

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2021

Findings Date: January 29, 2021

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: D-11982-20

Facility: Fresenius Medical Care Watauga County

FID #: 150300

County: Watauga

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

Project: Add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA or “the applicant”), proposes to add no more than two dialysis stations to the Fresenius Medical Care Watauga County (FMC Watauga County) facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

FMC Watauga County provides in-center (IC) dialysis as well as both a peritoneal dialysis (PD) program and home hemodialysis (HH) program.

Need Determination (Condition 2)

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Watauga County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the facility as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 75.00 percent or 3.0 patients per station per week, based on 48 in-center dialysis patients and 16 certified dialysis stations (48 patients / 16 stations = 3.0; 3.0 / 4 = 75.00%).

As shown in Table 9E, page 173, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 4 additional stations; thus, the applicant is eligible to apply to add up to four stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, pages 30-31 of the 2020 SMFP, states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 14-16; Section N, page 55; Section O, pages 57-60; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 15-16; Section C, pages 26-27; Section L, pages 49-52; Section N, pages 55-

56; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 16; Section F, pages 33-36; Section N, page 55; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy *GEN-3* based on the following:
 - BMA facilities encourages all staff to provide quality care to every patient at every treatment as part of their quality care program.
 - BMA facilities have a history of providing care and services to all persons in need of dialysis service, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.
 - The applicant takes on the burden of completing the project by seeking funds through the applicant's parent company, Fresenius Medical Care and not through federal and state monies or charitable contributions.

(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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

Patient Origin

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

The following table illustrates historical and projected patient origin.

FMC Watauga County Current Patient Origin						
County	Last Full Operating Year CY 2019 01/01/2019-12/31/2019					
	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Watauga	24	60.0%	1	50.0%	5	71.4%
Ashe	13	32.5%	1	50.0%	1	14.3%
Avery	2	5.0%			1	14.3%
Other States	1	2.5%				
Total	40	100.0%	2	100.0%	7	100.0%

Source: Section C, page 19

FMC Watauga County Projected Patient Origin						
County	Second Full Operating Year OY 2 01/01/2023-12/31/2023					
	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Watauga	24.79	40.6%	3.2	100.0%	10.13	71.7%
Ashe	29.26	47.9%			1	7.1%
Avery	5	8.2%			3	21.2%
Tennessee	2	3.3%				
Total	61.1	100.0%	3.2	100.0%	14.13	100.0%

Source: Section C, page 20

In Section C, pages 20-24 and Section Q, pages 70-74, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following analysis:

- The applicant begins its projections with the facility census as of June 30, 2020, as shown in the table below. There were 33 patients residing in Watauga County, 26 residing in other counties and three residing in other states.
- The applicant projects the growth of the Watauga County patient census using the Watauga County Five-Year AACR of 4.2%, as published in the 2020 SMFP. The applicant states that the facility serves a significant number of dialysis patients residing in Ashe County, therefore, the applicant projects the growth of the Ashe County patient census using the Ashe County Five-Year AACR of 18.7%, as published in the 2020 SMFP.
- As of June 30, 2020, the facility was serving five IC patients residing in Avery County. Avery County is contiguous to Watauga County. The applicant assumes that the five IC patients residing in Avery County will continue to dialyze at the facility.
- As of June 30, 2020, the facility was serving two IC patients residing in the state of Tennessee. Tennessee is contiguous to Watauga County. The applicant assumes that these patients reside in eastern Tennessee in close proximity to Watauga County and the facility. The applicant assumes that these patients will continue to dialyze at the facility.
- As of June 30, 2020, the facility was serving on IC patient residing in Guilford County and one IC patient residing in South Carolina. Neither Guilford County nor South Carolina are proximate to FMC Watauga County. The applicant assumes that these patients were transient patients and does not expect them to continue dialysis at the facility.
- FMC Watauga County offers home dialysis training and support for both hemodialysis and peritoneal dialysis. The applicant projects that after certification of the project, two patients per year will change from IC dialysis to home dialysis. The applicant projects that one patient will choose home hemodialysis and one patient will choose home peritoneal dialysis.

