

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 22, 2019

Findings Date: May 22, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: F-11664-19

Facility: Metrolina Kidney Center

FID #: 955949

County: Union

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

Project: Add no more than seven dialysis stations for a total of no more than 29 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 and/or the applicant), d/b/a Metrolina Kidney Center proposes to add seven dialysis stations to the existing facility for a total of no more than 29 stations upon completion of this project. Metrolina Kidney Center is also referred to as BMA Monroe in the application. Metrolina Kidney Center was recently certified to offer both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program. The home training program started on February 1, 2019. The parent company of Bio-Medical Applications of North Carolina, Inc. is Fresenius Medical Care Holdings, Inc. (Fresenius).

#### 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 no county need determination for Union County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Metrolina Kidney Center in the January 2019 SDR is 4.4286 patients per station per week. This utilization rate was calculated based on 93 in-center dialysis patients and 21 certified dialysis stations as of June 30, 2018 (93 patients /21 stations = 4.4286 patients per station per week). Application of the facility need methodology indicates that 7 additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		110.71%
Certified Stations		21
Pending Stations		1
<b>Total Existing and Pending Stations</b>		<b>22</b>
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		93
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		91
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.0440
(ii)	Divide the result of step (i) by 12	0.0037
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0220
(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	95.0440
(v)	Divide the result of step (iv) by 3.2 patients per station	29.7012
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>8</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 8 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 7 new stations and, therefore, is 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.”*

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 9, 11-12, Section K.1(g), page 46, Section N, page 56, Section O, pages 58-61, and Exhibits O-1 and O-2. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 17, Section L, pages 50-54, Exhibit L-1 and Section N, page 56. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 11-12, Section C, pages 14-16, Section F, pages 25-28, Section K, pages 46-47 and Section N.1, page 56. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **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.

- (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 seven dialysis stations to the existing facility, Metrolina Kidney Center, for a total of no more than 29 stations upon completion of this 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 Union County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC) patients, home hemodialysis (HH) patients and peritoneal (PD) patients.

**Metrolina Kidney Center: Dialysis Patients as of 12/31/18**

COUNTY	IC	HH	PD
Union	85	0	0
Georgia	1	0	0
Other States	2	0	0
Totals	88	0	0

Source: Table on page 19 of the application.

Note: During CY2018 Metrolina Kidney Center was not certified to provide home dialysis training and support.

COUNTY	OPERATING YEAR 1 CY2020			OPERATING YEAR 2 CY2021			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Union	106.2	6.7	6.7	118.8	7.5	7.5	100.0%	100.0%
Totals	106.2	6.7	6.7	118.8	7.5	7.5	100.0%	100.0%

Source: Table on page 14 of the application.

In Section C, pages 14-16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2018 and January 2019 SDRs. The facility need methodology shows a need for eight dialysis stations and the proposed project is for seven dialysis additional dialysis stations at Metrolina Kidney Center.

In Section C, pages 16-17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 14-16, the applicant describes its need methodology assumptions for projecting utilization based on the proposed project as follows:

- The applicant projects the first full operating year of the project will be January 1, 2020 – December 31, 2020 (CY2020) and the second full operating year will be January 1, 2021 – December 31, 2021 (CY2021).
- The applicant projects future patient populations for the facility starting as of December 31, 2018 with the 85 Union County IC patients dialyzing at Metrolina Kidney Center.
- As of December 31, 2018 there were also three patients from other states dialyzing at the facility. BMA does not project any patients from other states or any patients from other counties as part of Metrolina Kidney Center’s future patient population.
- The applicant calculates projected utilization by growing IC Union County patients at 11.8%, the Five-Year Average Annual Change Rate (AACR) for Union County, as shown in Table D in the January 2019 Semi-Annual Dialysis Report (SDR).

The information is reasonable and adequately supported because the proposed project is consistent with the facility need methodology.

### *Projected Utilization*

#### *In-Center Patients*

In Section C.1, pages 14-15, the applicant describes its assumptions and the methodology used to project utilization of IC patients, which are summarized as follows:

- Operating Year 1 = Calendar Year 2020 (CY2020)
- Operating Year 2 = Calendar Year 2021 (CY2021)
- As of December 31, 2018, Metrolina Kidney Center had 88 in-center patients, consisting of 85 residents of Union County and 3 patients residing in other states.
- BMA does not include the three patients from other states in projected patient populations of the facility.

- Utilization by Union County residents is projected to grow at 11.8%, the Five-Year Average Annual Change Rate (AACR) for Union County, as shown in Table D in the January 2019 Semi-Annual Dialysis Report (SDR).

The following table illustrates application of these assumptions and the methodology used.

