

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 27, 2021
Findings Date: September 3, 2021

Project Analyst: Tanya M. Saporito
Assistant Chief: Lisa Pittman

Project ID #: M-12040-21
Facility: Dunn Kidney Center
FID #: 944644
County: Harnett
Applicant(s): Bio-Medical Applications of North Carolina, Inc.
Project: Add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 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), proposes to add no more than three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

Need Determination

Chapter 9 of the 2021 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 9B, page 134, the county need methodology shows there is not a county need determination for additional dialysis stations in Harnett 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 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 124, the utilization rate reported for the facility is 80.0% or 3.2 patients per station per week, based on 112 in-center dialysis patients and 35 certified dialysis stations (112 patients / 35 stations = 3.2; $3.2 / 4 = 0.80$).

As shown in Table 9D, SMFP page 139, based on the facility need methodology for dialysis stations, the potential number of stations needed at Dunn Kidney Center is up to 10 additional stations; thus, the applicant is eligible to apply to add up to 10 dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

In this application the applicant proposes to add no more than three new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 10 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 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 21-22; Section N, page 77; Section O, pages 79-82; 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 in the delivery of dialysis services.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 33; Section L, pages 73-74; Section N, page 77; 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, pages 22-23 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 2021 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs that promote the concepts of quality, equitable access and maximum value for resources.

(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 three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

Patient Origin

On page 113, the 2021 SMFP defines the service area for the county need methodology 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 area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Dunn Kidney Center is located in Harnett County. Thus, the service area for this application is Harnett County. Facilities may serve residents of counties not included in their service area.

The applicant provides the following historical in-center (IC), home hemodialysis (HD) and peritoneal dialysis (PD) patient origin for Dunn Kidney Center for the last full fiscal year (FY), calendar year (CY) 2020, as summarized below:

COUNTY	HISTORICAL IN-CENTER CY 2020		HISTORICAL HHD CY 2020		HISTORICAL PD CY 2020	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Harnett	73	71.57%	4	57.14%	8	66.67%
Cumberland	4	3.92%	0	0.00%	0	0.00%
Johnston	4	3.92%	2	28.57%	3	25.00%
Sampson	20	19.61%	1	14.29%	1	8.33%
Wake	1	0.89%	0	0.00%	0	0.00%
Total	102	100.00%	7	100.00%	11 [12]*	100.00%

*The Project Analyst determined the number “11” was an error in the application.

Source: Section C.2, page 25.

The following table illustrates the projected IC, HHD and PD patient origin at Dunn Kidney Center in the second full fiscal year (FY) of operations, CY 2023:

COUNTY	PROJECTED IN-CENTER CY 2023		PROJECTED HHD CY 2023		PROJECTED PD CY 2023	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Harnett	86.94	74.99%	4.76	61.36%	9.53	70.43%
Cumberland	4	3.45%	0.00	0.00%	0.00	0.00%
Johnston	4	3.45%	2.00	25.76%	3.00	22.18%
Sampson	20	17.25%	1.00	12.88%	1.00	7.39%
Wake	1	0.86%	0.00	0.00%	0.00	0.00%
Total	115.94	100.00%	7.76	100.00%	13.53	100.00%

Source: Section C.3, page 26

Numbers may not sum due to rounding

In Section C, pages 26-29, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization. On page 26, the applicant states it

begins future projections with the actual facility census as of December 31, 2020 and projects growth of the Harnett County patient population using the Five Year Average Annual Change Rate (AACR) of 6.0% published in the 2021 SMFP.

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant begins with the December 31, 2020 actual patient census at Dunn Kidney Center.
- The applicant uses the Harnett County 6.0% AACR published in the 2021 SMFP which is a reliable measure for predicting patient growth by county.
- The applicant adds the patients who reside in counties other than Harnett to the facility census at the appropriate time.

Analysis of Need

In Section C, pages 30-31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. ...

The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 111.0 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 79.30%, or 3.17 patients per station and exceeds the minimum required by the performance standard.”