Analysis of Need

In Section C, page 25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 25, the applicant states:

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

...BMA has identified the population to be served as 57.4 in-center dialysis patients, and 14.9 home dialysis patients, projected to be dialyzing with the facility as of the end of the first Operating Year of the project. The in-center utilization rate is calculated to be 2.87 patients per station, or 71.1% utilization. This exceeds the minimum requirements of 10A NCAC 14C .2203.”

The information is reasonable and adequately supported based on the following:

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 2.87 in-center patients per station per week dialyzing at FMC Watauga County as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standards of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203.

Projected Utilization

In-Center

In Section C, page 22 and Section Q, page 72, the applicant provides historical and projected utilization, as illustrated in the following table.

FMC Watauga County	Watauga	Ashe
BMA begins with the Watauga County and Ashe County patient population of FMC Watauga County as of June 30, 2020.	25	16
Project the patient population forward for six months to December 31, 2020, using one half of the Watauga and Ashe County Five-Year AACR of 4.2% and 18.7%, respectively.	$25 \times 1.021 = 25.5$	$16 \times 1.0935 = 17.5$
Project the patient population forward for one year to December 31, 2021, using the Watauga and Ashe County Five-Year AACR of 4.2% and 18.7%, respectively.	$25.5 \times 1.042 = 26.6$	$17 \times 1.187 = 20.8$
Sum the Watauga and Ashe patients and add the patients residing in Avery County and Tennessee. This is the projected starting census for this project.	$26.6 + 20.8 + 5 + 2 = 54.4$	
Project the Watauga and Ashe patients forward for one year to December 31, 2022, using the Watauga and Ashe County Five-Year AACR of 4.2% and 18.7%, respectively.	$26.6 \times 1.042 = 27.71$	$20.8 \times 1.187 = 24.65$
Subtract two Watauga County patients projected to change to home dialysis.	$27.71 - 2 = 25.71$	24.65
Sum the Watauga and Ashe patients and add the patients residing Avery County and Tennessee. This is the projected ending census for Operating Year 1.	$25.71 + 24.65 + 5 + 2 = 57.4$	
Project the Watauga and Ashe patients forward for one year to December 31, 2023, using the Watauga and Ashe County Five-Year AACR of 4.2% and 18.7%, respectively.	$25.7 \times 1.042 = 26.79$	$24.65 \times 1.187 = 29.26$
Subtract two Watauga County patients projected to change to home dialysis.	$26.79 - 2 = 24.79$	29.26
Sum the Watauga and Ashe patients and add the patients residing in Avery County and Tennessee. This is the projected ending census for Operating Year 2.	$24.79 + 29.26 + 5 + 2 = 61.1$	

Projected patients for OY1 and OY2 are rounded to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 57 in-center patients and at the end of OY2 (CY2023) the facility is projected to serve 61 in-center patients.

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

- OY1: 2.85 patients per station per week or 82.78% ($57 \text{ patients} / 20 \text{ stations} = 2.85/4 = 0.71.25$ or 71.25%)
- OY2: 3.05 patients per station per week or 88.89% ($61 \text{ patients} / 20 \text{ stations} = 3.05/4 = 0.7625$ or 76.25%)

The projected utilization of 2.85 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In Section C, pages 20-21 and Section Q, pages 70-71, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant proposes to add four stations to FMC Watauga County for a total of no more than 20 IC dialysis stations upon project completion.
- The applicant begins its projections with the facility census as of June 30, 2020, as shown in the table below.