Begin January 1, 2019 with the 85 Union County patients	85
Project the Union County in-center patients forward to December 31, 2019, using the Five Year AACR for Union County.	$85 \times 1.118 = 95.03$
Project this Union County patient population forward one year to December 31, 2020 using the Five Year AACR for Union County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>	$95.03 \times 1.118 = \mathbf{106.24}$
Project this Union County patient population forward one year to December 31, 2021 using the Five Year AACR for Union County. <b>This is the projected ending census for Operating Year 1 (CY2021).</b>	$106.24 \times 1.118 = \mathbf{118.77}$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 106 and 118 in-center patients, respectively.

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

- OY1: 3.6551 patients per station per week, or 91.38% ( $106 \text{ patients} / 29 \text{ stations} = 3.6551 / 4 = 0.9138$  or 91.38%).
- OY2: 4.0689 patients per station per week, or 101.7% ( $118 \text{ patients} / 29 \text{ stations} = 4.0689/4 = 1.017$  or 101.7%).

The projected utilization of 3.6551 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 85 existing Union County patients.
- The Union County patients are projected to increase based on 11.8% per year which is the Five Year AACR for Union County as reported in Table D of the January 2019 SDR.

*HH Patient Utilization*

In Section C.1, pages 14-15, the applicant describes its assumptions and the methodology used to project utilization of HH patients, which are summarized as follows:

- The HH program at Metrolina Kidney Center started on February 1, 2019.

- The HH program had two patients by February 28, 2019.
- Based on discussions with nephrology physicians of Metrolina Nephrology Associates and the BMA Home Program Manager, BMA projects there will be 6 HH patients by the end of 2019.
- The HH patients are projected to increase for CY2020 and CY2021 based on the five-year AACR for Union County of 11.8% as reported in Table D of the January 2019 SDR.

The following table illustrates application of the assumptions and the methodology used to project HH patient utilization.

Begin January 1, 2019 with no HH patients.	0
Project the Union County HH patients forward to December 31, 2019.	6
Project this Union County HH patient population forward one year to December 31, 2020 using the Five Year AACR for Union County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>	$6 \times 1.118 = \mathbf{6.708}$
Project this Union County HH patient population forward one year to December 31, 2021 using the Five Year AACR for Gaston County. <b>This is the projected ending census for Operating Year 2 (CY2021).</b>	$6.708 \times 1.118 = \mathbf{7.5}$

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

- The applicant conservatively projects 6 HH patients as of December 2019 considering the HH program commenced on February 1, 2019 and already had 2 HH patients by February 28, 2019.
- The Union County patients are projected to increase based on 11.8% per year which is the Five Year AACR for Union County as reported in Table D of the January 2019 SDR.

*PD Patient Utilization*

In Section C.1, pages 14-16, the applicant describes its assumptions and the methodology used to project utilization of PD patients, which are summarized as follows:

- The PD program at Metrolina Kidney Center started on February 1, 2019.
- The PD program had one patient by February 28, 2019.

- Based on discussions with nephrology physicians of Metrolina Nephrology Associates and the BMA Home Program Manager, BMA projects there will be 6 PD patients by the end of 2019.
- The PD patients are projected to increase for CY2020 and CY2021 based on the five-year AACR for Union County of 11.8% as reported in Table D of the January 2019 SDR.

The following table illustrates application of the assumptions and the methodology used to project PD patient utilization.

Begin January 1, 2019 with no PD patients.	0
Project the Union County PD patients forward to December 31, 2019.	6
Project this Union County PD patient population forward one year to December 31, 2020 using the Five Year AACR for Union County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>	$6 \times 1.118 = \mathbf{6.708}$
Project this Union County PD patient population forward one year to December 31, 2021 using the Five Year AACR for Gaston County. <b>This is the projected ending census for Operating Year 2 (CY2021).</b>	$6.708 \times 1.118 = \mathbf{7.5}$

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

- The applicant conservatively projects 6 PD patients as of December 2019 considering the PD program commenced on February 1, 2019 and already had 1 PD patient by February 28, 2019.
- The Union County patients are projected to increase based on 11.8% per year which is the Five Year AACR for Union County as reported in Table D of the January 2019 SDR.

**Access**

In Section C, page 16, the applicant states,

*“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 51, 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.

**CY2021**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	8.1%
Medicare	44.4%
Medicare/Commercial	36.3%
Miscellaneous (incl. VA)	0.7%
Commercial Insurance	8.9%
Self Pay/Indigent/Charity	1.5%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 51 of the application.

Note: Totals might not foot due to rounding.

The projected payor mix is reasonable and adequately supported.

**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 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. 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

In Section E, page 23, 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 is not an effective alternative because the facility need methodology showed a need for eight additional stations at Metrolina Kidney Center.

*Relocate surplus stations from either Anson County or Mecklenburg County*- The applicant states the utilization of the BMA facilities is high in both counties and therefore cannot support relocating stations from those facilities.

