

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 27, 2023

Findings Date: January 27, 2023

Project Analyst: Cynthia Bradford

Co-signer: Mike McKillip

Project ID #: F-12303-22

Facility: Brookshire Dialysis

FID #: 150477

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add no more than nine dialysis stations pursuant to Condition 1 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

DVA Healthcare Renal Care Inc. (hereinafter “DVA” or “the applicant”) proposes to add nine stations to Brookshire Dialysis (BD) pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

Need Determination

Chapter 9 of the 2022 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 9C, on page 139 of the 2022 SMFP, the county need

methodology shows there is not a county need determination for additional dialysis stations in Mecklenburg County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2022 SMFP if the facility is a “new,” “small,” or “new and small” facility as defined in the 2022 SMFP, and if the facility’s current reported utilization is at least 75%, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 19, the applicant reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	38
Number of stations in the facility as of the data cut-off date in the SMFP	11
According to Table 9A in the & SMFP, the facility is designated as new, small, or new and small	Small
Number of stations proposed in this application	9
Number of in-center patients per station as of the current reporting date	3.45
Current Reporting Date (no more than 90 days before the application is submitted)	08/31/2022
Previous Reporting Date (six months prior to the Current Reporting Date)	02/28/2022

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 10 additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date *	38
2	# of In-Center Patients as of the Previous Reporting Date **	29
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	9
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.31
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.62
6	Multiply Line 5 by Line 1 (New Patients)	23.58
7	Add Line 6 to Line 1 (Total Patients)	61.58
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	21.99
9	# of Stations as of the Application Deadline [^]	11
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	10.99

* Current Reporting date should be no more than 90 days before the date the CON application was submitted.

** Previous Reporting date is six months prior to the Current Reporting date.

[^] Includes all stations that were: 1) certified; 2) CON approved but not yet certified; and 3) proposed to be added in applications still under review as of the application deadline.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 11, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for*

any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.” The applicant proposes to add nine new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2022 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.”

In Section B, pages 20-23, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 20, the applicant states:

“DaVita’s goal is to create a “Culture of Safety” in all of its facilities and to make this a core part of how we function. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients...”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.7 (a) and (d), pages 20 and 22, Section O, pages 78-79; 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.7 (b) and (d), pages 21-22, Section L, pages 67-71; 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.7 (c) and (d), page 22; Section N.2(a), page 75; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with Condition 1 of the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the applicant adequately demonstrates how BD's projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need.

- (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 nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

In Section C, page 25, the applicant states BD does not currently provide home peritoneal dialysis and home hemodialysis. The applicant does not project to begin offering those services in this application.

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

BD Current and Projected Patient Origin				
	Current – CY 2021		Projected FY 2 – CY 2026	
	# Patients	% Patients	# Patients	% Patients
Mecklenburg	27	90.0%	60.6031	92.4%
Gaston	1	3.3%	5	7.6%
Martin	1	3.3%	0	0.0%
Rutherford	1	3.3%	0	0.0%
TOTAL	30	100%	65.6031	100%

Source: Section C, pages 25-26

In Section C, pages 26-28, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant bases projected patient origin on the historical patient origin.
- The applicant explains the growth projections for the Mecklenburg County patient population.

Analysis of Need

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, the applicant states:

“The addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment -- three times a week for in-center patients. The additional stations provide opportunities to open appointment times on the more desirable first shift”.

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

- According to the 2022 SMFP, as of December 31, 2020, BD was operating at a rate of 1.45 patients per station per week, or 36.36% of capacity; the applicant reports in Section C, page 27, that as of August 31, 2022, the facility is operating at a rate of 3.45 patients per station per week, or 86.3 % of capacity.

- The applicant states that BD “has grown significantly since its certification in July of 2018. The following in-center patient projections apply a growth rate of 15.0% for the in-center patients living in Mecklenburg County, so as to be conservative. The period of the growth begins September 1, 2022 and is calculated forward to December 31, 2026. No growth calculations were performed for the patients living outside of Mecklenburg County”.