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

- The 2021 SMFP, Table 9D on page 139 shows a facility need determination for up to 10 dialysis stations at Dunn Kidney Center.
- The applicant applies the Harnett County 6.0% AACR as provided in the 2021 SMFP to project growth of the Harnett County patient census and projects no growth for the patients from outside Harnett County currently being served at Dunn Kidney Center.
- Then applicant shows that the facility will need the additional stations to accommodate the existing and projected patient population.

Projected Utilization

In Section Q, the applicant projects in-center, HHD and PD patient utilization, as illustrated in the following tables:

Dunn Kidney Center Projected In-Center Patient Utilization

FORM C UTILIZATION	LAST FULL FY CY 2020	INTERIM OY CY 2021	1 ST FULL OY CY 2022	2 ND FULL OY CY 2023
# of Patients at the Beginning of the Year	112	102	106	111
# of Patients at the End of the Year	102	106	111	116
Average # of Patients during the Year	107	104	109	113
# of Treatments / Patient / Year	148	148	148	148
Total # of Treatments*	16,072	15,420	16,088	16,796

Numbers may not sum due to rounding

Dunn Kidney Center Projected HHD Patient Utilization

FORM C UTILIZATION	LAST FULL FY CY 2020	INTERIM OY CY 2021	1 ST FULL OY CY 2022	2 ND FULL OY CY 2023
# of Patients at the Beginning of the Year	5	7	7	7
# of Patients at the End of the Year	7	7	7	8
Average # of Patients during the Year	6	7	7	8
# of Treatments / Patient / Year	148	148	148	148
Total # of Treatments*	958	1,054	1,090	1,129

Numbers may not sum due to rounding

Dunn Kidney Center Projected PD Patient Utilization

FORM C UTILIZATION	LAST FULL FY CY 2020	INTERIM OY CY 2021	1 ST FULL OY CY 2022	2 ND FULL OY CY 2023
# of Patients at the Beginning of the Year	11	12	12	13
# of Patients at the End of the Year	12	12	13	14
Average # of Patients during the Year	12	12	13	13
# of Treatments / Patient / Year	148	148	148	148
Total # of Treatments*	2,006	1,812	1,885	1,962

Numbers may not sum due to rounding

In Section C, pages 26-29, Section Q, pages 86-89 and supplemental information requested by the Agency, the applicant provides the assumptions and methodology used to project in-center, HHD and PD utilization, which are summarized below:

In-Center Utilization

- The applicant begins patient census projections with the actual facility census as of December 31, 2020 as reported to the Division of Health Service Regulation (DHSR) Healthcare Planning in February 2021.

- The applicant projects growth of the Harnett County patient census using the 6.0% Five Year AACR as published in the 2021 SMFP.
- The applicant assumes the patients from counties outside Harnett County who were dialyzing at Dunn Kidney Center as of December 31, 2020 were dialyzing at that facility by choice and assumes those patients will continue to dialyze at the facility. The applicant does not project any growth in those patients but adds them to the patient census at the appropriate points in time.
- The applicant states the new stations will be installed in existing space and projects they will be certified as of December 31, 2021.
- The applicant states OY 1 is CY 2022 and OY 2 is CY 2023.

The following table, from Section C page 27 and Section Q page 87 illustrates the application of the assumptions and methodology:

Dunn Kidney Center In-Center Patient Projections*

Begin with Harnett County patient population as of December 31, 2020.	73
Project Harnett County patient population forward one year to December 31, 2021 using the Harnett County Five Year AACR of 6.0%.	$73 \times 1.06 = 77.4$
Add patients from outside Harnett County. This is the beginning census for the facility.	$77.4 + 29 = 106.4$
Project Harnett County patient population forward one year to December 31, 2022 using the Harnett County Five Year AACR of 6.0%.	$77.4 \times 1.06 = 82.0$
Add patients from outside Harnett County. This is the ending census for the facility for OY 1 (CY 2022).	$82.0 + 29 = 111.0$
Project Harnett County patient population forward one year to December 31, 2023 using the Harnett County Five Year AACR of 6.0%.	$82.0 \times 1.06 = 86.9$
Add patients from outside Harnett County. This is the ending census for the facility for OY 2 (CY 2023).	$86.9 + 29 = 115.9$

In Project ID#M-11663-19, the applicant was approved to relocate 3 stations from Dunn Kidney Center. The applicant states that project was complete and the stations certified as of December 27, 2020.

