

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 25, 2018

Findings Date: May 25, 2018

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: E-11480-18

Facility: FMC of Catawba Valley

FID #: 010648

County: Catawba

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

Project: Add one dialysis station for a total of 25 dialysis stations upon completion of this project, Project I.D. #E-11209-16 (relocate six dialysis stations), and Project I.D. #E-11390-17 (add five stations)

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) d/b/a FMC of Catawba Valley (Catawba Valley) proposes to add one dialysis station to the existing facility for a total of 25 stations upon completion of this project, Project I.D. #E-11209-16 (relocate six dialysis stations), and Project I.D. #E-11390-17 (add five stations).

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of nine dialysis stations in Catawba County. Therefore, the January 2018 SDR does not indicate a need for additional stations in Catawba County based on the county

need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for Catawba Valley in the January 2018 SDR is 4.04 patients per station per week, or 101 percent, based on 101 in-center dialysis patients and 25 certified dialysis stations [$101 / 25 = 4.04$; $4.04 / 4 = 1.01$ or 101%].

Below is a table that illustrates the facility need for additional dialysis stations at Catawba Valley:

JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		101%
Certified Stations		25
Pending Stations		5
Total Existing and Pending Stations		30
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR2)		101
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR1)		93
Step	Description	Result
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.1720
(ii)	Divide the result of Step (i) by 12	0.0143
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0860
(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	109.6882
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.2776
	and subtract the number of certified and pending stations to determine the number of stations needed	4

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add one new station; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.4(a), page 8; Section K.1(g), page 43; Section N.1, page 52; 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.4(b), pages 9-10; Section C.3, page 17; Section L, pages 46-50; Section N.1, page 52; 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.4(c), page 10; Section C, pages 14-16; Section F, pages 24-31; Section K, pages 41-43; Section N.1, page 52; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

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

C

BMA proposes to add one dialysis station to its existing Catawba Valley facility for a total of 25 stations upon completion of this project, Project I.D. #E-11209-16 (relocate six dialysis stations), and Project I.D. #E-11390-17 (add five stations). Catawba Valley does not serve home hemodialysis or home peritoneal dialysis patients.

Patient Origin

On page 365, the 2018 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 Catawba County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin as provided in Section C, pages 14 and 19.

Catawba Valley Patients by County				
	Current (12/31/2017)		Projected (Operating Year 2)	
County	# of IC Patients	% of Total	# of IC Patients	% of Total
Catawba	98	98.9%	91.1	98.9%
Alexander	1	1.1%	1	1.1%
Total	99	100.0%	92	100.0%

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

Analysis of Need

In Section C, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 16, the applicant states:

“Dialysis treatment is not optional. It is life sustaining. Absent approval..., some patients would be forced to dialyze on a third, or evening shift, or seek dialysis at another location.

No patient should be forced to dialyze on the third, or evening shift. Dialysis is a difficult lifestyle. Couple that lifestyle with travel to the facility in winter months on rural roads and dialysis treatment becomes exceedingly challenging.

The only alternative to the third, or evening shift is for patients to be referred to another dialysis facility. Patients should not have to choose between dialysis in a convenient setting, close to their residence, or dialysis at an inconvenient time.

Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates.

Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates.

Patients should not have to make such choices. Approval of this application will assure patients of continued access to care in a convenient setting, at times which are convenient for the patient.”

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

- Catawba Valley is currently operating at a rate of 4.04 patients per station per day, or 101 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility via use of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

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

Catawba Valley Historical and Projected Patient Utilization					
County	Historical (as of 12/31/2017)	Operating Year 1 CY 2019	Operating Year 2 CY 2020	County Patients as % of Total	
				OY 1	OY 2
Catawba	98	84	91	98.8%	98.9%
Alexander	1	1	1	1.2%	1.1%
Total	99	85	92	100.0%	100.0%

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology it used to project utilization, which are summarized below.

- The applicant begins its utilization projections by using its facility census as of December 31, 2017.
- The applicant assumes that the patient population currently receiving treatment at Catawba Valley and who currently reside in Catawba County will increase at a rate of 8.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Catawba County published in the January 2018 SDR.
- The applicant assumes no population growth for the patient who utilizes the facility and lives in Alexander County, but assumes that the patient will continue to dialyze at Catawba Valley and is added to the calculations when appropriate.
- In its application for FKC Newton (Project I.D. #E-11209-16), the applicant projected that 28 patients residing in Catawba County and dialyzing at Catawba Valley would transfer care to FKC Newton, and the applicant subtracts the 28 patients projected to transfer from the calculations on December 31, 2018 (when FKC Newton is projected to be certified).
- The project is scheduled for completion on December 31, 2018. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 15, the applicant provides the calculations used to arrive at the projected patient census for OY1 and OY2 as summarized in the table below.

