

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 17, 2021

Findings Date: June 17, 2021

Project Analyst: Kim Meymandi

Team Leader: Gloria C. Hale

Project ID #: J-12051-21

Facility: Durham West Dialysis

FID #: 010285

County: Durham

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 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 Renal Healthcare, Inc. (hereinafter referred to as “the applicant” or DaVita) proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

Need Determination (Condition 2)

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 9C, the county need methodology shows there is not a county need determination for additional dialysis stations in Durham 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 dialysis center, as reported in the 2021 SMFP, is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Durham West Dialysis in Table 9A, page 122 of the 2021 SMFP, is 77.00% or 3.08 patients per station per week, based on 77 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2019 [$77 / 25 = 3.08$; $3.08 / 4 = 0.77$]. Therefore, the applicant exceeds the minimum utilization required in Condition 2.a and is eligible to apply for additional stations based on the facility need methodology in Condition 2.b.

As shown in Table 9D, page 138 of the 2021 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Durham West Dialysis is up to six additional stations; thus, the applicant is eligible to apply to add up to six additional dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than six new dialysis stations to Durham West Dialysis, which is consistent with the 2021 SMFP calculated facility need determination; 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.”

In Section B, pages 17-20, the applicant explains why it believes its application is consistent with Policy GEN-3. On pages 19-20, the applicant states:

“For all its patients – current patients as well as those included in the projected utilization – DaVita is committed to:

- *promoting a culture of safety;*
- *ensuring industry-leading quality of care;*
- *promoting equitable access; and*

- *maximizing healthcare value.*

As discussed in Sections B-3(a), (b), & (c), established policy and procedure will continue to guide this commitment.”

The applicant further discusses the promotion of safety and quality in Section N.2, page 65; and Section O, pages 67-69, and referenced exhibits.

The applicant further discusses the promotion of equitable access in Section C.6, pages 29-30; Section L, pages 58-63; and Section N.2, page 65; and referenced exhibits.

The applicant further discusses maximizing healthcare value for resources expended in Section N.2, page 65.

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 that the application is consistent with Policy GEN-3 based on how the facility’s projected volumes incorporate the concepts of 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 no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

The following table, summarized from page 14 of the application, shows the current and projected number of dialysis stations at Durham West Dialysis upon project completion.

Durham West Dialysis

# of Stations	Description	Project ID #
25	Total # of existing certified stations as reported in Table 9A of the 2021 SMFP	
6	# of stations to be added as part of this project	
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
- 4	# of stations previously approved to be deleted	J-11544-18*
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
27	Total # of stations upon completion of all facility projects	

*Project ID #J-11544-18 was certified on December 19, 2021

As outlined in the table above, in this application, the applicant proposes to add six dialysis stations for a total of 27 stations upon the completion of this project.

Patient Origin

On page 113, the 2021 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.*” The facility referred to in this application is located in Durham County. Thus, the service area for this facility consists of Durham County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 22, the applicant provides the patient origin for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients at Durham West Dialysis Center for the last full fiscal year (CY2020), as summarized in the table below.

Durham West Dialysis Historical Patient Origin - CY2020

COUNTY	# IC PATIENTS	% of IC Total	# HH Patients	% of HHD Total	# PD Patients	% of PD Total
Durham	58	75.3%	7	36.8%	12	46.2%
Alamance			1	5.3%		
Chatham			1	5.3%		
Cumberland			1	5.3%		
Granville	1	1.3%			2	7.7%
Guilford					2	7.7%
Johnston			2	10.5%		
Nash					1	3.8%
Orange	15	19.5%			5	19.2%
Person	1	1.3%				
Rockingham			1	5.3%		
Sampson					1	3.8%
Vance			2	10.5%		
Wake			3	15.8%	3	11.5%
Warren			1	5.3%		
South Carolina	1	1.3%				
Virginia	1	1.3%				
Total	77	100.0%	19	100.0%	26	100.0%

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year (CY2024) following project completion, as provided in Section C.3, page 23.