Projected Utilization

Form C Utilization subsection page 86 of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

12/31/2018	16	
12/31/2019	18	12.5%
12/31/2020	11	-11.1%
12/31/2021	30	87.5%
AACR		22.2%

“The proposed project is submitted pursuant to Condition 1 of the Facility Need Methodology because Brookshire Dialysis is categorized as a Small Facility. Projections for patient utilization begin with the patient population at Brookshire Dialysis as of the Current Reporting Date (8/31/2022). As of August 31, 2022, the census included 38 in-center patients. Of these 38 patients, 33 lived in the service area, Mecklenburg County and 5 lived outside of the service area.

The first full FY is projected to begin January 1, 2025 and end on December 31, 2025.

The second full FY is projected to begin January 1, 2026 and end on December 31, 2026.

While the Average Annual Change Rate for the Past Five Years (5YAACR) as indicated in Table 9B of the 2022 SMFP for the in-center patients living in Mecklenburg County was 2.1%, the facility’s growth has been significantly higher:

As the table above indicates, the facility has grown significantly since its certification in July of 2018. The following in-center patient projections apply a growth rate of 15.0% for the in-center patients living in Mecklenburg County, so as to be conservative. The period of the growth begins September 1, 2022 and is calculated forward to December 31, 2026. No growth calculations were performed for the patients living outside Mecklenburg County”.

In Section C, page 87, immediately following Form C in Section Q, the applicant provides the calculations used to project the patient census for OYs 1-3, as summarized in the table below.

	IC Stations	IC Patients
The applicant begins with the 38 patients dialyzing on 11 stations at the facility as of 8/30/2022	11	38
The facility's Mecklenburg County patient census is projected forward four months from 9/1/2022 to 12/31/2022 and is increased by 1/3 the conservative growth rate of 15%.		$33 \times 1.05 = 34.65$
The 5 patients from outside Mecklenburg County are added to the facility's census. This is the ending census as of first interim year		$34.65 + 5 = 39.65$
The facility's Mecklenburg County patient census is projected forward a year to 12/31/2023 and is increased by 15.0%		$34.65 \times 1.15 = 39.85$
The 5 patients from outside Mecklenburg County are added to the facility's census. This is the ending census for the first full interim year		$39.85 + 5 = 44.85$
The facility's Mecklenburg County patient census is projected forward a year to 12/31/2024 and is increased by 15.0%		$39.85 \times 1.15 = 45.82$
The 5 patients from outside Mecklenburg County are added to the facility's census. This is the ending census for the second full interim year		$45.82 + 5 = 50.82$
The proposed project is projected to be certified on 12/1/2025. This is the station count at the beginning of the project's first full fiscal year (FY1). The facility's Mecklenburg County patient census is projected forward a year to 12/31/2025 and is increased by 15.0%	$11 + 9 = 20$	$45.82 \times 1.15 = 52.70$
The facility's Mecklenburg County patient census is projected forward a year to 12/31/2026 and is increased by 15.0%.		$52.70 + 5 = 57.70$
The facility's Mecklenburg County patient census is projected forward a year to 12/31/2026 and is increased by 15.0%.		$52.70 \times 1.15 = 60.60$
The 5 patients from outside Mecklenburg County are added to the facility's census. This is the ending census as of the project's second full fiscal year (FY2).		$60.60 + 5 = 65.60$

Projected patients for FY1 and FY2 are rounded to the nearest whole number.