Catawba Valley	
Starting point of calculations is Catawba County patients dialyzing at Catawba Valley on December 31, 2017.	98
Catawba County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (8.1%).	$98 \times 1.081 = 105.9$
28 Catawba County patients, projected to transfer care to FKC Newton, are subtracted from the projected patient population.	$105.9 - 28 = 77.9$
The patient from Alexander County is added. This is the projected census on December 31, 2018 and the starting census for this project.	$77.9 + 1 = 78.9$
Catawba County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (8.1%).	$77.9 \times 1.081 = 84.3$
The patient from Alexander County is added. This is the projected census on December 31, 2019 (OY1).	$84.3 + 1 = 85.3$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (8.1%).	$84.3 \times 1.081 = 91.1$
The patient from Alexander County is added. This is the projected census on December 31, 2020 (OY2).	$91.1 + 1 = 92.1$

The applicant projects to serve 85 in-center patients on 25 stations, which is 3.4 patients per station per week ($85 \text{ patients} / 25 \text{ stations} = 3.4$), by the end of OY1 and 92 in-center patients on 25 stations, which is 3.68 patients per station per week ($92 \text{ patients} / 25 \text{ stations} = 3.68$), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The January 2018 SDR states that Catawba Valley’s utilization was 4.04 patients per station per week (a utilization rate of 101 percent) as of June 30, 2017.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Catawba County as published in the January 2018 SDR to project growth of Catawba County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development.
- The applicant does not project growth for its patient who does not reside in Catawba County.
- The applicant’s projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 17, the applicant states:

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

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

In Section L, page 47, 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.

Catawba Valley Projected Payor Mix CY 2020	
Payment Source	% Total Patients
Self-Pay/Indigent/Charity	1.63%
Medicare	67.16%
Medicaid	7.05%
Commercial Insurance	7.30%
Medicare/Commercial	13.42%
Misc. (including VA)	3.44%
Total	100.00%

The applicant states on page 47 that the future payor mix is based on Catawba Valley's historical experience in 2017. 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

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

- Relocate Stations from FMC Hickory

On page 23, the applicant states that its proposal is the most effective alternative because the facility need methodology shows additional stations are needed, and FMC Hickory is also applying for new stations because its facility utilization is higher than 80 percent (87.14 percent per the January 2018 SMFP).

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 applicant utilizes the facility need methodology to show the need for an additional station.
- The applicant's projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant adequately demonstrates that transferring stations from another facility in the same county is not a less costly or more effective option to increase the number of stations at Catawba Valley.

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. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Catawba Valley shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Catawba Valley shall develop no more than one additional dialysis station for a total of no more than 25 certified stations upon completion of this project, Project I.D. #E-11209-16 (relocate six dialysis stations), and Project I.D. #E-11390-17 (add five stations), which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Catawba Valley 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

BMA proposes to add one dialysis station to its existing Catawba Valley facility for a total of 25 stations upon completion of this project and related projects.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant states that it projects no capital costs for the proposed project. In Section F.10, page 27, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
Catawba Valley	Operating Year 1 CY 2019	Operating Year 2 CY 2020
Total Treatments	12,152	13,041
Total Gross Revenues (Charges)	\$48,462,176	\$52,007,508
Total Net Revenue	\$3,700,228	\$3,970,924
Average Net Revenue per Treatment	\$304	\$304
Total Operating Expenses (Costs)	\$3,195,619	\$3,351,964
Average Operating Expense per Treatment	\$263	\$257
Net Income/Profit	\$504,609	\$618,961

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
- 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 following reason:

- 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

BMA proposes to add one dialysis station to its existing Catawba Valley facility for a total of 25 stations upon completion of this project, Project I.D. #E-11209-16 (relocate six dialysis stations), and Project I.D. #E-11390-17 (add five stations).

On page 365, the 2018 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 Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, there are three existing dialysis facilities and two approved but not yet operational dialysis facilities in Catawba County, as shown in the table below.

Existing/Approved Dialysis Facilities in Catawba County – Table B January 2018 SDR						
Facility	Owner	# Patients	Location	# Certified Stations	# Approved Stations	% Utilization
Catawba County Dialysis	DaVita	0	Hickory	0	10	0.0%
FMC of Catawba Valley	Fresenius	101	Conover	25	-6	101.0%
FMC Hickory Home	Fresenius	28	Hickory	0	0	--
FMC of Hickory	Fresenius	122	Hickory	35	-6	87.1%
FKC Newton	Fresenius	0	Newton	0	12	0.0%

FMC Hickory Home, which is a separately licensed dialysis facility providing exclusively home peritoneal dialysis (PD) training and support, has no stations. According to Table C of the January 2018 SDR, FMC Hickory Home had 28 PD patients as of June 30, 2017.

In Section G, page 32, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Catawba County. The applicant states:

“The Catawba County ESRD patient population is increasing at a rate of 8.1%, meaning that new dialysis stations and new facilities will be needed.”