*Relocate surplus stations from a contiguous county*- The applicant states that this was not the most effective alternative as relocating stations pursuant to Policy ESRD-2 is not permitted in April according to the application schedule in the 2019 SMFP.

*Relocate stations from FKC Indian Trail*- This was not possible as FKC Indian Trail only has the minimum of 10 dialysis stations.

*Apply for fewer than seven stations*- Projected utilization at Metrolina Kidney Center exceeds 3.2 patients per station. Applying for less than seven stations would leave the facility with an insufficient number of stations to meet the need.

On page 23, the applicant states that its proposal is the most effective alternative because

- The projected population to be served has a demonstrated need for the proposed additional stations.
- The facility need methodology shows a need for 8 additional dialysis stations at the facility based on projected utilization.
- The capital cost of the proposed project is only \$26,250 since the applicant can utilize existing space at the facility.

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

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 7 additional dialysis stations for a total of no more than 29 certified stations at Metrolina Kidney Center upon completion of this project, 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 seven dialysis stations to the existing facility, Metrolina Kidney Center, for a total of no more than 29 stations upon completion of this project.

**Capital and Working Capital Costs**

In Section F, page 25, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$26,250
<b>Total</b>	<b>\$26,250</b>

In Section F.1, page 25, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 28-29, the applicant states that there will be no start-up costs and no initial operating costs since Metrolina Kidney Center is an existing facility.

**Availability of Funds**

In Section F.2, page 26, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	BMA	Total
Accumulated reserves or OE *	\$26,250	\$26,250
<b>Total Financing</b>	<b>\$26,250</b>	<b>\$26,250</b>

\* OE = Owner's Equity

Exhibit F-1 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 contains a copy of the Consolidated Balance Sheets from Fresenius Medical Care Holdings, Inc., which showed that as of December 31, 2017 Fresenius Medical Care Holdings, Inc. had \$569,818,000 in cash and equivalents, \$19,822,127,000 in total assets and \$10,542,494,000 in net assets (total assets less total liabilities).

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section R, Form B, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>
Total Treatments	16,598	18,672
Total Gross Revenues (Charges)	\$61,192,824	\$74,463,936
Total Net Revenue	\$4,984,682	\$5,620,604
Average Net Revenue per Treatment	\$300	\$301
Total Operating Expenses (Costs)	\$4,651,240	\$4,982,387
Average Operating Expense per Treatment	\$280	\$267
Net Income	\$333,442	\$638,217

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 for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - 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 seven dialysis stations to the existing facility, Metrolina Kidney Center, for a total of no more than 29 stations upon completion of this 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 Union County. Facilities may also serve residents of counties not included in their service area.

BMA operates two of the four dialysis facilities in Union County, as shown in the table below.

**Union County Dialysis Facilities  
 as of June 30, 2018**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Metrolina Kidney Center*	BMA	93	Monroe	21	1	110.71%
Fresenius Kidney Care Indian Trail	BMA	3	Indian Trail	10	0	7.50%
Marshville Dialysis**	DVA	32	Marshville	12	4	66.67%
Union County Dialysis***	DVA	103	Monroe	30	-4	85.83%

Source: Table B, January 2019 SDR

\*Metrolina Kidney Center was certified for 22 dialysis stations as of December 3, 2018. (See Exhibit A-3 of the application.)

\*\*Marshville Dialysis was conditionally approved to relocate 4 dialysis stations from Union County Dialysis for a total of 16 dialysis stations. (Project ID #F-11490-18).

\*\*\*Union County Dialysis was conditionally approved for 3 additional dialysis stations (Project ID# F-11322-17).

In Section G, pages 33-34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis stations in Union County. The applicant states:

*“BMA is not creating unnecessary duplication of existing or approved health services. Rather this application seeks to ensure that adequate dialysis resources are available for the patient population choosing to dialyze at the Metrolina Kidney Center.”*

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

- Based on the facility need methodology in the January 2019 SDR there is a need for up to eight additional dialysis stations.
- The applicant adequately demonstrates that the proposed seven dialysis stations are needed in addition to the existing or approved dialysis stations at Metrolina Kidney Center.

### **Conclusion**

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- 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.

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

C

In Section H.1, page 35, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(CY2018)	2nd Full Fiscal Year (CY2021)
RNs	5.00	5.00
PCT	10.50	10.50
Home Training Nurse	1.00	2.00
Dietician	1.00	1.00
Social Worker	0.15	0.15
Clinical Manager	1.00	1.00
Admin (FMC Dir. Ops)	1.00	1.00
In-Service	0.15	0.15
Clerical	1.50	1.50
Chief Tech	0.15	0.15
Equipment Tech	1.00	1.00
<b>TOTAL</b>	<b>22.45</b>	<b>23.45</b>

The assumptions and methodology used to project staffing are provided in Sections H and R. 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.3 and H.4, page 36, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-1 and H-2, the applicant provides supporting documentation. In Section I.3, page 40, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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.