County	June 30, 2020		
	IC	HH	PD
Watauga	25	1	7
Ashe	16		1
Avery	5		3
Guilford	1		
South Carolina	1		
Tennessee	2		
Total	50	1	11

Source: Section C, page 20

- The applicant projects the growth of the Watauga County patient census using the Watauga County Five-Year AACR of 4.2%, as published in the 2020 SMFP.
- The applicant states that the facility serves a significant number of dialysis patients residing in Ashe County, therefore, the applicant projects the growth of the Ashe County patient census using the Ashe County Five-Year AACR of 18.7%, as published in the 2020 SMFP.
- As of June 30, 2020, the facility was serving five IC patients residing in Avery County. Avery County is contiguous to Watauga County. The applicant assumes that the five IC patients residing in Avery County will continue to dialyze at the facility. The applicant will carry these patients forward into projections of future patient populations but not project any growth of this segment of the patient population. These patients will be added at the appropriate time.
- As of June 30, 2020, the facility was serving two IC patients residing in the state of Tennessee. Tennessee is contiguous to Watauga County. The applicant assumes that these patients reside in eastern Tennessee in close proximity to Watauga County and the facility. The applicant assumes that these patients will continue to dialyze at the facility. The applicant will carry these patients forward into projections of future patient populations but not project any growth of this segment of patient the population. These patients will be added at the appropriate time.
- As of June 30, 2020, the facility was serving on IC patient residing in Guilford County and one IC patient residing in South Carolina. Neither Guilford County nor South Carolina are proximate to FMC Watauga County. The applicant assumes that these patients were transient patients and does not expect them to continue dialysis at the

facility. The applicant will not carry these patients forward into projections of future patient populations.

- FMC Watauga County offers home dialysis training and support for both hemodialysis and peritoneal dialysis. The applicant states that the home patient population in BMA facilities in North Carolina is generally increasing, which is consistent with President Trump’s Executive Order on Advance American Kidney Health.¹ The applicant projects that after certification of the project, two patients per year will change from IC dialysis to home dialysis. The applicant projects that one patient will choose home hemodialysis and one patient will choose home peritoneal dialysis. These patients will be subtracted from future IC patient populations and added to home patient populations.
- The project is scheduled for completion on December 31, 2021. The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

Home Hemodialysis (HH) and Peritoneal Dialysis (PD)

In Section C, pages 23-24 and Section Q, pages 73-74, the applicant provides historical and projected utilization, as illustrated in the following tables.

FMC Watauga County Home Hemodialysis	
BMA begins with the Watauga County patient population Watauga County as of June 30, 2020.	1
Project the Watauga County patient population forward for six months to December 31, 2020, using one half of the Watauga County Five-Year AACR of 4.2%.	$1 \times 1.021 = 1.02$
Project the Watauga County patient population forward for one year to December 31, 2021, using the Watauga County Five-Year AACR of 4.2%. This is the projected starting census for this project.	$1.02 \times 1.042 = 1.06$
Project the Watauga County patient population forward for one year to December 31, 2022, using the Watauga County Five-Year AACR of 4.2%.	$1.06 \times 1.042 = 1.11$
Add the patient projected to change to home dialysis. This is the projected ending census for Operating Year 1.	$1.11 + 1 = 2.11$
Project the Watauga County patients forward for one year to December 31, 2023, using the Watauga County Five-Year AACR of 4.2%.	$2.11 \times 1.042 = 2.20$
Add the patient projected to change to home dialysis. This is the projected ending census for Operating Year 1.	$2.2 + 1 = 3.20$

¹ <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>

FMC Watauga County Peritoneal Dialysis	
BMA begins with the Watauga County patient population Watauga County as of June 30, 2020.	7
Project the Watauga County patient population forward for six months to December 31, 2020, using one half of the Watauga County Five-Year AACR of 4.2%.	$7 \times 1.021 = 7.15$
Project the Watauga County patient population forward for one year to December 31, 2021, using the Watauga County Five-Year AACR of 4.2%.	$7.15 \times 1.042 = 7.45$
Add four patients residing in Ashe and Avery Counties. This is the projected starting census for this project.	$7.45 + 4 = 11.45$
Project the Watauga County patient population forward for one year to December 31, 2022, using the Watauga County Five-Year AACR of 4.2%.	$7.45 \times 1.042 = 7.76$
Add one patient projected to change to home dialysis	$7.76 + 1 = 8.76$
Add four patients residing in Ashe and Avery Counties. This is the projected starting census for Operating Year 1.	$8.76 + 4 = 12.76$
Project the Watauga County patients forward for one year to December 31, 2023, using the Watauga County Five-Year AACR of 4.2%.	$8.76 \times 1.042 = 9.13$
Add one patient projected to change to home dialysis	$9.13 + 1 = 10.13$
Add the four patients residing in Ashe and Avery Counties This is the projected ending census for Operating Year 2.	$10.13 + 4 = 14.13$

In Section C, pages 22-23 and Section Q, pages 72-73, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the facility census as of June 30, 2020, as shown in the table below.