- Based on the calculations above, by the end of FY1 Brookshire Dialysis is projected to have: 58 patients / 20 certified stations = 2.90 patients / station $2.90 / 4 = .725$ or 72.5% utilization rate
- By the end of FY2, Brookshire Dialysis is projected to have: 66 patients / 20 certified stations = 3.30 patients / station $3.30 / 4 = .825$ or 82.5% utilization rate

- For # of Treatments / Patient / Year: o Assumes patients receives treatment 3 times a week, 52 weeks a year.
- Includes a missed treatment rate of 5% $3 \times 52 \times 0.95 = 148$

The applicant projects to serve 58 patients on 20 stations, which is 2.90 patients per station per week (58 patients / 20 stations = 2.90), by the end of OY1, 66 patients on 20 stations, which is 3.3 patient per station per week (66 patients / 20 stations = 3.3) by the end of OY2. This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- BD was operating at a rate of 3.45 patients per station per week, or 86.86% of capacity, on August 30, 2022.
- The applicant projects future utilization based on historical utilization.
- Even though the applicant projects a much higher growth rate for its patient population than the Mecklenburg County 5-year AACR as published in the 2022 SMFP, it uses a projected growth rate that is lower than its recent growth rates.

Access to Medically Underserved Groups

In Section C, page 31, the applicant states:

“We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need. Brookshire Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons”.

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

Medically Underserved Groups	Estimated % of Total Patients in FY 2
Low-income persons	86.8%
Racial and ethnic minorities	88.2%
Women	41.2%
Persons with disabilities	100%
Persons 65 and older	35.3%
Medicare beneficiaries	73.7%
Medicaid recipients	13.2%

Source: Section C, page 31

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 applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

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 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 nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

In Section E, page 40, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo. This alternative was dismissed given the growth rate at the facility. The data as of the current reporting date clearly indicates that the facility census is trending upward at this small facility.
- Relocate stations from another DaVita facility. Of the seven other DaVita facilities in Mecklenburg County, five are operating at less than 75% capacity, as reported in Table 9A of the Proposed 2023 SMFP. However, this alternative was also dismissed. Relocating stations from these facilities would negatively impact each facility's operations and the patients presently served and projected to be served as it would disrupt patient and teammate scheduling at the facility, particularly as we continue to navigate patient care during a pandemic with its unpredictable surges. Additionally, DaVita is considering offering home hemodialysis services at some of these facilities which impacts the stations available for relocation.

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

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

Conclusion

The Agency reviewed the:

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

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

- 1. DVA Healthcare Renal Care Inc., (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 1 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than 9 additional in-center (and home hemodialysis) dialysis stations for a total of no more than 20 in-center (and home hemodialysis) dialysis stations at Brookshire Dialysis 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. The first progress report shall be due on July 1, 2023
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 nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects \$133,650 in capital costs for medical equipment and \$12,600 in non-medical equipment, and \$12,600 in capital costs for furniture for a total capital cost of \$158,940. Immediately following Form F.1a in Section Q, the applicant provides the assumptions and methodology used to project capital costs. The applicant's projected capital costs are reasonable and adequately supported because they are based on the cost of the necessary furniture and equipment.

In Section F, page 43, the applicant states there are no projected working capital costs because BD is an existing facility that is currently serving patients.

Availability of Funds

In Section F, pages 44-45, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the Chief Accounting Officer of DaVita Kidney Care, the parent company of the applicant, authorizing the use

of accumulated reserves for the capital needs of the project. Exhibit F-2 Consolidated Statements of Income for 2021 for DaVita Inc. that indicates the applicant has adequate cash resources to fund the project. In Exhibit F-2 page 3, the applicant provides select pages of the 2021 Consolidated Balance Sheet for DaVita Inc. to support the statements in the letter.

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

- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The letter from the applicant and the selected pages from the 2021 Consolidated Balance Sheet demonstrate the availability of adequate cash and assets to fund the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects that operating expenses will exceed revenues in the first two full fiscal years following completion of the project, but revenues will exceed operating expenses in the third full fiscal year following completion of the project, as shown in the table below.