Durham West Dialysis Projected Patient Origin - CY2024

COUNTY	# IC PATIENTS	% of IC Total	# HH Patients	% of HHD Total	# PD Patients	% of PD Total
Durham	58	75.3%	11	36.8%	16	53.33%
Alamance			1	4.3%		
Chatham			1	4.3%		
Cumberland			1	4.3%		
Granville	1	1.3%			2	6.67%
Guilford					2	6.67%
Johnston			2	8.7%		
Nash					1	3.33%
Orange	15	19.5%			5	16.67%
Person	1	1.3%				
Rockingham			1	4.3%		
Sampson					1	3.33%
Vance			2	8.7%		
Wake			3	13.0%	3	10.0%
Warren			1	4.3%		
South Carolina	1	1.3%				
Virginia	1	1.3%				
Total	77	100.0%	23	100.0%	30	100.00%

Totals may not sum due to rounding

In Section C, page 23, the applicant provides the assumptions and methodology it used to project IC, HH and PD patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin at Durham West Dialysis based on its existing population.
- The applicant conservatively projects no increase in the number of IC patients due to stations being relocated over the past three years.

Analysis of Need

In Section C.3, pages 23-24, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“In Project ID# J-11544-18, DaVita was approved to develop Hope Valley Dialysis in Durham County by relocating 6 stations from Southpoint Dialysis and 4 stations from Durham West Dialysis. That project was certified on December 19, 2020 leaving Durham West Dialysis with 21 certified stations.”

Application of the facility need methodology shows that the facility is eligible to apply for up to six dialysis stations. In section Q Form C, Utilization Assumptions and Methodology, the applicant provides information as to why the population projected to utilize the proposed services needs the proposed services, as summarized below:

- As of December 31, 2020, the facility had a patient census of 77 in-center patients dialyzing on 21 stations for a station utilization rate of 92% [$77 / 21 = 3.67$; $3.67 / 4 = 0.9175$].
- Assuming a flat growth rate of 0.0% to project future utilization, the facility will have 77 in-center patients and operate at a utilization rate of 71.3% on the 27 dialysis stations at the end of the project's first operating year, thus demonstrating the need for the proposed additional stations [$77 / 27 = 2.85$; $2.85 / 4 = 0.7125$].

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

- The applicant demonstrates the need for the additional stations at Durham West Dialysis based on its existing and future patient population.
- The applicant provides supporting documentation for its projected utilization in Section Q Form C.

Projected Utilization

In Section Q Form C Utilization, the applicant provides projected IC, HHD and PD utilization, as illustrated in the following table.

Form C Utilization	Last Full OY 01/01/2020- 12/31/2020	Interim Year 01/01/2021- 12/31/2021	Interim Year 01/01/2022- 12/31/2022	First Full OY 01/01/2023- 12/31/2023	Second Full OY 01/01/2024- 12/31/2024
In-Center Patients					
# of Patients at the Beginning of the Year	77.00	77.00	77.00	77.00	77.00
# of Patients at the End of the Year	77.00	77.00	77.00	77.00	77.00
Average # of Patients during the Year	77.00	77.00	77.00	77.00	77.00
# of In-center Treatments / Patient / Year	150.23	148.20	148.20	148.20	148.20
Total # of In-center Treatments	11,568.00	11,411.40	11,411.40	11,411.40	11,411.40
Home Hemodialysis Patients					
# of Patients at the Beginning of the Year	27.00	19.00	20.00	21.00	22.00
# of Patients at the End of the Year	19.00	20.00	21.00	22.00	23.00
Average # of Patients during the Year	23.00	19.50	20.50	21.50	22.50
# of In-center Treatments / Patient / Year	182.04	148.20	148.20	148.20	148.20
Total # of In-center Treatments					
PD Patients					
# of Patients at the Beginning of the Year	31.00	26.00	27.00	28.00	29.00
# of Patients at the End of the Year	26.00	27.00	28.00	29.00	30.00
Average # of Patients during the Year	28.50	26.50	27.50	28.50	29.50
# of Treatments / Patient / Year	160.77	148.20	148.20	148.20	148.20
Total # of Treatments	4,582.00	3,927.30	4,075.50	4,223.70	4,371.90
Total Patients					
# of Patients at the Beginning of the Year	135.00	122.00	124.00	126.00	128.00
# of Patients at the End of the Year	122.00	124.00	126.00	128.00	130.00
Average # of Patients during the Year	128.50	123.00	125.00	127.00	129.00
# of Treatments / Patient / Year	158.26	148.20	148.20	148.20	148.20
Total # of Treatments	20,337.00	18,228.60	18,525.00	18,821.40	19,117.80

