicant provides the methodology for projecting HH patients, increasing the HH patient population residing in Mecklenburg County annually by applying the Five Year AACR for Mecklenburg County of 5.1% and by adding the HH patients residing in other counties and South Carolina, as follows:

	HH Patients
The applicant begins with the Mecklenburg County HH patient census at the facility on June 30, 2017.	17
The Mecklenburg County HH patient census is projected forward six months to December 31, 2017, increased by the Five Year AACR for Mecklenburg County of 5.1%.	17 x 1.0255 = 17.43
The census of Mecklenburg County HH patients is increased by the Five Year AACR for Mecklenburg County of 5.1% to project the census forward one year to December 31, 2018.	17.43 x 1.051 = 18.32
The applicant adds nine HH patients from other counties and South Carolina. This is the projected starting census for OY1.	18.32 + 9 = 27.32
The census of Mecklenburg County HH patients is increased by the Five Year AACR for Mecklenburg County of 5.1% to project the census forward one year to December 31, 2019.	18.32 x 1.051 = 19.25
The applicant adds nine HH patients from other counties and South Carolina. This is the projected ending census for OY1.	19.25 + 9 = 28.25
The census of Mecklenburg County HH patients is increased by the Five Year AACR for Mecklenburg County of 5.1% to project the census forward one year to December 31, 2020.	19.25 x 1.051 = 20.24
The applicant adds nine HH patients from other counties and South Carolina. This is the projected ending census for OY2.	20.24 + 9 = 29.24

Therefore, the applicant projects to serve 28 HH patients in OY1 and 29 HH patients in OY2.

Projected Utilization of PD patients

In supplemental information, the applicant provides the methodology for projecting PD patients, increasing the PD patient population residing in Mecklenburg County annually by applying the Mecklenburg County Five Year AACR of 5.1% and by adding PD patients residing in other counties and South Carolina, as follows:

	PD Patients
The applicant begins with the Mecklenburg County PD patient census at the facility on June 30, 2017.	62
The Mecklenburg County PD patient census is projected forward six months to December 31, 2017, increased by the Five Year AACR for Mecklenburg County of 5.1%.	62 x 1.0255 = 63.58
The census of Mecklenburg County PD patients is increased by the Five Year AACR for Mecklenburg County of 5.1% to project the census forward one year to December 31, 2018.	63.58 x 1.051 = 66.82
The applicant adds 11 PD patients from other counties and South Carolina. This is the projected starting census for OY1.	66.82 + 11 = 77.82
The census of Mecklenburg County PD patients is increased by the Five Year AACR for Mecklenburg County of 5.1% to project the census forward one year to December 31, 2019.	66.82 x 1.051 = 70.23
The applicant adds 11 PD patients from other counties and South Carolina. This is the projected ending census for OY1.	70.23 + 11 = 81.23
The census of Mecklenburg County PD patients is increased by the Five Year AACR for Mecklenburg County of 5.1% to project the census forward one year to December 31, 2020.	70.23 x 1.051 = 73.81
The applicant adds 11 PD patients from other counties and South Carolina. This is the projected ending census for OY2.	73.81 + 11 = 84.81

Therefore, the applicant projects to serve 81 PD patients in OY1 and 84 PD patients in OY2.

In summary, the applicant adequately identifies the patient origin and adequately demonstrates the need for three additional dialysis stations at FMC Charlotte.

Access

In Section C.3, pages 17-18, the applicant states that BMA has a long history of serving the underserved population in the state and that each facility serves *"low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons."* The applicant further states that BMA will continue to provide access to all persons, including low income and medically underinsured persons. In Section L.7, page 56, the applicant states that 75.05% of FMC Charlotte's patients were Medicare or Medicaid recipients in CY2016. In Section L.1, page 53, the applicant projects that 74.1% of all of FMC Charlotte's patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the

extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The population to be served by the proposed project will be from the same counties as they have been historically, with the exception of those likely to be transient patients from other states.
- The applicant uses reasonable assumptions and applies the facility need methodology, including the application of the Mecklenburg County Five Year AACR published in the July 2017 SDR, to project the number of in-center, HH, and PD patients to be served at the facility.
- The applicant projects that the facility will serve a similar percentage of Medicaid and Medicare recipients as it has historically.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

NA

The applicant proposes to add three dialysis stations to an existing facility, therefore there will be no reduction or elimination of a service, including the relocation of a facility.

(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 E.1, page 24, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that the facility's projected utilization will be greater than 80% at the end of OY1, therefore maintaining the status quo would result in higher utilization rates and potentially cause admissions to be restricted. Therefore, this is not the most effective alternative.