County	June 30, 2020		
	IC	HH	PD
Watauga	25	1	7
Ashe	16		1
Avery	5		3
Guildford	1		
South Carolina	1		
Tennessee	2		
Total	50	1	11

Source: Section C, page 22

- The applicant projects the growth of the Watauga County patient census using the Watauga County Five-Year AACR of 4.2%, as published in the 2020 SMFP.
- As of June 30, 2020, the facility was serving one home peritoneal dialysis patient residing in Ashe County, and three peritoneal dialysis patients residing in Avery County. The applicant assumes that these patients will continue to dialysis at the FMC Watauga County. The applicant will carry these patients forward into projections of

future patient populations but not project any growth of this segment of the patient population. These patients will be added at the appropriate time.

- The applicant assumes that two patients are projected to change to home dialysis annually. The applicant projects that one patient will choose home hemodialysis and one patient will choose home peritoneal dialysis. These patients will be added to home patient population each year.
- The project is scheduled for completion on December 31, 2021. The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.2 percent for Watauga County patients which reflects the Watauga County Five-Year AACR, as published in Table 9C of the 2020 SMFP.
- The applicant utilized a projected annual growth rate of 18.7 percent for Ashe County patients which reflects the Ashe County Five-Year AACR, as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Avery County IC patients and its IC patients residing in Eastern Tennessee.
- The applicant conservatively does not project growth for its PD patients residing in Ashe and Avery Counties.
- The applicant accounts for the IC patients projected to change to HH and PD dialysis.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 IC patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 26, the applicant states:

“Fresenius operates more than 100 dialysis facilities across North Carolina. Each of these facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

...

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	58.1%
Racial and ethnic minorities	8.1%
Women	54.8%
Persons with Disabilities	56.5%
The elderly	54.8%
Medicare beneficiaries	87.1%
Medicaid recipients	30.6%

Source: Section C, page 27

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The facility's history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.
- The applicant's estimated percentage for each underserved group is based on the current facility census of FMC Watauga County.

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 all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose a reduction, elimination or relocation of 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 two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

In Section E, page 32, 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:

Not Applying to Expand the Facility-The applicant states that this alternative was not acceptable due to the in-center utilization at FMC Watauga County. The applicant states that the in-center population increased by ten patients in the six months ended June 30, 2020.

Applying for Fewer than four Stations-The applicant states that this alternative was considered less effective due to the number of patients projected to be receiving dialysis at the facility.

On page 32, the applicant states that its proposal is the most effective alternative because expanding the facility would avoid higher utilization rates and fewer opportunities for patient admission.

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

- The applicant's proposal would address the projected increase in patient utilization at the facility.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than four additional in-center dialysis stations for a total of no more than 20 in-center (and home hemodialysis) stations at Fresenius Medical Care Watauga County upon project completion.**
 3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on February 1, 2022 and so forth.**
 4. **The certificate holder 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 two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q, page 76, the applicant projects the total capital cost of the project, as shown in the table below.

FMC Watauga County Capital Costs	
Non-Medical Equipment	\$3,000
Consultant Fees	\$12,000
Total	\$15,000

In Section Q, page 77, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions that are based on what is required to add the four additional stations. The applicant states that this includes water treatment system, patient TVs, and dialysis chairs.

In Section F, pages 34-35, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is a facility that is already operational.

Availability of Funds

In Section F, page 33, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$15,000	\$15,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$15,000	\$ 15,000

* OE = Owner's Equity

Exhibit F-2 contains a letter dated October 15, 2020, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. The letter states that in their 2019 Consolidated Balance Sheet, Fresenius Medical Care Holdings, Inc. had over \$446 million in cash and over \$25 billion in assets to fund the capital cost of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides adequate documentation of Fresenius Medical Care Holdings, Inc. consolidated balance sheets it proposes to use to fund the capital needs of the project.

