ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: July 15, 2020
Findings Date: July 15, 2020

Project Analyst: Julie M. Faenza
Assistant Chief: Lisa Pittman

Project ID #: F-11872-20
Facility: FMC Charlotte
FID #: 955947
County: Mecklenburg
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add no more than 3 dialysis stations pursuant to facility need for a total of no more than 48 stations upon project completion

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 or "the applicant") proposes to add three stations to FMC Charlotte (FMC-C) for a total of 48 stations upon project completion.

Need Determination

Chapter 9 of the 2020 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 Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Mecklenburg County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station

per week, as stated in Condition 2.a. The utilization rate reported for FMC-C on page 159 of the 2020 SMFP is 89.2 percent or 3.57 patients per station per week, based on 157 in-center dialysis patients and 44 certified dialysis stations (157 patients / 44 stations = 3.57; 3.57 / 4 = 89.2%).

As shown in Table 9E on page 172 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC-C is up to 11 additional stations; thus, the applicant is eligible to apply to add up to 11 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to FMC-C, which is consistent with the 2020 SMFP calculated facility need determination for up to 11 dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on pages 30-31 of the 2020 SMFP, 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, pages 14-15; Section N, pages 51-53; Section O, pages 54-57; 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, pages 15-16; Section C, pages 23-24; Section L, pages 46-49; Section N, pages 51-53; 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 16; Section C, pages 20-21; Section F, pages 30-33; Section N, pages 51-53; and referenced exhibits. The information provided by the applicant 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 based on the following:

- The application is consistent with Condition 2 of the facility need methodology for dialysis stations.

- The application is consistent with Policy GEN-3.

(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 three stations to FMC-C for a total of 48 stations upon project completion.

In Section C, pages 19-21, the applicant documents that FMC-C currently provides home hemodialysis (HH) and home peritoneal dialysis (PD) training and support, and projects FMC-C will continue to provide training and support for home dialysis modalities during the first two operating years following project completion.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as *"…the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

FMC-C Current & Projected Patient Origin												
	Current – CY 2019						Projected – CY 2022					
	IC* Patients		HH Patients		PD Patients		IC* Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Mecklenburg	155	96.88%	3	100.00%	6	85.71%	175.4	97.77%	3.4	100.00%	6.8	87.16%
Cabarrus	0	0.00%	0	0.00%	1	14.29%	0	0.00%	0	0.00%	1	12.84%
Gaston	3	1.88%	0	0.00%	0	0.00%	3	1.67%	0	0.00%	0	0.00%
South Carolina	1	0.63%	0	0.00%	0	0.00%	1	0.56%	0	0.00%	0	0.00%
Other States	1	0.63%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Total	**160**	**100.00%**	**3**	**100.00%**	**7**	**100.00%**	**179.4**	**100.00%**	**3.4**	**100.00%**	**7.8**	**100.00%**

*IC = In-Center
Note: Table may not foot due to rounding.
Source: Section C, pages 19-20

In Section C, pages 20-21, and the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 22, 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. The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will generally dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient's demise.*
>
> *The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment."*

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

- According to the 2020 SMFP, as of December 31, 2018, FMC-C was operating at a rate of 3.57 patients per station per week, or 89.2 percent of capacity.

- According to the December 2019 FMC-C ESRD Data Collection Form, during CY 2019 FMC-C had a net gain of one dialysis station for a total of 45 certified stations on December 31, 2019. On December 31, 2019, FMC-C was serving 160 patients. Even though the utilization rate is lower than published in the 2020 SMFP, on December 31, 2019, FMC-C was operating at a rate of 3.56 patients per station per week, or 89 percent (160 patients / 45 stations = 3.56; 3.56 / 4 = 89%).

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, pages 19-20, and Form C in Section Q, the applicant provides historical and projected utilization, as shown in the table below.