- Apply for Fewer Stations – The applicant states that its projected utilization will exceed 3.2 patients per station, therefore adding less stations would not be appropriate. Therefore, this is not the most effective alternative.

- Relocate stations to FMC Charlotte – The applicant states it considered relocating dialysis stations from other BMA facilities in Mecklenburg County to FMC Charlotte, however all of the other facilities are operating at over 80% of capacity with the exception of the new FMC Southwest Charlotte and new FMC Regal Oaks facilities. Therefore, this is not the most effective alternative.

In Section C.2, page 17, the applicant states that the projected population at FMC Charlotte has a need for the additional stations and that *"failure to add stations will lead to higher in-center utilization rates at the facility."* Therefore, the proposed alternative represented in the application and in supplemental information 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.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- Two alternative methods provided by the applicant for meeting the needs for the proposed project would not address the higher utilization rates projected for the facility.
- One alternative method would negatively impact access to dialysis services at other BMA dialysis facilities in Mecklenburg County that are already operating at over 80% of capacity.

This determination is based on a review of the:

- Information in the application, and
- Information which was publicly available during the review and used by the Agency.

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 Charlotte shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations**

conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall materially comply with the last made representation.

2. **Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall develop no more than three additional dialysis stations for a total of no more than 44 certified stations upon completion of the project and Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte), which shall include any isolation or home hemodialysis stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of no more than 44 dialysis stations which shall include any home hemodialysis training or isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add three dialysis stations to the existing facility for a total of 44 certified dialysis stations upon completion of this project, Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte).

Capital and Working Capital Costs

In Section F.1, page 26, the applicant states that there will be no capital cost for the project. In Sections F.10-F.12, page 29, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since FMC Charlotte is an existing facility.

Financial Feasibility

In supplemental information, the applicant states in its assumptions for in-center patients, HH patients, and PD patients, that the calculated average annual number of patients, rounded down, is used to calculate the respective revenues for each modality. The table below illustrates the applicant's assumptions.

FMC Charlotte
Average Number of Projected Patients by Modality, OY1 and OY2

Year	Beginning Census	Ending Census	Average Number of Patients Rounded Down to Nearest Whole Number
In-Center Patients			
OY1 (CY2019)	152.31	155.72	154
OY2 (CY2020)	155.72	163.50	159
HH Patients			
OY1 (CY2019)	27.32	28.25	27
OY2 (CY2020)	28.25	29.24	28
PD Patients			
OY1 (CY2019)	77.82	81.23	79
OY2 (CY2020)	81.23	84.81	83

In supplemental information, the applicant provides pro forma financial statements for the first two operating years of the project following completion. In 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.

FMC Charlotte

	OY1 (CY2019)	**OY2 (CY2020)**
Total Treatments (In-Center, HH and PD)	38,532	40,014
Total Gross Revenues (Charges)	$ 153,665,616	$ 159,575,832
Deductions from Gross Revenues	$ 136,739,383	$ 141,962,721
Total Net Revenue	$ 16,926,233	$ 17,613,111
Average Net Revenue per Treatment (In-Center, HH and PD)	$ 439	$ 440
Total Operating Expenses (Costs)	$ 12,841,253	$ 13,233,903
Average Operating Expense per Treatment (In-Center, HH and PD)	$ 333	$ 331
Net Income	**$ 4,084,980**	**$ 4,379,208**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the supplemental information for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

The information in the application and supplemental information, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- No working capital is needed since the facility is existing and operational,
- No funding is needed for capital costs, and
- The applicant projects that revenues will exceed operating expenses in the first two operating years of the project.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add three dialysis stations to the existing facility for a total of 44 certified dialysis stations upon completion of this project, Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte).

On page 373, the 2017 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.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 18 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

Mecklenburg County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2016

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	93.75%
BMA of East Charlotte	BMA	Charlotte	25	92.00%
BMA of North Charlotte	BMA	Charlotte	36	102.78%
BMA West Charlotte	BMA	Charlotte	29	86.21%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	84.72%
Charlotte East Dialysis	DaVita	Charlotte	34	88.24%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Fresenius Medical Care Southwest Charlotte***	BMA	Charlotte	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	74.39%
South Charlotte Dialysis	DaVita	Charlotte	22	86.36%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2017 SDR, Table B.
* Facility under development.
** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.
*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