The FMC Hickory and FMC Catawba Valley facilities were operating at or above 80% utilization as of December 31, 2017. The two facilities combined utilization was 3.7167 patients per station.

...

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 FMC Catawba Valley facility.”

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

- There is a facility need determination, as calculated using the methodology in the January 2018 SDR, for the proposed dialysis station.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 33, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Catawba Valley – Current and Projected Facility Staffing		
Position	Current # of FTEs	OY 1 # of FTEs
Medical Director*	0.00	0.00
Registered Nurse	3.50	5.50
LPN	1.00	1.00
Patient Care Tech	9.50	9.50
Dietitian	0.80	0.80
Social Worker	0.80	0.80
Clinical Manager	1.00	1.00
Administration	0.15	0.15
In-Service	0.25	0.25
Clerical	1.00	1.00
Chief Tech	0.10	0.10
Equipment Tech	0.50	0.50
Total	18.60	20.60

*On page 33, the applicant states that the Medical Director is a contract position and is not an employee of the facility.

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, page 34, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 38, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating his intent to continue serving as medical director for the facility.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

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

Catawba Valley – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	Referral to FMC Hickory/FMC Hickory Home Program
Home training HH PD	FMC Hickory FMC Hickory Home Program
Accessible follow-up program	FMC Hickory/FMC Hickory Home Program
Psychological counseling	Catawba County Behavioral Health
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Catawba Valley Medical Center, Frye Regional Medical Center
Emergency care	Crash cart on site/staff trained; ambulance transport to hospital
Blood bank services	Catawba Valley Medical Center, Frye Regional Medical Center
Diagnostic and evaluation services	Catawba Valley Medical Center, Frye Regional Medical Center
X-ray services	Catawba Valley Medical Center, Frye Regional Medical Center
Laboratory services	Spectra
Pediatric nephrology	NC Baptist Hospital
Vascular surgery	Dr. Randal Bast – Horizon Surgical Center
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	NC DHHS, Vocational Rehab Services
Transportation	DSS of Catawba County, Greenway Transportation, Premier Medical Transportation, Specialty Transport

The applicant provides supporting documentation in Exhibits I-1 through I-5.

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

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
- 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.

- (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 50, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

Payment Source	% Total Patients
Self-Pay/Indigent/Charity	1.63%
Medicare	67.16%
Medicaid	7.05%
Commercial Insurance	7.30%
Medicare/Commercial	13.42%
Misc. (including VA)	3.44%
Total	100.00%

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

County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Catawba	17%	51%	24%	15%	10%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table>; Latest Data 7/1/16 as of 8/22/17

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

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

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

*Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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, page 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 49, 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:

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

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

- 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.

- (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 47, 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.

Catawba Valley Projected Payor Mix CY 2020	
Payment Source	% Total Patients
Self-Pay/Indigent/Charity	1.63%
Medicare	67.16%
Medicaid	7.05%
Commercial Insurance	7.30%
Medicare/Commercial	13.42%
Misc. (including VA)	3.44%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.63 percent of total services will be provided to self-pay, indigent, and charity care patients, 67.16 percent to Medicare patients (not including those who are covered both by Medicare and by commercial insurance), and 7.05 percent to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (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
- 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.

- (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 51, 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
- Information which was publicly available during the review and used by the Agency

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

BMA proposes to add one dialysis station to its existing Catawba Valley facility for a total of 25 stations upon completion of this project, Project I.D. #E-11209-16 (relocate six dialysis stations), and Project I.D. #E-11390-17 (add five stations).

On page 365, the 2018 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 Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, there are three existing dialysis facilities and two approved but not yet operational dialysis facilities in Catawba County, as shown in the table below.

Existing/Approved Dialysis Facilities in Catawba County – Table B January 2018 SDR						
Facility	Owner	# Patients	Location	# Certified Stations	# Approved Stations	% Utilization
Catawba County Dialysis	DaVita	0	Hickory	0	10	0.0%
FMC of Catawba Valley	Fresenius	101	Conover	25	-6	101.0%
FMC Hickory Home	Fresenius	28	Hickory	0	0	--
FMC of Hickory	Fresenius	122	Hickory	35	-6	87.1%
FKC Newton	Fresenius	0	Newton	0	12	0.0%

FMC Hickory Home, which is a separately licensed dialysis facility providing exclusively home PD training and support, has no stations. According to Table C of the January 2018 SDR, FMC Hickory Home had 28 PD patients as of June 30, 2017.

In Section N, page 52, 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 52, the applicant states:

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

...

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering a convenient venue for dialysis care and treatment, and promoting access to care.”

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

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

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A, page 4, and Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 112 of this type of facility located in North Carolina.

In Section O, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all of the problems have been corrected. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 112 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Catawba Valley is an existing 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, page 14, the applicant projects that Catawba Valley will serve 85 patients on 25 stations, or a rate of 3.4 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 14-16, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.