As the table above shows, using conventional rounding, the applicant's methodology results in a projection of 111 in-center patients by the end of the first full FY, OY 1 (CY 2022), for a utilization rate of 3.17 patients per station per week or 79.3% ($111 \text{ patients} / 35 \text{ stations} = 3.17 \text{ patients per station per week}$; $3.17 / 4 = 0.7928$). By the end of OY 2 (CY 2023), following the applicant's methodology and assumptions, the facility will have 116 in-center patients dialyzing at the center for a utilization rate of 83% ($116 / 35 = 3.31$; $3.31 / 4 = 0.8285$). The projected utilization of 3.17 patients per station per week in OY 1 exceeds the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

Home Hemodialysis and Peritoneal Dialysis Utilization

- The applicant begins patient census projections with the actual HHD and PD facility census as of December 31, 2020 as reported to the Division of Health Service Regulation (DHSR) Healthcare Planning in February 2021.
- The applicant projects growth of the Harnett County HHD and PD patient census using the 6.0% Five Year AACR as published in the 2021 SMFP.
- The applicant assumes three HHD patients and four PD patients from counties outside Harnett County who were dialyzing at Dunn Kidney Center as of December 31, 2020 were dialyzing at that facility by choice and assumes those patients will continue to dialyze at the facility. The applicant does not project any growth in those patients but adds them to the patient census at the appropriate points in time.
- The same assumptions with regard to projected certification date and OYs are applied to home trained patients, both HHD and PD.

The following table, from Section C page 28 and Section Q page 88 illustrates the application of the assumptions and methodology specifically regarding HHD patients:

Dunn Kidney Center HHD Patient Projections

Begin with Harnett County patient population as of December 31, 2020.	4
Project Harnett County patient population forward one year to December 31, 2021 using the Harnett County Five Year AACR of 6.0%.	$4 \times 1.06 = 4.2$
Add patients from outside Harnett County. This is the beginning census for the facility.	$4.2 + 3 = 7.2$
Project Harnett County patient population forward one year to December 31, 2022 using the Harnett County Five Year AACR of 6.0%.	$4.2 \times 1.06 = 4.5$
Add patients from outside Harnett County. This is the ending census for the facility for OY 1 (CY 2022).	$4.5 + 3 = 7.5$
Project Harnett County patient population forward one year to December 31, 2023 using the Harnett County Five Year AACR of 6.0%.	$4.5 \times 1.06 = 4.8$
Add patients from outside Harnett County. This is the ending census for the facility for OY 2 (CY 2023).	$4.8 + 3 = 7.8$

The following table, from Section C page 29 and Section Q page 89 illustrates the application of the assumptions and methodology specifically regarding PD patients:

Dunn Kidney Center PD Patient Projections

Begin with Harnett County patient population as of December 31, 2020.	8
Project Harnett County patient population forward one year to December 31, 2021 using the Harnett County Five Year AACR of 6.0%.	$8 \times 1.06 = 8.5$
Add patients from outside Harnett County. This is the beginning census for the facility.	$8.5 + 4 = 12.5$
Project Harnett County patient population forward one year to December 31, 2022 using the Harnett County Five Year AACR of 6.0%.	$8.5 \times 1.06 = 9.0$
Add patients from outside Harnett County. This is the ending census for the facility for OY 1 (CY 2022).	$9.3 + 4 = 13.0$
Project Harnett County patient population forward one year to December 31, 2023 using the Harnett County Five Year AACR of 6.0%.	$9.0 \times 1.06 = 9.5$
Add patients from outside Harnett County. This is the ending census for the facility for OY 2 (CY 2023).	$9.5 + 4 = 13.5$