FMC-C Historical & Projected Utilization												
	Historical – CY 2019						Projected – CY 2022					
	IC* Patients		HH Patients		PD Patients		IC* Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Mecklenburg	155	96.88%	3	100.00%	6	85.71%	175.4	97.77%	3.4	100.00%	6.8	87.16%
Cabarrus	0	0.00%	0	0.00%	1	14.29%	0	0.00%	0	0.00%	1	12.84%
Gaston	3	1.88%	0	0.00%	0	0.00%	3	1.67%	0	0.00%	0	0.00%
South Carolina	1	0.63%	0	0.00%	0	0.00%	1	0.56%	0	0.00%	0	0.00%
Other States	1	0.63%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Total	**160**	**100.00%**	**3**	**100.00%**	**7**	**100.00%**	**179.4**	**100.00%**	**3.4**	**100.00%**	**7.8**	**100.00%**

*IC = In-Center
Note: Table may not foot due to rounding.

In Section C, pages 19-21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census on December 31, 2019. On page 19, the applicant states that on December 31, 2019, its in-center patient census was comprised of 155 Mecklenburg County patients, three Gaston County patients, one South Carolina patient, and one patient from another state; its HH patient census was comprised of three Mecklenburg County patients; and its PD patient census was comprised of six Mecklenburg County patients and one Cabarrus County patient.

- The applicant projects growth of the Mecklenburg County patient population at an annual growth rate of 4.2 percent, which is the Mecklenburg County Five Year Average Annual Change Rate (AACR) as published in the 2020 SMFP.

- The applicant assumes the in-center patient from another state dialyzing at FMC-C on December 31, 2019 was a transient patient and does not include the patient in future projections.

- The applicant projects all other patients residing outside of Mecklenburg County (including the patient residing in South Carolina) and dialyzing at FMC-C on December 31, 2019 were doing so by patient choice. The applicant does not project growth in the patient population from outside of Mecklenburg County but adds them to the projections where appropriate.

- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 21, and in the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the tables below.

FMC-C In-Center Projected Utilization	
Starting point of calculations is Mecklenburg County in-center patients dialyzing at FMC-C on December 31, 2019.	155
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Mecklenburg County Five Year AACR (4.2%).	155 X 1.042 = 161.5
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2020 and the starting census for this project.	161.5 + 4 = 165.5
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County Five Year AACR (4.2%).	161.5 X 1.042 = 168.3
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2021 (OY1).	168.3 + 4 = 172.3
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County Five Year AACR (4.2%).	168.3 X 1.042 = 175.4
The patients from outside Mecklenburg County are added. This is the projected census on December 31, 2022 (OY2).	175.4 + 4 = 179.4

The applicant projects to serve 172.3 patients on 48 stations, which is 3.59 patients per station per week (172.3 patients / 48 stations = 3.59), by the end of OY1 and 179.4 patients on 48 stations, which is 3.74 patients per station per week (179.4 patients / 48 stations = 3.74), by the end of OY2. This exceeds the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

FMC-C HH Projected Utilization	
Starting point of calculations is Mecklenburg County HH patients dialyzing at FMC-C on December 31, 2019.	3
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Mecklenburg County Five Year AACR (4.2%). This is the starting census for the project.	3 X 1.042 = 3.1
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County Five Year AACR (4.2%). This is the projected census on December 31, 2021 (OY1).	3.1 X 1.042 = 3.3
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County Five Year AACR (4.2%). This is the projected census on December 31, 2022 (OY2).	3.3 X 1.042 = 3.4

FMC-C PD Projected Utilization	
Starting point of calculations is Mecklenburg County PD patients dialyzing at FMC-C on December 31, 2019.	6
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Mecklenburg County Five Year AACR (4.2%).	6 X 1.042 = 6.3
The Cabarrus County patient is added. This is the projected census on December 31, 2020 and the starting census for the project.	6.3 + 1 = 7.3
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County Five Year AACR (4.2%).	6.3 X 1.042 = 6.5
The Cabarrus County patient is added. This is the projected census on December 31, 2021 (OY1).	6.5 + 1 = 7.5
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County Five Year AACR (4.2%).	6.5 X 1.042 = 6.8
The Cabarrus County patient is added. This is the projected census on December 31, 2022 (OY2).	6.8 + 1 = 7.8

Projected utilization is reasonable and adequately supported for the following reasons:

- FMC-C was operating at a rate of 3.56 patients per station per week, or 89 percent of capacity, on December 31, 2019.
- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the Mecklenburg County patient population using the Five Year AACR for Mecklenburg County of 4.2 percent as published in the 2020 SMFP.
- The applicant projects no growth for patients residing outside of Mecklenburg County and adequately supports the decisions to include or exclude patients residing outside of Mecklenburg County who were dialyzing at the facility on December 31, 2019.