In Section Q, Form C Utilization, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

In-Center Patients

- Project ID #J-11544-18, involving the relocation of 4 stations from Durham West Dialysis, was certified on December 19, 2020, leaving Durham West Dialysis with a total of 21 stations.
- As of December 31, 2020, 58 of the center’s 77 IC dialysis patients lived in Durham County and 19 lived outside of the service area.
- Operating year one (OY1) is projected to begin January 1, 2023 and end December 31, 2023.
- Operating year two (OY2) is projected to begin January 1, 2024 and end December 31, 2024.

- Durham West Dialysis has experienced a declining census over the past three years.
- The applicant conservatively assumes a flat growth rate of 0.0% for the entire population with the growth rate beginning January 1, 2021 and projects the population forward to December 31, 2024.

The table below summarizes the applicant’s methodology based on the applicant’s stated assumptions.

	IC Stations	IC Patients
The applicant begins with the 77 patients dialyzing on 21 stations at the facility as of 12/31/20.	21	77
The applicant projects the patient census forward a year to 12/31/2021 with no projected growth.		$77 \times 1.0 = 77$
The applicant projects the patient census forward a year to 12/31/2022 with no projected growth.		$77 \times 1.0 = 77$
The project is projected to be certified on 1/1/2023. This is the station count at the beginning of OY1.	$21 + 6 = 27$	
The applicant projects the patient census forward a year to 12/31/2023 with no projected growth. This is the projected ending census for OY1.		$77 \times 1.0 = 77$
The applicant projects the patient census forward a year to 12/31/2024 with no projected growth. This is the projected ending census for OY2.		$77 \times 1.0 = 77$

Source: Table in Section Q

The applicant projects to serve 77 in-center patients in OY1 and OY2. Thus, the applicant projects that Durham West Dialysis will have a utilization rate of 71.3% or 2.9 patients per station per week ($77 \text{ patients} / 27 \text{ stations} = 2.852 / 4 = 0.713$ or 71.3%) in OY1 and OY2. The projected utilization of 2.9 patients per station per week at the end of OY1 and 2.9 patients per station per week at the end of OY2 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing patient census at Durham West Dialysis as of December 31, 2020.
- The applicant projects IC utilization using no growth rate, which is conservative given the facility’s declining growth rate for the past three years.
- The projected utilization rate by the end of OY1 and OY2 is above the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Home Hemodialysis and Peritoneal Patients

- As of December 31, 2020, 7 of the center’s 19 HHD patients lived in Durham County and 12 lived outside of the service area.
- As of December 31, 2020, 12 of the center’s 26 PD patients lived in Durham County and 14 lived outside of the service area.
- Operating year one (OY1) is projected to begin January 1, 2023 and end December 31, 2023.
- Operating year two (OY2) is projected to begin January 1, 2024 and end December 31, 2024.
- The applicant projects that the facility’s home training program will grow at a rate of at least one patient per year during the period of growth.
- The applicant assumes patients will receive treatment three times a week, 52 weeks a year and a missed treatment rate of 5% [$3 \times 52 \times 0.95 = 148$].
- Average number of patients during the year equals the mean of the beginning and ending facility census by year.

The following table summarizes the end of year census and average number of patients each year for the HHD and PD home-training programs at Durham West Dialysis.