Following is a table from pages 29 and 89 of the application that summarizes projected utilization for in-center, HHD and PD patients at Dunn Kidney Center in each of the first two operating years, CYs 2022 and 2023:

PATIENTS	OY 1 CY 2022	OY 2 CY 2023
In-Center	110.0	115.9
HHD	7.5	7.8
PD	13.0	13.5

Projected utilization of in-center, HHD and PD patients is reasonable and adequately supported based on the following:

- The applicant bases the beginning in-center, HHD and PD patient census on the most recent historical patient census at the facility.
- The applicant projects the growth of the Harnett County patient census for in-center, HHD and PD patients using the Five-Year AACR of 6.0%, as reported in the 2021 SMFP and does not project growth of those patients from outside Harnett County.
- The projected in-center utilization rate by the end of OY 1 exceeds the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section C.6, page 33, the applicant describes the parent company, Fresenius Medical Care, and its provision of access to medically underserved groups. The applicant states:

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

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.

Fresenius Medical Care and its 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.”

On page 33, the applicant provides the estimated percentage for each medically underserved group it will serve during OY 2, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	57.6%
Racial and ethnic minorities	61.0%
Women	53.4%
Persons with disabilities	33.9%
Persons 65 and older	41.5%
Medicare beneficiaries	78.8%
Medicaid recipients	34.7%

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 Fresenius corporate policy commits to provide services to all patients referred for ESRD services.
- Fresenius’ facilities have historically provided care to all in need of ESRD services, including underserved persons.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Supplemental information requested 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add no more than three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

In Section E, page 42, 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:

- Choose not to file an application for additional stations at the facility – the applicant states that failure to apply for additional stations would result in high utilization rates. Therefore, the applicant states this alternative is less effective because it could potentially interrupt patient admissions to the facility.
- Add fewer stations –the applicant states that this alternative would have the same adverse effect on utilization as not applying for additional stations; therefore, the applicant determined that this was not the most effective alternative.
- Add more stations– the applicant states that this alternative would be less cost-effective because the facility does not have space for more than three additional dialysis stations. Additionally, the three proposed stations are to replace three stations that were relocated pursuant to Project ID #M-11663-19, which approved a relocation of three stations from Dunn Kidney Center to FMC Dialysis Services of South Ramsey.

Based on the explanations above, the applicant states that its proposal is the most effective alternative to meet the increased demand for dialysis stations at the facility.

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 application is conforming or conditionally conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. (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 2021 SMFP, the certificate holder shall develop no more than three additional in-center dialysis stations for a total of no more than 35 stations 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 third month. The first progress report shall be due on December 1, 2021. The second progress report shall be due on March 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 three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q, on Form F.1a, the applicant states, “BMA has not projected to incur any capital costs with this project.”

In Section F, page 46, the applicant states that there will be no start-up or initial operating costs associated with this project.

Financial Feasibility

In Section Q, the applicant provides 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 each of the first two full fiscal years of operation following completion of the proposed project, as shown in the table below:

	INTERIM YEAR (CY 2021)	1 ST FFY (CY 2022)	2 ND FFY (CY 2023)
Total Treatments	18,285	19,063	19,887
Total Gross Revenues (Charges)	\$115,033,451	\$119,924,352	\$125,108,706
Total Net Revenue	\$4,964,564	\$5,173,826	\$5,395,637
Average Net Revenue per Treatment	\$271.51	\$271.41	\$271.31
Total Operating Expenses (Costs)	\$4,446,706	\$4,712,330	\$4,848,359
Average Operating Expense per Treatment	\$243.19	\$247.20	\$243.80
Net Income	\$517,858	\$461,496	\$547,728

Numbers may not sum due to rounding.