Access

In Section C, page 23, the applicant states:

> *"Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women,* [people with disabilities]*, 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.*
>
> *Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender,* [disability]*, age or any other grouping/category or basis for being an underserved person."*

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-C Projected Payor Mix CY 2022						
	In-Center		HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	9.70	5.42%	0.00	0.00%	0.38	4.91%
Commercial Insurance*	19.00	10.62%	0.53	15.62%	2.28	29.31%
Medicare*	119.90	66.84%	2.65	78.09%	3.65	46.85%
Medicaid*	15.30	8.55%	0.00	0.00%	0.59	7.58%
Medicare/Commercial	12.10	6.73%	0.11	3.16%	0.73	9.34%
Misc. (including VA)	3.30	1.84%	0.11	3.13%	0.16	2.01%
Total	**179.4**	**100.00%**	**3.39**	**100.00%**	**7.79**	**100.00%**

*Including any managed care plans

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 three stations to FMC-C for a total of 48 stations upon project completion.

In Section E, page 29, 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 maintaining the status quo would not be responsive to the growth of the patient census; therefore, this is not an effective alternative.

- Apply for Fewer than Three Stations: the applicant states applying for fewer stations would also not be responsive to the growth of the patient census; therefore, this is not an effective alternative.

- Apply for More than Three Stations: the applicant states its physical plant cannot support more than 46 in-center stations and two HH stations to train and support HH patients in limited additional space; therefore, this is not an effective alternative.

On page 29, the applicant states its proposal is the most effective alternative because the growth of the patient census requires the facility to add stations and it does not have the physical space to add more than three stations.

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 2020 State Medical Facilities Plan, Bio-Medical Applications of North Carolina, Inc. shall develop no more than three additional in-center dialysis stations at FMC Charlotte for a total of no more than 48 in-center (and home hemodialysis) stations at FMC Charlotte upon project completion.**

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 three stations to FMC-C for a total of 48 stations upon project completion.

Capital and Working Capital Costs

In Section F, page 30, and on Form F.1a in Section Q, the applicant states the project will not incur any capital costs.

In Section F, pages 31-32, the applicant states there are no projected working capital costs 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. On Form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FMC-C	**Full Fiscal Year 1 CY 2021**	**Full Fiscal Year 2 CY 2022**
Total Treatments	26,563	27,647
Total Gross Revenues (Charges)	$167,104,964	$173,927,848
Total Net Revenue	$8,866,994	$9,228,596
Average Net Revenue per Treatment	$334	$334
Total Operating Expenses (Costs)	$8,658,164	$8,792,505
Average Operating Expense per Treatment	$326	$318
Net Income/Profit	**$208,830**	**$436,091**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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 three stations to FMC-C for a total of 48 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as *"…the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 27 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 27 of these dialysis facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	**Owner**	**Location**	**# of Certified Stations**	**Utilization**
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
Renaissance Park Dialysis*	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis***	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis***	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records
*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.
**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; the 2020 SMFP lists both the existing operational facility and the replacement facility.

In Section G, page 36, 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 the additional stations are needed to support the growing patient census at the facility. The applicant also states the stations are for patients being served by this facility, not for patients being served by another provider, and states the projected growth of the patient census is based on the Mecklenburg County Five Year AACR.

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 2020 SMFP, for the proposed dialysis stations.

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing and 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

On Form H in Section Q, the applicant provides information about current and projected staffing for the proposed services. The applicant projects no changes to its current staffing for the project's first two operating years.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 37, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating his support for the proposed project and 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 39, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

FMC-C – Ancillary and Support Services	
Services	**Provider**
In-center dialysis/maintenance	On site
Self-care training	On site
Home training HH PD Accessible follow-up program	 On site On site On site
Psychological counseling	CMC Mental Health or Randolph Behavioral Health
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Provided by facility staff until ambulance arrival
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	On site
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Metrolina Vascular Access Care, Carolinas Medical Center, Novant Health Presbyterian Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Carolinas Medical Center Rehabilitation
Transportation	Charlotte Area Transportation, Medicaid Transport Services, Local cab vendors

In Section I, page 40, the applicant describes its existing relationships with other local health care and social service providers.

