

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 17, 2019

Findings Date: June 17, 2019

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: E-11667-19

Facility: FMC of Catawba Valley

FID #: 10648

County: Catawba

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

Project: Add no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton)

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 proposes to add no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton)

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows

there is a surplus of 10 dialysis stations in Catawba County. However, the January 2019 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 and that utilization of each facility in the county is 80% 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 FMC of Catawba Valley in the January 2019 SDR is 4.16 patients per station per week, or 104.00 percent, based on 104 in-center dialysis patients and 25 certified dialysis stations [$104 / 25 = 4.16$; $3.58 / 4 = 1.0400$ or 104.00%].

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

April 1 Review-January SDR		
Required SDR Utilization		80%
FMC of Catawba Valley		
January 2019 SDR		
Facility Utilization Rate (as of 6/30 of the previous year)		104.00%
Certified Stations		25
Pending Stations		6
Total Existing and Pending Stations		31
In-Center Patients as of 6/30/18 (January 2018 SDR) (SDR2)		104
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		99
Step	Description	Result
	Difference (SDR2 - SDR1)	5
(i)	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.1010
(ii)	Divide the result of Step (i) by 12	0.0084
(iii)	Multiply the result of Step (ii) by 12	0.0505
(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	109.2525
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.1414
	and subtract the number of certified and pending stations to determine the number of stations needed	3

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three 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 three new stations; therefore, the application 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a and d), pages 8 and 10-11; Section K.1, pages 42-44; Section N.1, page 54; Section O, pages 56-59, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 9-11; Section C.3, pages 17-18; Section L, pages 48-52; Section N.1, page 54, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 10-13; Section C, pages 14-17; Section F, pages 25-30; Section K, pages 42-44; Section N.1, page 54, and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application

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

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

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

C

The applicant proposes to add no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton).

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 for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 20, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by FMC of Catawba Valley, as shown below.

FMC of Catawba Valley patients by County-12/31/2018	
County	# of IC Patients
Catawba	96
Other states	1
Total	97

In Section C.1, page 14, the applicant provides the projected patient origin for FMC of Catawba Valley for IC patients for the first two operating years (OY) following completion of the project, as shown in the table below.

FMC of Catawba Valley Patients by County – Operating Years 1 & 2				
County	Operating Year 1 CY 2020	Operating Year 2 CY 2021	County Patients as % of Total	
	IC	IC	OY 1	OY 2
Catawba	82.5	90.1	100.0%	100.0%
Total*	82	90	100.0%	100.0%

Note: Tables may not foot due to rounding.

*Rounded down to the whole patient.

The applicant provides the assumptions and methodology used to project patient origin on pages 15-18. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, pages 5-6, the applicant states that the application is filed pursuant to the facility need methodology in the 2019 SMFP, utilizing the data from the January 2019 SDR. The applicant proposes to add no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton). 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 15-16, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility as follows:

- The applicant begins the projections by using the in-center patient census in Catawba County as of December 31, 2018.
- In Project ID #E-11209-16 (relocate six stations to FKC Newton from FMC of Catawba Valley), the applicant projected that 28 patients residing in Catawba county and dialyzing at FMC of Catawba Valley would transfer their care to FKC Newton. Although the project has been delayed, the applicant projects FKC Newton will be certified by June 30, 2019. The applicant subtracts 28 patients from projections effective June 30, 2019.
- The applicant assumes that it is reasonable to expect that the patient residing in another state will not travel to the facility for three weekly treatments. Therefore, this patient is not included in the projections.
- The applicant assumes that the in-center patients currently receiving treatment at FMC of Catawba Valley and who currently reside in Catawba County, will increase at a rate of 9.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Catawba County ESRD patients published in the January 2019 SDR.
- The project is scheduled for completion on December 31, 2019.

- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)
- Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

Projected Utilization

In Section C, pages 15-16, the applicant provides the assumptions and methodology used to project utilization during the first two years of operation following project completion.

FMC of Catawba Valley	In-Center Dialysis
Begin with 96 Catawba County ESRD patients dialyzing at the center on December 31, 2018.	96
Project this population forward for 6 months to June 30, 2019, using one half of the Catawba County Five Year Annual Change Rate	$96 \times 1.0455 = 100.4$
BMA subtracts 28 Catawba County residents projected to transfer their care to the FKC Newton facility.	$100.4 - 28 = 72.4$
BMA projects this patient population forward for 6 months to December 31, 2019, again using one half of the Catawba County Five Year Average Annual Change Rate. This is the projected certification date for this project.	$72.4 \times 1.0455 = 75.7$
BMA projects growth of the Catawba County patients for one year to December 31, 2020. This is the ending census for Operating Year 1.	$75.70 \times 1.091 = 82.5$
BMA projects growth of the Catawba County patients for one year to December 31, 2021. This is the ending census for Operating Year 2.	$82.5 \times 1.091 = 90.1$

Source: Section C, page 16

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2020) the facility is projected to serve 82 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 90 in-center patients.