According to Table D in the July 2017 SDR, there is a surplus of fourteen dialysis stations in Mecklenburg County. The applicant proposes to add three dialysis stations for a total of 44

dialysis stations upon completion of the project. However, the applicant is applying for additional stations based on the facility need methodology. As of December 31, 2016, FMC Charlotte was serving 156 patients on 43 dialysis stations per week, which is 3.63 patients per station per week or 90.7% of capacity. The applicant does not propose to establish a new facility. In supplemental information, the applicant adequately demonstrates that FMC Charlotte will serve a total of 155 in-center patients on 44 dialysis stations at the end of OY1 (CY2019), for a utilization rate of 3.52 patients per station per week, or 88% of capacity (155/ 44 = 3.52; 3.52/ 4 = 88%). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add three additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant is not proposing to develop a new dialysis facility, rather it is proposing to add dialysis stations based on the facility need methodology.
- All other operational BMA dialysis facilities in Mecklenburg County, with the exception of Fresenius Medical Care Southwest Charlotte which is a new facility, are operating at over 80% of capacity.
- The applicant expects to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

This determination is based on a review of the:

- Information in the application, including any exhibits, and
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section H.1, page 38, the applicant provides the current and projected staffing for the facility, which will remain at 59.80 full-time equivalent (FTE) employees upon completion of the proposed project. Projected direct care staff in OY2, from Section H.7, page 41, is shown in the following table:

FMC Charlotte
Direct Care Staff
OY2

Direct Care Positions	# of FTEs	Hours per Year per FTE	Total Annual FTE Hours	Total Annual Hours of Operation	#FTE Hours per Hour of Operation
RN	9	2,080	18,720	4,680	4.00
LPN	2	2,080	4,160	4,680	0.89
Patient Care Technician	29	2,080	60,320	4,680	12.89
Home Training RN	10	2,080	20,800	4,680	4.44
Total	50	2,080	104,000	4,680	**22.22**

In Section H.6, page 40, the applicant states that dialysis services will be available from 7:00 a.m. to 10:00 p.m., Monday through Saturday, however the applicant also states, on page 39, *"The facility's normal hours of operation do not include the Tuesday-Thursday-Saturday evening shift."* The applicant states, on pages 39-40, that the facility will be re-opened on an on-call basis for patients from a hospital who need dialysis treatment and this may necessarily be on Tuesday, Thursday and Saturday evenings. The applicant's total annual hours of operation, 4,680, includes three shifts per day for a total of 15 hours per day. Therefore, the Project Analyst notes that the total hours of operation and the number of FTE hours per hour of operation reported in the table above are likely to be greater than what the facility experiences on average since the applicant states, on page 45, that re-opening for a medical emergency occurs only an average of three times weekly. In addition, the Project Analyst assumes that the full complement of direct care staffing is not required every evening or on those occasions when dialysis is needed on an on-call basis from an area hospital.

In Section H.3, pages 38-39, the applicant states that it does not anticipate any difficulties filling staff positions and that it employs aggressive recruiting and advertising efforts to hire staff, along with providing a range of benefits and competitive salaries to attract and maintain staff. Exhibit I-5 contains a copy of a letter from Benjamin Hippen, M.D., stating his support for the project and his willingness to continue serving as the Medical Director for the facility.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of FMC Charlotte.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 42, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, I-3 and I-4 contain copies of agreements with providers for laboratory services, hospital services, and transplants, respectively.

In Section I.3, page 44, the applicant provides a listing of nephrologists at Metrolina Nephrology Associates who have agreed to provide medical coverage at the facility and who have expressed support for the project. In addition, the applicant states, on page 45, that BMA has informal relationships with other physicians in the area. Moreover, Exhibit I-5 contains a letter from the medical director of the facility that expresses his support for the proposed project.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- A list of current and projected necessary ancillary and support services, and by whom they will be obtained, is provided.
- The applicant identifies nephrologists in the area who have agreed to provide medical coverage at the facility, and
- The facility's medical director has provided a letter of support.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

(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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective January 1, 1987.

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

NA

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion 12 is not applicable to this review.

(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.7, page 56, the applicant reports that 75.1% of the in-center patients who received treatments at FMC Charlotte in CY2016 had some or all of their services paid for by Medicare or Medicaid. The table below, from page 56 of the application, provides the historical (CY2016) payment source for all of FMC Charlotte's patients:

Payment Source	Total Facility*
Self-Pay/Indigent/Charity	2.1%
Commercial Insurance	21.4%
Medicare	65.0%
Medicaid	4.9%
Misc., including VA	1.5%
Medicare/Commercial Insurance	5.1%
Total	**100.0%**

*The percentages are rounded to the nearest tenth.

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 & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*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."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] percentages for North Carolina and the aggregate data for

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

all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28[2]. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The information in the application, including any exhibits, is reasonable and adequately supported because 75.1% of FMC Charlotte's dialysis patients were Medicare or Medicaid recipients in CY2016.

