

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 24, 2019

Findings Date: May 24, 2019

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: F-11668-19

Facility: FMC of North Charlotte

FID #: 955788

County: Mecklenburg

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

Project: Add one dialysis station for a total of 40 dialysis stations upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station)

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. (BMA) proposes to add one dialysis station to FMC of North Charlotte (FMC-NC) for a total of 40 dialysis stations at FMC of North Charlotte upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station).

Need Determination

The 2019 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 January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there

is a surplus of 37 dialysis stations in Mecklenburg County. Therefore, the January 2019 SDR does not indicate a need for additional stations in Mecklenburg County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for FMC-NC in the January 2019 SDR is 4.23 patients per station per week, or 105.63 percent, based on 169 in-center dialysis patients and 40 certified dialysis stations [$169 / 40 = 4.23$; $4.23 / 4 = 1.0563$ or 105.63%].

Application of the facility need methodology indicates that up to a potential maximum of 16 additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW – JANUARY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		105.63%
Certified Stations		40
Pending Stations		0
Total Existing and Pending Stations		40
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR2)		169
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		158
Step	Description	Result
	Difference (SDR2 - SDR1)	11
(i)	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.1392
(ii)	Divide the result of Step (i) by 12	0.0116
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0696
(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	180.7658
(v)	Divide the result of Step (iv) by 3.2 patients per station	56.4893
	and subtract the number of certified and pending stations to determine the number of stations needed	16

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 16 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2019 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 one new station and is therefore consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 8; Section K, pages 42-44; Section N, pages 53-54; Section O, pages 55-58; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 9; Section C, page 15; Section L, pages 47-51; Section N, pages 53-54; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 10; Section C, pages 13-14; Section F, pages 22-29; Section K, pages 42-44; Section N, pages 53-54; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

The applicant proposes to add one dialysis station to FMC-NC for a total of 40 dialysis stations upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station).

The July 2018 SDR refers to this facility as BMA of North Charlotte. The January 2019 SDR refers to this facility as FMC of North Charlotte. The application uses both names in different places. According to clarifying information from the applicant, the facility is as listed in the January 2019 SDR – FMC of North Charlotte.

FMC-NC does not currently offer either home hemodialysis training or home peritoneal dialysis training and does not plan to offer either home hemodialysis training or home peritoneal dialysis training following completion of the proposed project.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station 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.

The following table illustrates current and projected patient origin.

FMC-NC – Current and Projected Patient Origin						
County	Current (12/31/2018)		Projected OY 1 (CY 2020)		Projected OY 2 (CY 2021)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Mecklenburg	152	98.1%	147	98.0%	153	98.1%
Cabarrus	2	1.3%	2	1.3%	2	1.3%
Rowan	1	0.6%	1	0.7%	1	0.6%
Total	155	100.0%	150	100.0%	156	100.0%

Source: Section C, pages 13 and 17

In Section C, pages 13-14, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 14-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. As a general rule, patients will receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... Failure to receive dialysis care will ultimately lead to the patient’s demise.

In this application, BMA has projected a patient population of 150 patients to be dialyzing at the BMA North Charlotte facility at the end of the first year. Failure to add this additional station will lead to higher utilization rates at the facility.”

Additionally, in Section B, page 6, the applicant demonstrates the need for the proposed project using the facility need methodology.

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

- FMC-NC is currently operating at a rate of 4.23 patients per station per day, or 105.63 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, pages 13 and 17, the applicant provides historical and projected utilization as illustrated in the following table.

FMC-NC – Historical and Projected Utilization						
	Historical (12/31/2018)		Projected OY 1 (CY 2020)		Projected OY 2 (CY 2021)	
County	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Mecklenburg	152	98.1%	147	98.0%	153	98.1%
Cabarrus	2	1.3%	2	1.3%	2	1.3%
Rowan	1	0.6%	1	0.7%	1	0.6%
Total	155	100.0%	150	100.0%	156	100.0%

In Section C, pages 13-14, the applicant provides the assumptions and methodology it used to project utilization, which are summarized below.

- The applicant begins its utilization projections by using its facility census as of December 31, 2018.
- The applicant assumes that the patient population currently receiving treatment at FMC-NC and who currently reside in Mecklenburg County will increase annually at a rate of 3.9 percent, which is the Five Year Average Annual Change Rate (AACR) for Mecklenburg County published in the January 2019 SDR.
- The applicant assumes no population growth for the patients who utilize the facility and live in other counties, but assumes that the patients will continue to dialyze at FMC-NC and adds them to the calculations when appropriate.
- In its application for FKC Mallard Creek (Project I.D. #F-11375-17), the applicant projected that 16 patients residing in Mecklenburg County and dialyzing at FMC-NC would transfer care to FKC Mallard Creek, and the applicant subtracts the 16 patients projected to transfer from the calculations on December 31, 2019 (when FKC Mallard Creek is projected to be certified).
- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 14, the applicant provides the calculations used to arrive at the projected patient census for OY1 and OY2, as summarized in the table below.