In Section I.1, page 39, 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:

<b>METROLINA KIDNEY CENTER DIALYSIS Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On-Site
Self-care training (in-center)	On-Site
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On-Site
Psychological counseling	Referral to Daymark Recovery Services, Monroe
Isolation – hepatitis	On-Site
Nutritional counseling	On-Site
Social Work services	On-Site
Acute dialysis in an acute care setting	CMC Union CMC Union County Hospital
Emergency care	BMA/ Transport to Hospital
Blood bank services	CMC Union County Hospital
Diagnostic and evaluation services	CMC Union County Hospital
X-ray services	CMC Union County Hospital
Laboratory services	SPECTRA
Pediatric nephrology	Carolinas Medical Center, Charlotte
Vascular surgery	Metrolina Surgical Specialists; Mid-Carolina Surgery Specialists; Metrolina Access Center
Transplantation services	Carolinas Medical Center, Charlotte
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services
Transportation	Adventure Vans, DSS, Union County Transportation; Union County Ambulance Services

Source: Table on page 39 of the application.

On page 39, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-2 through I-4.

In Section I, pages 40-42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2 through 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.

- (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 make more than minor renovations to 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 54, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown in the table below.

**Metrolina Kidney Center Payor Mix  
 CY2018**

<b>Payor Category</b>	<b>Percent of Total Patients*</b>
Medicaid	10.70%
Medicare	60.72%
Medicare/Commercial	8.49%
Miscellaneous (incl. VA)	5.86%
Commercial Insurance	9.65%
Self Pay/Indigent/Charity	4.58%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 54 of the application.

\*During CY2018 Metrolina Kidney Center was not certified to provide home dialysis training and support.

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.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial and Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>
Union	12%	51%	28%	10%	6%	10%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>

Latest Data 7/1/17 as of 7/17/18

\* Excludes "White alone, 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 25-26<sup>1</sup>) 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.

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, in Section L.3 (e), page 53, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”*

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

In Section L.6, page 53, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

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 51, 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.

CY2021	
Payor Category	Percent of Total Patients
Medicaid	8.1%
Medicare	44.4%
Medicare/Commercial	36.3%
Miscellaneous (incl. VA)	0.7%
Commercial Insurance	8.9%
Self Pay/Indigent/Charity	1.5%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 51 of the application.

Note: Totals might not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.5% of total services will be provided to self-pay/indigent/charity patients, 80.7% to Medicare patients and 8.1% to Medicaid patients.

On page 51, the applicant provides the assumptions and methodology used 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 its most recent historical payor mix, including home training projections based on BMA's experience at FMC Charlotte.

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.4, page 53, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 55, 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 seven dialysis stations to the existing facility, Metrolina Kidney Center, for a total of no more than 29 stations upon completion of this project.

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 Union County. Facilities may also serve residents of counties not included in their service area.

BMA operates two of the four dialysis facilities in Union County, as shown in the table below.

**Union County Dialysis Facilities  
 as of June 30, 2018**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Metrolina Kidney Center*	BMA	93	Monroe	21	1	110.71%
Fresenius Kidney Care Indian Trail	BMA	3	Indian Trail	10	0	7.50%
Marshville Dialysis**	DVA	32	Marshville	12	4	66.67%
Union County Dialysis***	DVA	103	Monroe	30	-4	85.83%

Source: Table B, January 2019 SDR

\*Metrolina Kidney Center was certified for 22 dialysis stations as of December 3, 2018. (See Exhibit A-3 of the application.)

\*\*Marshville Dialysis was conditionally approved to relocate 4 dialysis stations from Union County Dialysis for a total of 16 dialysis stations. (Project ID #F-11490-18).

\*\*\*Union County Dialysis was conditionally approved for 3 additional dialysis stations (Project ID# F-11322-17).

In Section N, pages 56-57, 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 56, the applicant states:

*“The applicant does not expect this proposal to have effect on the competitive climate in Union County. The applicant does not project to serve dialysis patients currently being served by another provider.”*

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

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 dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of more than 100 Fresenius related dialysis facilities located in North Carolina.

In Section O.3, page 61, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to (immediate jeopardy) quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- The applicant is not proposing to establish a new ESRD facility.

(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.2, pages 14-16, the applicant provides the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The applicant projects to serve 106 IC patients on 29 stations, which is 3.6551 patients per station per week ( $106 \text{ patients} / 29 \text{ stations} = 3.6551$ ), by the end of OY1. 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).

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

-C- In Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project utilization of the facility.