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 47, the applicant provides the historical payor mix during CY 2019 for its existing services, as shown in the table below.

FMC-C Historical Payor Mix CY 2019						
	In-Center		HH		PD	
Payment Source	**# Patients**	**% Patients**	**# Patients**	**% Patients**	**# Patients**	**% Patients**
Self-Pay	8.67	5.42%	0.00	0.00%	0.34	4.91%
Commercial Insurance*	16.99	10.62%	0.47	15.62%	2.05	29.31%
Medicare*	106.95	66.84%	2.34	78.09%	3.28	46.85%
Medicaid*	13.68	8.55%	0.00	0.00%	0.53	7.58%
Medicare/Commercial	10.77	6.73%	0.09	3.16%	0.65	9.34%
Misc. (including VA)	2.95	1.84%	0.09	3.13%	0.14	2.01%
Total	**160**	**100.00%**	**3**	**100.00%**	**7**	**100.00%**

*Including any managed care plans

In Section L, page 46, the applicant provides the following comparison.

	Percentage of Total Patients Served by FMC-C during CY 2019	Percentage of the Population of Mecklenburg County
Female	33.5%	51.9%
Male	66.5%	48.1%
Unknown	0.0%	0.0%
64 and Younger	52.9%	88.8%
65 and Older	47.1%	11.2%
American Indian	0.0%	0.8%
Asian	0.6%	6.4%
Black or African-American	82.4%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	1.8%	46.4%
Other Race	5.9%	13.4%
Declined / Unavailable	8.8%	0.0%

Sources: BMA Internal Data, US Census Bureau

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 47-48, 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 48, 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.

(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 during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FMC-C Projected Payor Mix CY 2022						
	In-Center		HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	9.70	5.42%	0.00	0.00%	0.38	4.91%
Commercial Insurance*	19.00	10.62%	0.53	15.62%	2.28	29.31%
Medicare*	119.90	66.84%	2.65	78.09%	3.65	46.85%
Medicaid*	15.30	8.55%	0.00	0.00%	0.59	7.58%
Medicare/Commercial	12.10	6.73%	0.11	3.16%	0.73	9.34%
Misc. (including VA)	3.30	1.84%	0.11	3.13%	0.16	2.01%
Total	**179.4**	**100.00%**	**3.39**	**100.00%**	**7.79**	**100.00%**

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.42 percent of in-center services and 4.91 percent of PD services will be provided to self-pay patients; 73.57 percent to in-center patients, 81.25 percent to HH patients, and 56.19 percent to PD patients who will have some or all of their care paid for by Medicare (includes Medicare/commercial); and 8.55 percent of in-center services and 7.58 percent of PD services to Medicaid patients.

On page 49, 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 because it is based on the historical payor mix.

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 49, 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 50, 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-2.

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 three stations to FMC-C for a total of 48 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as *"…the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 27 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 27 of these dialysis facilities is shown in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
Renaissance Park Dialysis*	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis***	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis***	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records
*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.
**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; the 2020 SMFP lists both the existing operational facility and the replacement facility.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 51, the applicant states:

> *"The applicant does not expect this proposal to have any effect on the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Charlotte facility begins with the current patient population and projects growth of that population consistent with the Mecklenburg County Five Year Average Annual Change Rate published in the 2020 SMFP."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 52, the applicant states:

> *"This is a proposal to add three stations to the FMC Charlotte facility. The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the FMC Charlotte facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area."*

Regarding the impact of the proposal on quality, in Section N, page 52, the applicant states:

> *"Quality of care is always in the forefront at Fresenius related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment."*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 52, the applicant states:

> *"All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. …. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women,* [people with disabilities]*, 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.*
>
> *Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender,* [disability]*, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities."*

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N 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

On Form A in Section Q, 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 125 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 57, 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 125 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, including Temporary Rule 10A NCAC 14C .2203, 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 kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- FMC-C 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:*

(1) *an existing dialysis facility; or*
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 21, and on Form C in Section Q, the applicant projects that FMC-C will serve 172.3 patients on 48 stations, or a rate of 3.59 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 19-21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.