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

- OY1: 3.2800 patients per station per week or 82.00% ($82 \text{ patients} / 25 \text{ stations} = 3.2800/4 = 0.8200$ or 82.00%)
- OY2: 3.6000 patients per station per week or 90.00% ($90 \text{ patients} / 25 \text{ stations} = 3.6000/4 = 0.9000$ or 90.00%)

The project utilization of 3.28 patients per station per week at the end of OY1 is equal to or exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 17, the applicant states all of Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population in North Carolina.

In Section L.1, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FMC of Catawba Valley Projected Payor Mix Project Year 2, CY 2021		
Payment Source	% Total Patients	% of In-Center Patients
Self-Pay/Indigent/Charity	2.84%	2.84%
Medicare	66.62%	66.62%
Medicaid	4.39%	4.39%
Commercial Insurance	5.47%	5.47%
Medicare/Commercial	16.18%	16.18%
Misc. (including VA)	4.50%	4.50%
Total	100.00%	100.00%

Note: Totals may not foot due to rounding.

As shown in the table above, during the second year of operation, the applicant projects that 83% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 4% to Medicaid patients.

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

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton).

In Section E, pages 24, the applicant describes the alternatives it considered and explains why the alternatives not chosen are 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 there is a need to add additional stations to FMC of Catawba Valley to assure patients continued access to dialysis care.
- Relocate Stations from FMC Hickory-The applicant states that FMC Hickory facility utilization exceeds 87%. Relocating from this facility will leave the facility short of capacity.

In Section E.2, Page 24, the applicant states that its proposal is the most effective alternative because the project will meet the facility need, as demonstrated in the application, and the project does not require any capital cost.

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 facility is operating at over 100% capacity as of the January 2019 SDR.
- The applicant utilizes the facility need methodology to show the need for additional stations.
- 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 maintaining the status quo is not the most effective alternative to meet the need for additional dialysis stations at FMC of Catawba Valley because of the growth of the patient population dialyzing at the facility.

Conclusion

The Agency reviewed the:

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

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and 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 three additional dialysis stations for a total of no more than 25 certified stations at FMC of Catawba Valley upon completion of this project, and the following projects: Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton), 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 no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID#E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton).

Capital and Working Capital Costs

In Section F.1, page 25, the applicant states there are no capital cost for the proposed project. The applicant is relocating three dialysis stations from the facility and replacing it with three

stations in an existing space. The applicant states they will lease the dialysis equipment. The cost of the leasing equipment is included in Form A of the application.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
FMC of Catawba Valley	Operating Year 1 CY 2020	Operating Year 2 CY 2021
Total Treatments	11,707	12,745
Total Gross Revenues (Charges)	\$46,687,516	\$50,827,060
Total Net Revenue	\$3,527,840	\$3,840,636
Average Net Revenue per Treatment	\$301.34	\$301.34
Total Operating Expenses (Costs)	\$3,343,147	\$3,507,588
Average Operating Expenses per Treatment	\$285.56	\$275.21
Net Income/Profit	\$184,693	\$333,048

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. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

The 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 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.

The applicant proposes to add no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID #E-11209-16 (relocate six stations to FKC Newton), Project ID #E-11390-17 (add 5 stations), Project ID #E-11480-18 (add one station), and Project ID #E-11649-19 (relocate three stations to FKC Newton).

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

The applicant operates two existing and one approved facility in Catawba County. DaVita is the only other provider in Catawba County. The Catawba County facilities are shown below.

Facility Name	Provider Name	Location	# of Stations	Utilization
FMC Dialysis Services of Hickory	Fresenius Medical Care	Hickory	35	90.71%
FMC of Catawba Valley	Fresenius Medical Care	Conover	25	104.00%
FKC Newton*	Fresenius Medical Care	Newton	12	NA
Catawba County Dialysis**	DaVita	Hickory	10	NA
FMC Hickory Home Program	Fresenius Medical Care	Hickory	0	NA

Source: January 2019 SDR

*Not yet operational

**No patients reported as of 6/30/18

In Section G, page 33, 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 9.1% 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, 2018. BMA is not creating unnecessary duplication of existing or approved health services. Rather this application seeks to ensure 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 because the applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing and approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 reason 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 pages 34 and 36, the applicant provides current and projected staffing in full time equivalents (FTEs) for FMC of Catawba Valley as demonstrated in the chart below. The applicant projects no increase in direct staffing in Operating Year 2. The applicant states that the Medical Director is not directly employed by the facility, and thus is not reflected in the staffing chart.