BD	FY 1 – CY 2025	FY 2 – CY 2026
Total Treatments	8,042	9,137
Total Gross Revenues (Charges)	\$2,848,853	\$3,236,804
Total Net Revenue	\$2,524,993	\$2,868,842
Average Net Revenue per Treatment	\$313	\$313
Total Operating Expenses (Costs)	\$2,477,605	\$2,661,042
Average Operating Expense per Treatment	\$308	\$291
Net Revenue/(Loss)	\$47,388.69	\$207,799.69

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- 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 that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (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 nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

On page 115, the 2022 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2020, there were 25 existing or approved facilities providing dialysis and/or dialysis home training and support in Mecklenburg County. Information on these 25 dialysis facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2021				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	43	56.98%
BMA Nations Ford	BMA	Charlotte	28	83.93%
BMA of East Charlotte*	BMA	Charlotte	26	75.00%
BMA West Charlotte*	BMA	Charlotte	29	76.72%
FKC Mallard Creek**	BMA	Charlotte	0	0%
FKC Regal Oaks	BMA	Charlotte	17	92.65
FKC Southeast Mecklenburg	BMA	Pineville	10	75.00%
FMC Aldersgate	BMA	Charlotte	16	73.44%
FMC Charlotte***	BMA	Charlotte	48	71.35%
FMC Matthews	BMA	Matthews	21	101.19%
FMC of North Charlotte	BMA	Charlotte	40	89.38%
FMC Southwest Charlotte	BMA	Charlotte	21	86.90%
INS Charlotte****	BMA	Charlotte	2	0%
INS Huntersville****	BMA	Huntersville	0	0%
Brookshire Dialysis	DaVita	Charlotte	11	68.18%
Charlotte Dialysis	DaVita	Charlotte	33	71.21%
Charlotte East Dialysis	DaVita	Charlotte	34	80.88%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	71.88%
DSI Glenwater Dialysis	DSI	Charlotte	42	60.71%
Huntersville Dialysis	DaVita	Huntersville	21	76.19%
Mint Hill Dialysis	DaVita	Mint Hill	21	69.05%
Mountain Island Lake Dialysis**	DaVita	Charlotte	0	0%
North Charlotte Dialysis Center	DaVita	Charlotte	33	68.18%
South Charlotte Dialysis*	DaVita	Charlotte	27	68.52%
Sugar Creek Dialysis	DaVita	Charlotte	21	46.43%

Source: Table 9A, Chapter 9, 2022 SMFP; Agency records

*Facility which exists and is operational, but which has been approved to relocate to a new site with additional stations.

**Facility under development or which was not operational at the time of data collection for the 2022 SMFP.

***Facility with an application under review to relocate an existing and operational facility to a new site.

****Facility which is dedicated exclusively to providing HH and PD training and support.

In Section G, page 52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“Based on the facility need methodology in the 2022 SMFP under Condition 1, Brookshire Dialysis qualifies to add up to 11 dialysis stations.

.... we demonstrate the need that Brookshire Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Mecklenburg County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- The applicant proposes to increase the number of dialysis stations in Mecklenburg County based on Condition 1 of the facility need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Mecklenburg 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 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.

C

The applicant proposes to add nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

BD Current and Projected Staffing		
	10/31/2022	OYs 1-2 (CYs 2025-2026)
Administrator	1.00	1.00
Registered Nurses	1.25	2.25
Patient Care Technicians	3.25	6.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.00	0.00
Admin/Business Office	.50	1.00
Bio Medical Technician	0.50	0.50
TOTAL	7.50	11.75

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q.

In Section H, pages 52-53, 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 applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

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.

- (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 nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 55-58, 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 facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 58, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the Facility Administrator attesting to the relationship between the medical director's physician practice and the facility.

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 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 67, the applicant provides the historical payor mix during CY 2021 for its existing services, as shown in the table below.

BD Historical Payor Mix CY 2021		
Payment Source	# of Patients	% of Patients
Commercial Insurance*	3.00	10.00%
Medicare*	24.00	80.00%
Medicaid*	2.00	6.70%
Misc. (including VA)	1.00	3.30%
Total	30.0	100.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

In Section L, page 68, the applicant provides the following comparison.