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

- Charges and expenses are based on historical facility operations projected forward into the operating years.
- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 2.5%
- 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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal
 - The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for the county need methodology 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 area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* The facility in this application is in Harnett County. Thus, the service area for this application is Harnett County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are four existing or approved dialysis facilities in Harnett County, all of which are owned and operated by Fresenius Medical Care. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

HARNETT COUNTY DIALYSIS FACILITIES CERTIFIED STATIONS AND UTILIZATION AS OF DECEMBER 31, 2019				
DIALYSIS FACILITY	OWNER	LOCATION	# OF CERTIFIED STATIONS	UTILIZATION
Dunn Kidney Center*	Fresenius	Dunn	35	80.00%
FMC Anderson Creek	Fresenius	Cameron	14	100.00%
Fresenius Medical Care Angier Dialysis	Fresenius	Angier	10	77.50%
Fresenius Medical Care of Lillington	Fresenius	Lillington	16	89.06%

Source: 2021 SMFP, Table 9A.

*At the time the data for the 2021 SMFP was provided, the three stations relocated pursuant to Project ID #M-11663-19 had not been relocated. Those stations were certified as of December 21, 2020, and the facility now has 32 stations.

In Section G, pages 51-52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Harnett County. On page 51, the applicant states that this application is based upon facility performance and demonstrated need at the facility and is not specific to Harnett County as a whole. The applicant states:

“Further, three of the four dialysis facilities operating in Harnett County were operating at or above the 70% threshold as of December 31, 2020. Only the FMC Angier facility utilization decreased in 2020; this decrease was the result of adding stations. On the whole, FMC Angier census increased by one patient in 2020.

...

While some capacity does exist at FMC Angier and FMC Lillington, these facilities are not proximate to the BMA Dunn location. It is a road trip of approximately 16.4 miles from Lillington to the BMA Dunn facility. It is a road trip of approximately 17 miles from Angier to the BMA Dunn facility. There is no reason for patients to travel from either Lillington or Angier to the BMA Dunn 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 Dunn Kidney Center needs additional stations to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed addition of the three dialysis stations is needed in addition to the existing and approved stations in Harnett County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to add no more than three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

In Section Q Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the facility following the proposed station addition, as summarized in the following table:

POSITION	CURRENT FTE POSITIONS	FTE POSITIONS OY 1	FTE POSITIONS OY 2
Administrator	1.00	1.00	1.00
RN	3.00	4.00	4.00
LPN	1.00	1.00	1.00
Home Training Nurse	1.50	1.50	1.50
Patient Care Technician (PCT)	10.50	11.50	11.50
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Business Office	2.00	2.00	2.00
FMC Director Operations	0.15	0.15	0.15
Chief Technician	0.25	0.25	0.25
FMC In-Service	0.25	0.25	0.25
Total	22.65	24.65	24.65

Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q, page 102. The applicant states the current facility staff is adequate to accommodate the proposed station addition. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H.3, pages 54-55, the applicant describes the methods used to recruit or fill new positions should they become available, 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 is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies in regard to recruitment, training and continuing education.

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 three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 56, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 56-61, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at Dunn Kidney Center.
- The applicant discusses how it provides and will continue to provide each necessary ancillary and support service at Dunn Kidney Center.

Coordination

In Section I, page 61, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant proposes to add stations in existing space in an existing facility from which three stations were recently relocated. The applicant does not propose to:

- construct any new space
- 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 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 69 the applicant provides the historical payor mix for in-center dialysis during CY 2020, as summarized in the table below:

PAYOR CATEGORY	IN-CENTER		HHD		PD	
	# PTS	% OF TOTAL	# PTS	% OF TOTAL	# PTS	% OF TOTAL
Self-Pay	1.1	1.05%	0.0	0.00%	0.0	0.00%
Insurance*	4.2	4.09%	1.3	18.10%	3.3	27.46%
Medicare*	69.1	67.74%	4.0	57.56%	5.8	48.01%
Medicaid*	10.2	10.03%	0.0	0.00%	0.0	0.00%
Other (VA/Medicare Advantage)	17.4	17.09%	1.7	23.34%	2.9	24.53%
Total	102	100.00%	7	100.00%	12	100.00%

*Includes managed care plans
 Source: application page 69.