FMC-NC In-Center Projections	
Starting point of calculations is Mecklenburg County patients dialyzing in-center at FMC-NC on December 31, 2018.	152
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (3.9%).	$152 \times 1.039 = 157.9$
16 Mecklenburg County patients, projected to transfer care to FKC Mallard Creek, are subtracted from the projected patient population.	$157.9 - 16 = 141.9$
The patients from other counties are added. This is the projected census on December 31, 2019 and the starting census for this project.	$141.9 + 3 = 144.9$
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.9%).	$141.9 \times 1.039 = 147.5$
The patients from other counties are added. This is the projected census on December 31, 2020 (OY1).	$147.5 + 3 = 150.5$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (3.9%).*	$147.5 \times 1.039 = 153.2$
The patients from other counties are added. This is the projected census on December 31, 2021 (OY2).	$153.2 + 3 = 156.2$

*On page 14, the applicant appears to have made a typo. The applicant appears to multiply the Mecklenburg County patient population by 5.1% instead of 3.9%; however, the results are the same as if the applicant used the correct 3.9% rate.

The applicant rounds down and projects to serve 150 in-center patients on 40 stations, which is 3.75 patients per station per week ($150 \text{ patients} / 40 \text{ stations} = 3.75$), by the end of OY1 and

156 in-center patients on 40 stations, which is 3.90 patients per station per week (156 patients / 40 stations = 3.90), by the end of OY2. This 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 is reasonable and adequately supported for the following reasons:

- The January 2019 SDR states that FMC-NC’s utilization was 4.23 patients per station per week (a utilization rate of 105.63 percent) as of June 30, 2018.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Mecklenburg County as published in the January 2019 SDR to project growth of Mecklenburg County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development.
- The applicant does not project growth for its patients who do not reside in Mecklenburg County.
- 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).

Access

In Section C, page 15, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FMC-NC Projected Payor Mix CY 2021	
Payment Source	% of Patients
Self-Pay/Indigent/Charity	1.68%
Medicare	63.02%
Medicaid	14.11%
Commercial Insurance	9.66%
Medicare/Commercial	9.56%
Misc. (including VA)	1.97%
Total	100.00%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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 does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to add one dialysis station to FMC-NC for a total of 40 dialysis stations upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station).

In Section E, page 21, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the Status Quo:** the applicant states that maintaining the status quo would lead to higher utilization rates and potentially restrict patient admissions. Therefore, this is not an effective alternative.
- **Relocate Stations From Another Mecklenburg County Facility:** the applicant states that, as of December 31, 2018, all but one of its facilities in Mecklenburg County were operating above 80 percent utilization, and the one facility with utilization below 80 percent is new and has only 10 stations. Therefore, this is not an effective alternative.

On page 21, the applicant states that its proposal is the most effective alternative because it will have no capital expenditures and is necessary to meet the need for dialysis patients in Mecklenburg County.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station at FMC of North Charlotte for a total of no more than 40 certified stations at FMC of North Charlotte upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-**

17 (add 10 stations), and Project I.D. #F-11475-18 (add one station), which shall include any home hemodialysis training or isolation stations.

3. Bio-Medical Applications of North Carolina, Inc. 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 add one dialysis station to FMC-NC for a total of 40 dialysis stations upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station).

Capital and Working Capital Costs

In Section F.1, page 22, the applicant projects no capital costs for the proposed project. In Sections F.10 and F.11, pages 24 and 25, respectively, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. 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.

Projected Revenues and Operating Expenses		
FMC-NC	Operating Year 1 CY 2020	Operating Year 2 CY 2021
Total Treatments	21,785	22,674
Total Gross Revenues (Charges)	\$86,878,580	\$90,423,912
Total Net Revenue	\$6,431,646	\$6,694,108
Average Net Revenue per Treatment	\$295	\$295
Total Operating Expenses (Costs)	\$5,824,416	\$6,005,413
Average Operating Expense per Treatment	\$267	\$265
Net Income/Profit	\$607,230	\$688,695

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because 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.

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

C

The applicant proposes to add one dialysis station to FMC-NC for a total of 40 dialysis stations upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station 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 Table B of the January 2019 SDR, there are 26 facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 18 of which are operational. Information on all 26 of these dialysis facilities, from Table B of the January 2019 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	92.19%
BMA Nations Ford	BMA	Charlotte	28	90.18%
BMA of East Charlotte	BMA	Charlotte	26	79.81%
BMA West Charlotte	BMA	Charlotte	29	86.21%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	70.83%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	92.05%
FMC Matthews	BMA	Matthews	21	115.48%
FMC of North Charlotte	BMA	Charlotte	40	105.63%
FMC Southwest Charlotte	BMA	Charlotte	13	76.92%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	22.22%
Charlotte Dialysis	DaVita	Charlotte	36	77.78%
Charlotte East Dialysis	DaVita	Charlotte	34	80.88%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	65.63%
DSI Glenwater Dialysis	DSI	Charlotte	42	72.62%
Huntersville Dialysis	DaVita	Huntersville	14	100.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	78.13%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	37	70.27%
South Charlotte Dialysis***	DaVita	Charlotte	23	90.22%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: January 2019 SDR, Table B.