	Percentage of Total Patients Served by BD during CY 2021	Percentage of the Population of the Service Area
Female	41.2%	51.7%
Male	58.8%	48.3%
Unknown	0.0%	0.0%
64 and Younger	64.7%	88.1%
65 and Older	35.3%	11.9%
American Indian	0.0%	0.9%
Asian	0.0%	6.5%
Black or African-American	88.2%	33.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	11.8%	56.6%
Other Race	0.0%	2.6%
Declined / Unavailable	0.0%	0.0%

Conclusion

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 69, the applicant states it has no such obligation.

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against BD.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 70, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

BD Projected Payor Mix CY 2026		
Payment Source	# of Patients	% of Patients
Commercial Insurance*	6.56	10.00%
Medicare*	52.48	80.00%
Medicaid*	4.37	6.70%
Misc. (including VA)	2.19	3.30%
Total	65.50	100.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, 80% of services will be provided to Medicare patients, and 6.7% of services will be provided to Medicaid patients.

On page 70, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on recent facility experience at BD.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 70-71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. 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 applicant provides a copy of a letter sent to Central Piedmont Community College offering the facility as a training site for nursing students.
- The applicant states it often receives calls to utilize the facility for health professional training programs and discusses the process for intake when it receives such an inquiry.

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 nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

On page 115, the 2022 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2021, there were 25 existing or approved facilities providing dialysis and/or dialysis home training and support in Mecklenburg County. Information on these 25 dialysis facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2021				
	Owner	Location	# of Certified Stations	Utilization
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	43	56.98%
BMA Nations Ford	BMA	Charlotte	28	83.93%
BMA of East Charlotte*	BMA	Charlotte	26	75.00%
BMA West Charlotte*	BMA	Charlotte	29	76.72%
FKC Mallard Creek**	BMA	Charlotte	0	0%
FKC Regal Oaks	BMA	Charlotte	17	92.65
FKC Southeast Mecklenburg	BMA	Pineville	10	75.00%
FMC Aldersgate	BMA	Charlotte	16	73.44%
FMC Charlotte***	BMA	Charlotte	48	71.35%
FMC Matthews	BMA	Matthews	21	101.19%
FMC of North Charlotte	BMA	Charlotte	40	89.38%
FMC Southwest Charlotte	BMA	Charlotte	21	86.90%
INS Charlotte****	BMA	Charlotte	2	0%
INS Huntersville****	BMA	Huntersville	0	0%
Brookshire Dialysis	DaVita	Charlotte	11	68.18%
Charlotte Dialysis	DaVita	Charlotte	33	71.21%
Charlotte East Dialysis	DaVita	Charlotte	34	80.88%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	71.88%
DSI Glenwater Dialysis	DSI	Charlotte	42	60.71%
Huntersville Dialysis	DaVita	Huntersville	21	76.19%
Mint Hill Dialysis	DaVita	Mint Hill	21	69.05%
Mountain Island Lake Dialysis**	DaVita	Charlotte	0	0%
North Charlotte Dialysis Center	DaVita	Charlotte	33	68.18%
South Charlotte Dialysis*	DaVita	Charlotte	27	68.52%
Sugar Creek Dialysis	DaVita	Charlotte	21	46.43%

Source: Table 9A, Chapter 9, 2022 SMFP; Agency records

*Facility which exists and is operational, but which has been approved to relocate to a new site with additional stations.

**Facility under development or which was not operational at the time of data collection for the 2022 SMFP.

***Facility with an application under review to relocate an existing and operational facility to a new site.

****Facility which is dedicated exclusively to providing HH and PD training and support.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, the applicant states:

“The expansion of Brookshire Dialysis will have no effect on competition in Mecklenburg County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita”.

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, the applicant states:

“The expansion of Brookshire Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services...”

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 75, the applicant states:

“DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients”.

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 75-76, the applicant states:

“...the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients”.

See also Sections 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 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 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

The applicant proposes to add nine dialysis stations to BD pursuant to Condition 1 of the facility need methodology for a total of 20 stations upon project completion.

On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 108 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 108 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new 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- BD is an existing facility. Therefore, this Rule 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 27, and on Form C in Section Q, the applicant projects that BD will serve 58 patients on 20 stations, or a rate of 2.9 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 25-27, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.