In Section L, page 70, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	53.4%	50.5%
Male	46.6%	49.5%
Unknown	--	--
64 and Younger	58.5%	87.2%
65 and Older	41.5%	12.8%
American Indian	0.85%	1.7%
Asian	0.0%	1.3%
Black or African-American	60.2%	21.9%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	39.0%	60.7%
Other Race	0.0%	14.2%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 71, the applicant states that Dunn Kidney Center is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 71, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

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.3(a), page 72, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY 2023) following completion of the project, as summarized in the table below:

PAYOR CATEGORY	IN-CENTER		HHD		PD	
	# PTS	% OF TOTAL	# PTS	% OF TOTAL	# PTS	% OF TOTAL
Self-Pay	1.3	1.05%	0.0	0.00%	0.0	0.00%
Insurance*	5.0	4.09%	1.5	18.10%	3.9	27.46%
Medicare*	82.1	67.74%	4.6	57.56%	6.8	48.01%
Medicaid*	12.2	10.03%	0.0	0.00%	0.0	0.00%
Other (VA/Medicare Advantage)	20.7	17.09%	2.0	24.34%	3.5	24.53%
Total	121.2	100.00%	8.0	100.00%	14.1	100.00%

*Includes managed care plans

Source: application page 72.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.05% of IC dialysis services will be provided to self-pay patients, 67.74% to Medicare recipients and 10.03% to Medicaid recipients.

On page 72, 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 bases payor mix upon treatment volumes rather than patients
- The applicant bases future payor mix percentages on CY2020 payor mix percentages for treatment volumes
- The applicant includes Medicare Advantage in the Other category, rather than including it in the category of Medicare, as the application directs

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 74, 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 three (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

In Section M, page 75, 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 will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides documentation of its willingness to continue to provide applicable health professional training programs in the area with access to the facility for training.

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 (3) dialysis stations to Dunn Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 35 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for the county need methodology 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 area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* The facility in this application is in Harnett County. Thus, the service area for this application is Harnett County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are four existing or approved dialysis facilities in Harnett County, all of which are owned and operated by Fresenius Medical Care. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

HARNETT COUNTY DIALYSIS FACILITIES CERTIFIED STATIONS AND UTILIZATION AS OF DECEMBER 31, 2019				
DIALYSIS FACILITY	OWNER	LOCATION	# OF CERTIFIED STATIONS	UTILIZATION
Dunn Kidney Center*	Fresenius	Dunn	35	80.00%
FMC Anderson Creek	Fresenius	Cameron	14	100.00%
Fresenius Medical Care Angier Dialysis	Fresenius	Angier	10	77.50%
Fresenius Medical Care of Lillington	Fresenius	Lillington	16	89.06%

Source: 2021 SMFP, Table 9A.

*At the time the data for the 2021 SMFP was provided, the three stations relocated pursuant to Project ID #M-11663-19 had not been relocated. Those stations were certified as of December 21, 2020, and the facility now has 32 stations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, 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 facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 77, the applicant states:

“Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:

‘We deliver superior care that improves that quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’”

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 77, the applicant states:

“All Fresenius Medical Care 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 patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.”

See also Sections 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 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

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

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

C

In Section Q Form O, 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 over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility in North Carolina was found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius 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.

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 application is conforming or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- Dunn Kidney Center is an existing facility.

(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 Q Form C and in supplemental information requested by the Agency, the applicant projects that Dunn Kidney will serve 109 in-center patients on 35 dialysis stations. The projected utilization of 3.1 ($109 / 35 = 3.1$) patients per station per week for OY 1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-29, Section Q, pages 86-89 and supplemental information requested by the Agency, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.