* Facility under development or which was not operational at the time of data collection for the January 2019 SDR.

**Facility which is dedicated exclusively to providing HH and PD training and support.

***Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section G, pages 31-33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“Mecklenburg County has the largest ESRD patient population of any county in North Carolina. The January 2019 SDR reports that as of June 30, 2018 there were 1,736 dialysis patients residing in Mecklenburg County. This is equiavlent [sic] to 9.49% of the total ESRD patient population of NC.

...

...all of these [BMA facilities in Mecklenburg County] were operating at or above the 80% utilization level as of December 31, 2018, except for BMA Nations Ford,

operating at 79.46%, and FMC Aldersgate facility, which was only certified as of October 1, 2018. In fact ... the average utilization [sic] across all BMA facilities was 3.60 patients per station, significantly higher than the average station utilization in Mecklenburg County.

...

.... The ESRD census of Mecklenburg County is increasing. The number of patients choosing to dialyze with BMA is increasing. BMA suggests additional stations are needed within Mecklenburg County and will continue to be needed.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination, as calculated using the methodology in the January 2019 SDR, for the proposed dialysis station.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 34, the applicant provides information about current and projected staffing for the proposed services. The applicant does not project to change its current staffing levels upon project completion.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 34-35, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1 and H-2. In Section I, page 38, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director expressing his

support for the proposed project and indicating his intent to continue serving as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 37, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

FMC-NC – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	Referral to FMC Charlotte Home Training Program
Home training HH PD Accessible follow-up program	Referral to FMC Charlotte Home Training Program Referral to FMC Charlotte Home Training Program Referral to FMC Charlotte Home Training Program
Psychological counseling	Referral to CMC Randolph Road
Isolation – hepatitis	Referral to FMC Charlotte
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Crash cart on site/staff trained; ambulance transport to hospital
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	Spectra
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	CMC; Sanger Heart & Vascular; MNA Vascular Access Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Charlotte Area Transportation (CATS); A-1 Wheelchair Transport, or area taxi services

The applicant provides supporting documentation in Exhibits I-1 through I-4.

In Section I, pages 38-40, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-4 and I-5.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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. Therefore, Criterion (9) is not applicable to this review.

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

NA

The applicant does not propose to construct any new space or 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, page 51, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

FMC-NC Historical Payor Mix CY 2018	
Payment Source	% of Patients
Self-Pay/Indigent/Charity	2.19%
Medicare	63.60%
Medicaid	14.26%
Commercial Insurance	8.57%
Medicare/Commercial	9.47%
Misc. (including VA)	1.90%
Total	100.00%

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	11%	52%	53%	12%	6%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table>; Latest Data 7/1/17 as of 7/17/18

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

**"Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, pages 49-50, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- (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, page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FMC-NC Projected Payor Mix CY 2021	
Payment Source	% of Patients
Self-Pay/Indigent/Charity	1.68%
Medicare	63.02%
Medicaid	14.11%
Commercial Insurance	9.66%
Medicare/Commercial	9.56%
Misc. (including VA)	1.97%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.68 percent of services will be provided to self-pay, indigent, and charity care patients; 72.58 percent to patients who will have some or all of their care paid for by Medicare; and 14.11 percent to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes 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, page 52, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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 add one dialysis station to FMC-NC for a total of 40 dialysis stations upon completion of this project, Project I.D. #F-11375-17 (relocate 12 stations to develop FKC Mallard Creek), Project I.D. #F-11400-17 (add 10 stations), and Project I.D. #F-11475-18 (add one station).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station 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 Table B of the January 2019 SDR, there are 26 facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 18 of which are operational. Information on all 26 of these dialysis facilities, from Table B of the January 2019 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	92.19%
BMA Nations Ford	BMA	Charlotte	28	90.18%
BMA of East Charlotte	BMA	Charlotte	26	79.81%
BMA West Charlotte	BMA	Charlotte	29	86.21%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	70.83%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	92.05%
FMC Matthews	BMA	Matthews	21	115.48%
FMC of North Charlotte	BMA	Charlotte	40	105.63%
FMC Southwest Charlotte	BMA	Charlotte	13	76.92%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	22.22%
Charlotte Dialysis	DaVita	Charlotte	36	77.78%
Charlotte East Dialysis	DaVita	Charlotte	34	80.88%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	65.63%
DSI Glenwater Dialysis	DSI	Charlotte	42	72.62%
Huntersville Dialysis	DaVita	Huntersville	14	100.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	78.13%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	37	70.27%
South Charlotte Dialysis***	DaVita	Charlotte	23	90.22%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: January 2019 SDR, Table B.

* Facility under development or which was not operational at the time of data collection for the January 2019 SDR.

**Facility which is dedicated exclusively to providing HH and PD training and support.

***Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section N, pages 53-54, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 53, the applicant states:

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

...

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the

application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 114 dialysis facilities located in North Carolina.

In Section O, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC-NC is an existing facility. Therefore, this Rule is not applicable to this review.

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

-C- In Section C, page 13, the applicant projects that FMC-NC will serve 150 patients on 40 stations, or a rate of 3.75 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-14, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.