- The applicant provides a letter from an appropriate company officer confirming the availability of the funding proposed for the capital needs of the project and a commitment to use that funding accordingly.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

FMC Watauga County	OY 1	OY 2
Total Treatments	10,294	11,145
Total Gross Revenues (Charges)	64,760,354	70,116,033
Total Net Revenue	2,932,295	3,173,645
Average Net Revenue per Treatment	\$284.85	\$284.75
Total Operating Expenses (Costs)	\$2,866,448	\$2,994,714
Average Operating Expense per Treatment	\$278.45	\$268.70
Net Income	\$65,847	\$178,931

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Q, pages 80-86. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant’s provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
 - Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

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

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Watauga County as of December 31, 2018. The applicant is the only provider of dialysis services in Watauga County.

Facility Name	Certified Stations as of 12/31/2018	# IC Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station Per Week
FMC Watauga County	16	48	75.00%	3.0000
Total	16	48		

Source: 2020 SMFP, Table B, page 164

In Section G, page 38, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Watauga County. The applicant states:

“The stations are needed by the patient population projected to be served by the facility...The applicant has not projected to serve patients currently served in another facility, or served by another provider. The stations are needed at FMC Watauga County to support the projected patient census at the facility.”

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

- The applicant adequately demonstrates that the proposed dialysis stations is needed in addition to the existing or approved dialysis stations.
- There is a facility need determination in the 2020 SMFP for the proposed four 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 all the reasons described 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.

The applicant proposes to add no more than two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

In Section Q, page 87, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 08/2020	2nd Full Fiscal Year (OY 2)
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses (RNs)	2.00	2.00
Home Training Nurse	1.00	1.50
Technicians (PCT)	4.00	4.50
Dietician	0.67	0.67
Social Worker	0.67	0.67
Maintenance	0.50	0.50
Administration/Business Office	0.75	0.75
Other: FMC Director Operations	0.15	0.15
Other: In-Service	0.15	0.15
Other: Chief Tech	0.15	0.15
TOTAL	11.04	12.04

The assumptions and methodology used to project staffing are provided in Section Q, page 88. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The facility has historically provided a wide range of personnel benefits and maintained competitive salaries to attract qualified staff, which allowed the facility to maintain sufficient health manpower.
- All new employees are thoroughly trained in the clinical aspects of their job including facility and corporate policies and procedures.

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

The applicant proposes to add no more than two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 41, the applicant identifies the necessary ancillary and support services for the proposed services. On page 41, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The stated ancillary and support services are currently available. The facility has a history of providing these services through their existing providers.
- In Section I, page 41, the applicant provides a list of providers for the stated ancillary and support services.

Coordination

In Section I, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

The applicant and its Fresenius Medical Care related facilities have long-standing relationships with physicians, local hospitals, and other health professionals within the community. The applicant has agreements in place for home training, lab services, hospital affiliation and transplant.

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 all the reasons described above.

- (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 ... persons [with disabilities], 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 population 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 last full operating year (CY 2019) for the proposed services, as shown in the table below.

FMC Watauga County Historical Payor Mix 01/01/2019-12/31/2019, CY 2019						
Payor Source	IC		HH		PD	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	1.35	3.38%	0.00	0.00%	0.00	0.00%
Insurance*	2.49	6.23%	0.00	0.00%	1.38	19.75%
Medicare*	27.38	68.44%	0.00	0.00%	4.36	62.30%
Medicaid*	1.83	4.58%	0.00	0.00%	0.05	0.67%
Medicare/Commercial	5.19	12.98%	2.00	100.00%	1.19	17.01%
Other: Misc. Incl. VA	1.75	4.38%	0.00	0.00%	0.02	0.27%
Total	40.00	100.00%	2.00	100.00%	7.00	100.00%

*Including any managed care plans

In Section L, page 49, the applicant provides the following comparison.