This determination is based on a review of the:

- Information in the application, including any applicable exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section L.3, page 54, 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 applicant will treat all patients the same regardless of race or handicap status."*

In Section L.6, page 55, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facility in the past five years. Therefore, the application is conforming to this criterion.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

[2] http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

- The applicant does not have any obligation to provide uncompensated care or community service under any federal regulations, and
- The applicant states that no BMA North Carolina facility has had any civil rights complaints filed against it in the past five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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(b), page 53, the applicant projects that 74.1% of all patients who will receive treatments at FMC Charlotte in OY2, CY2020, will have some or all of their services paid for by Medicare or Medicaid. The table below, from page 53 of the application, shows the projected OY2 payor mix for the facility for all patients:

FMC Charlotte
Projected Payor Mix, OY2 (CY2020)

Payment Source	Percent of All Patients*
Self-Pay/Indigent/Charity	2.9%
Commercial Insurance	21.2%
Medicare	63.0%
Medicaid	5.0%
VA	1.8%
Medicare/Commercial Insurance	6.1%
Total	**100.0%**

*Percentages are rounded to the nearest tenth.

In Section L.1, page 53, the applicant provides the assumption used to project payor mix, stating that it is based on the facility's recent performance. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC Charlotte.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant projects that 74.1% of it dialysis patients will be Medicare or Medicaid recipients based on historical payor mix of the facility.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 55, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Charlotte, stating that any nephrologist may apply for privileges to admit patients and receive referrals from other nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant states that patients will be admitted for dialysis through physicians with admitting privileges.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 57, the applicant states that BMA has communicated with local nursing programs, inviting them to utilize FMC Charlotte as an educational opportunity for their nursing students. Exhibit M-1 contains a copy of correspondence from the applicant to Central Piedmont Community College offering FMC Charlotte as a clinical training site for the college's nursing students.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant has demonstrated its intent to offer the facility as a clinical training site.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

(15) Repealed effective January 1, 1987.
(16) Repealed effective January 1, 1987.
(17) Repealed effective January 1, 1987.
(18) Repealed effective January 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Charlotte proposes to add three dialysis stations to the existing facility for a total of 44 certified dialysis stations upon completion of this project, Project I.D. #F-11306-17 (add 7 stations), Project I.D. #F-11099-15 (relocate 6 stations to FMC Aldersgate), and Project I.D. #F-11345-17 (relocate 3 stations to FMC Southwest Charlotte).

On page 373, the 2017 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.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 18 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

Mecklenburg County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2016

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	93.75%
BMA of East Charlotte	BMA	Charlotte	25	92.00%
BMA of North Charlotte	BMA	Charlotte	36	102.78%
BMA West Charlotte	BMA	Charlotte	29	86.21%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	84.72%
Charlotte East Dialysis	DaVita	Charlotte	34	88.24%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Fresenius Medical Care Southwest Charlotte***	BMA	Charlotte	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	74.39%
South Charlotte Dialysis	DaVita	Charlotte	22	86.36%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2017 SDR, Table B.
* Facility under development.
** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.
*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

In Section N.1, page 58, the applicant discusses how any enhanced competition will have a positive impact on the 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. …In this application, BMA projects that greater than 84% of the In-center patients will be relying upon government payors (Medicare /Medicaid / VA). 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 B, C, F, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality and access to the proposed services in Section B, pages 6, 8-12; Section C, pages 15-20; Section F, page 27; Section K, pages 47-48; Section L, pages 52-55; Section N, page 58; and Section O, pages 60-64. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the project,
- The applicant adequately demonstrates that the proposed project will be cost-effective,
- The applicant adequately demonstrates it will provide quality services, and
- The applicant demonstrates that it will provide adequate access to medically underserved populations.

This determination is based on a review of:

- The information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

(19) Repealed effective January 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.

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina that it or an affiliated company owns and operates. In Section O.2, page 62, and Section O.3, pages 63-64, the applicant identifies two of its facilities, BMA East Rocky Mount, and RAI West College Warsaw, that were 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 provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibits O-1, O-2, and O-3. The applicant states, on page 64, 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 has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

(21) Repealed effective January 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria 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.*

-NA- The applicant is proposing to add dialysis stations to an existing facility, FMC Charlotte. Therefore, this performance standard is not applicable.

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

-C- In supplemental information, the applicant projects to serve 155 in-center patients by the end of OY1, which is 3.52 patients per station per week (155/ 44 = 3.52). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-17, the applicant provides the assumptions used to project utilization of the facility. In supplemental information, the applicant provides the methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.