FMC of Catawba Valley Facility Staffing		
Position	Current # FTEs	Projected # FTEs
	CY 2019	OY1 (CY2021)
Registered Nurse	5.00	5.00
Patient Care Technician	13.00	13.00
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Clinical Manager	1.00	1.00
Administration	0.15	0.15
In-Service	0.15	0.15
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	1.00	1.00
Total	23.45	23.45

The assumptions and methodology used to project staffing are provided in Section 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, page 35, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 39, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services. In Section H, page 35, the applicant describes its physician recruitment plans. In Exhibits H-1 and H-2, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how each ancillary and support service is made available.

FMC of Catawba Valley – Necessary Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training: HH PD Accessible follow-up program	FMC Hickory FMC Hickory Home Program FMC Hickory or FMC Hickory Home Program
Psychological counseling	Catawba Valley 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, or Frye Regional Medical Center
Emergency care	Ambulance transport to the hospital
Blood bank services	Catawba Valley Medical Center, or Frye Regional Medical Center
Diagnostic and evaluation services	Catawba Valley Medical Center, or Frye Regional Medical Center
X-ray services	Catawba Valley Medical Center, or Frye Regional Medical Center
Laboratory services	Spectra
Pediatric nephrology	NC Baptist Hospital
Vascular surgery	Horizon Surgical Center, Dr. Randal Bas
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	NC Dept. of Health and Human Services, Vocational Rehab and Independent Living Services
Transportation	DSS Catawba County, Greenway Transportation, Premier Transportation; Specialty Transport

Source: Section I, page 38

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1, I-2, 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

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 52, the applicant provides the historical payor mix during Calendar Year 2018 (CY 2018) for its existing services, as shown in the table below.

FMC of Catawba Valley Historical Payor Mix CY 2018	
Payment Source	% Total Patients
Self-Pay/Indigent/Charity	1.88%
Medicare	67.50%
Medicaid	4.13%
Commercial Insurance	5.24%
Medicare/Commercial	16.81%
Misc. (including VA)	4.44%
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.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Catawba	17%	51%	25%	13%	10%	13%
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 geographical 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 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 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's

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

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, pages 50-51, 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. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act."

In Section L, page 51, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 49, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FMC of Catawba Valley Projected Payor Mix Project Year 2, CY 2021	
Payment Source	% Total Patients
Self-Pay/Indigent/Charity	2.84%
Medicare	66.62%
Medicaid	4.39%
Commercial Insurance	5.47%
Medicare/Commercial	16.18%
Misc. (including VA)	4.50%
Total	100.00%

As shown in the table above, during the second year of operation, the applicant projects that 83% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 4% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

In Section L, page 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 53, the applicant describes the extent to which health professional training programs in the area will 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 no more than three dialysis stations for a total of no more than 25 stations upon completion of this project, Project ID#E-11209-16 (relocate six stations to FKC Newton), Project ID#E11390-17 (add 5 stations), Project ID#E-11480-18 (add one station), and Project ID#E-11649-19 (relocate three stations to FKC Newton).

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

The applicant operates two existing and one approved facility in Catawba County. DaVita is the only other provider in Catawba County. The Catawba County facilities are shown below.

Facility Name	Provider Name	Location	# of Stations	Utilization
FMC Dialysis Services of Hickory	Fresenius Medical Care	Hickory	35	90.71%
FMC of Catawba Valley	Fresenius Medical Care	Conover	25	104.00%
FKC Newton*	Fresenius Medical Care	Newton	12	NA
Catawba County Dialysis**	DaVita	Hickory	10	NA
FMC Hickory Home Program	Fresenius Medical Care	Hickory	0	NA

Source: January 2019 SDR

*Not yet operational

**No patients reported as of 6/30/18

In Section N, page 54, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 54, 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. The projected patient population for FMC of Catawba Valley facility begins with the patients currently served by BMA, and a growth of that patient population consistent with the Catawba County five year average annual change rate of 9.1% as published within the January 2019 SDR.

...

The facility also has added value stemming from the strength of our relationship with Piedmont Nephrology and Hypertension Associates, P.A.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.”

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 B, C, F, K, N and R of the application and any exhibits).
- Quality services will be provided (see Sections B, K, and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections, B, C, L, and N of the application and any exhibits).

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 114 of this type of facility located in North Carolina.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- FMC of 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, pages 14-18, the applicant documents the need for the project and demonstrates that it will serve a total of 82 in-center patients on 25 stations at the end of the first operating year, which is 3.2800 patients per station per week or a utilization rate of 82 percent. The discussion regarding analysis of need 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.1, pages 15-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.