Last Full Operating Year			
FMC Watauga County	Percentage of Total Patients Served by the Facility or Campus	Percentage of the Population of the Service Area	
		Watauga	Ashe
Female	54.8%	50.2%	51.0%
Male	45.2%	49.8%	49.0%
Unknown			
64 and Younger	45.2%	83.6%	73.4%
65 and Older	54.8%	16.4%	26.6%
American Indian	0.0%	0.4%	0.4%
Asian	0.0%	1.2%	0.5%
Black or African-American	1.6%	1.9%	1.0%
Native Hawaiian or Pacific Islander	0.0%		0.1%
White or Caucasian	91.9%	91.4%	92.3%
Other Race	6.5%	5.1%	5.7%
Declined / Unavailable	0.0%		

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

In Section L, page 49, the applicant states that the facility provides dialysis care to a significant number of patients residing in Ashe County, therefore it is appropriate to include statistics for Ashe County.

The Agency reviewed the:

- Application
 - Exhibits to the application
 - Information which was publicly available during the review and used by the Agency
- (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 ... persons [with disabilities] 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, page 50, the applicant states:

“BMA does not have any obligations under any applicable federal regulations to provided uncompensated care, community service, or access by minorities and handicapped persons.”

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.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 51, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FMC Watauga County Projected Payor Mix, OY 2						
Payor Source	IC		HH		PD	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	2.06	3.38%	0.00	0.00%	0.00	0.00%
Insurance*	3.81	6.23%	0.00	0.00%	2.79	19.75%
Medicare*	41.79	68.44%	2.81	88.05%	8.80	62.30%
Medicaid*	2.80	4.58%	0.00	0.00%	0.09	0.67%
Medicare/Commercial	7.93	12.98%	0.38	11.95%	2.40	17.01%
Other: Misc. Incl. VA	2.67	4.38%	0.00	0.00%	0.04	0.27%
Total	61.06	100.00%	3.20	100.00%	14.13	100.00%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.38% of total IC services will be provided to self-pay patients, 68.44% of total IC services, 88.05% of total HH services and 62.30% of total PD services to Medicare patients and 4.58% of total IC services and 0.67% of total PD services to Medicaid patients.

On page 51-52, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant's projected payor mix is based upon the FMC Watauga County facility recent history of actual treatment volumes at the facility.
- The applicant does not project a significant change to the payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

In Section M, page 53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The facility has a history of allowing health-related education and training programs visit the facility to observe and receive instructions while patients receive treatment.
- The applicant provides a copy of a letter sent to Appalachian State University encouraging to the school to include FMC Watauga County facility in their clinical rotations for nursing students.

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 all the reasons described above.

- (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 two dialysis stations to the FMC Watauga County facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 in-center (IC) dialysis stations upon project completion.

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

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Watauga County as of December 31, 2018. The applicant is the only provider of dialysis services in Watauga County.

Facility Name	Certified Stations as of 12/31/2018	# IC Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station Per Week
FMC Watauga County	16	48	75.00%	3.0000
Total	16	48		

Source: 2020 SMFP, Table B, page 164

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 54, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Watauga County facility begins with the current patient population and projects growth of the population consistent with the respective County Five Year Average Annual Change Rate published in the 2020 SMFP...”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 55, the applicant states:

“The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the FMC Watauga County facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to patients of the area.”

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 55, the applicant states:

“Quality of care is always at the forefront at Fresenius related facilities... Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 55, the applicant states:

“All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina.

...

It is corporate policy to provide all services to all patient 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 undeserved.

...

Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

See also Section B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described 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 Q, pages 63-68, the applicant identifies the kidney treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 126 of this type of facility located in North Carolina.

In Section O, page 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care resulting in immediate jeopardy had not occurred in any of the 126 facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 126 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in:*
(1) *an existing dialysis facility; or*
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*
shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 21 and Section Q, page 72, the applicant projects that FMC Watauga County will serve 57 in-center patients on 20 stations, or a rate of 2.8 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 20-21, and Section Q, pages 70-71, 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.