HHD Patient Projections	Start Date	# of patients at start of year	# of patients at end of year	Average # of patients/year
Interim Full FY	1/1/2021	19.0	20.0	19.5
Interim Full FY	1/1/2022	20.0	21.0	20.5
OY1	1/1/2023	21.0	22.0	21.5
OY2	1/1/2024	22.0	23.0	22.5
PD Patient Projections				
Interim Full FY	1/1/2021	26.0	27.0	26.5
Interim Full FY	1/1/2022	27.0	28.0	27.5
OY1	1/1/2023	28.0	29.0	28.5
OY2	1/1/2024	29.0	30.0	29.5

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

- The applicant begins the projections with the existing HHD and PD patient census at Durham West Dialysis as of January 1, 2021.
- The applicant projects the HHD and PD home-training programs at Durham West Dialysis will increase by at least one patient per year during the period of growth, which is reasonable, and conservative given the higher numbers of HHD and PD patients that were trained in CY2020.

Access to Medically Underserved Groups

In Section C, page 29, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, color national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.

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. ...

Durham West 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.”

On page 30, the applicant provides the estimated percentage for each medically underserved group during CY 2024, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Low Income persons	85.7%
Racial and ethnic minorities	58.2%
Women	41.8%
Persons with disabilities	100.0%
Persons 65 and older	32.0%
Medicare beneficiaries	75.3%
Medicaid recipients	9.1%

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 currently serves the needs of medically underserved groups that utilize ESRD services and proposes to continue to do so.
- The applicant has policies in place to prevent discrimination.

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 no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section E, page 37, 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* - The applicant states that maintaining the status quo is not an effective alternative due to the high utilization rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that they operate eight facilities in Durham County. Four of the facilities are operating at greater than 75% capacity and relocating any stations from these facilities would negatively impact the patients served. The other four facilities are all small facilities and relocating stations from these facilities would reduce the station count for each of them to below 10 stations.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **DVA Renal Healthcare, 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 six additional in-center dialysis stations for a total of no more than 27 in-center stations at Durham West Dialysis upon completion of this project.**
 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 sixth month. The first progress report shall be due on January 1, 2022. The second progress report shall be due on July 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 six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant illustrates projected capital cost of the project, as shown in the table below:

Durham West Dialysis Capital Cost

ITEM	COST
Medical Equipment	\$45,000
Non-Medical Equipment	\$5,319
Furniture	\$8,400
Total	\$58,719

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 39, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Availability of Funds

In Section F, page 38, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DVA Renal Healthcare, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$58,719	\$58,719
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$58,719	\$58,719

* OE = Owner's Equity

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

- Exhibit F contains the Consolidated Financial Statements for the year ending December 31, 2020 that shows DaVita, Inc., parent company to DVA Renal Healthcare, Inc. currently has \$325 million in cash and cash equivalents and \$16 billion in total assets.

Financial Feasibility

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

Durham West Dialysis Projected Revenue and Operating Expenses

	OY 1 CY 2023	OY 2 CY 2024
Total In-Center Treatments	18,821	19,118
Total Gross Revenue (charges)	\$8,363,522	\$8,524,290
Total Net Revenue	\$8,718,600	\$8,884,960
Average Net Revenue per Treatment	\$463	\$465
Total Operating Expenses (costs)	\$4,000,413	\$4,016,912
Average Operating Expense per Treatment	\$213	\$210
Net Income / Profit	\$4,718,187	\$4,868,048

*Source: application Form F.2, Section Q

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for the reasons stated 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 the reasons stated 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 no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

On page 113, the 2021 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-Graham counties and Avery-Mitchell-Yancey counties.” Thus, the service area for this facility is Durham County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 122, of the 2021 SMFP, there are 13 existing or approved dialysis facilities in Durham County, eight of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2021 SMFP is provided below:

Durham County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Percent Utilization as of 12/31/2019	Patients Per Station Per Week as of 12/31/2019
Bull City Dialysis (DaVita)	16	51	79.69%	3.19
Downtown Durham Dialysis (DaVita)	10	11	27.50%	1.10
Durham Dialysis (DaVita)	17	98	144.12%	5.76
Durham Regional Dialysis (DaVita)	10	26	65.00%	2.60
Durham West Dialysis (DaVita)	25	77	77.00%	3.08
FMC Dialysis Services of Briggs Avenue (BMA)	29	91	78.45%	3.14
FMC Dialysis Services West Pettigrew (BMA)	24	73	76.04%	3.04
Freedom Lake Dialysis (BMA)	26	84	80.77%	3.23
Fresenius Kidney Care Eno River (BMA)	0	0	0.00%	0.0
Fresenius Medical Care South Durham Dialysis (BMA)	20	65	81.25%	3.25
Hope Valley Dialysis (DaVita)	0	0	0.00%	0.00
Research Triangle Park Dialysis (DaVita)	10	20	50.00%	2.00
Southpoint Dialysis (DaVita)	16	80	125.00%	5.00
Total	203	676		

In Section G, page 45, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“While adding stations at this facility does increase the number of stations in Durham County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s 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 for the following reasons:

- There is a facility need determination in the 2021 SMFP at Durham West Dialysis for the proposed six dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Durham County.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Durham West Dialysis, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	OY1 (1/1/2023 to 12/31/2023)	OY2 (1/1/2024 to 12/31/2024)
Administrator	1.00	1.00	1.00
RNs	3.25	3.50	3.50
Home Training Nurse	1.00	1.00	1.00
Technicians (PCT)	9.50	10.25	10.25
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Admin/Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
TOTAL	18.25	19.25	19.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 46-47, 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 an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Durham West Dialysis.
- The increased costs are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.

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 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 no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

Ancillary and Support Services

In Section I, pages 48-51, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is and will continue to be made available and provides supporting documentation in Exhibits H.1a and H.1b. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The stated ancillary and support services are currently available.
- The applicant provides evidence that the ancillary and support services are currently being provided.

Coordination

In Section I, page 51 , the applicant describes its existing 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 applicant provides a listing of established relationships with the existing health care system in Exhibit I.2.
- The applicant provides a letter from the facility administrator in Exhibit I.2. committing to the continuation of the established relationships.

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

- (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 58, the applicant provides the historical payor mix for Durham West Dialysis during the last full operating year (CY2020) for its existing services, as shown in the table below.

**Durham West Dialysis
 Historical Payor Mix CY 2020**

Payor Category	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.0	1.3%	0.0	0.0%	0.0	0.0%
Insurance*	9.0	11.7%	2.0	10.5%	12.0	46.2%
Medicare*	58.0	75.3%	16.0	84.2%	11.0	42.3%
Medicaid*	7.0	9.1%	1.0	5.3%	1.0	3.8%
Miscellaneous (Incl. VA)	2.0	2.6%	0.0	0.0%	2.0	7.7%
Total	77.0	100.0%	19.0	100.0%	26.0	100.0%

*Including any managed care plans

In Section L, page 59, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population in the Service Area *
Female	41.8%	52.3%
Male	58.2%	47.7%
Unknown	0.0%	0.0%
64 and Younger	68.0%	86.4%
65 and Older	32.0%	13.6%
American Indian	0.0%	0.9%
Asian	1.6%	5.5%
Black or African-American	56.6%	36.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	41.8%	54.0%
Other Race	0.0%	2.6%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... 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, the applicant states in Section L, page 60, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 60, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 61, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Durham West Dialysis
 Projected Payor Mix CY2024**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.0	1.3%	0.0	0.0%	0.0	0.0%
Insurance*	9.0	11.7%	2.42	10.5%	13.85	46.2%
Medicare*	58.0	75.3%	19.37	84.2%	12.69	42.3%
Medicaid*	7.0	9.1%	1.21	5.3%	1.15	3.8%
Miscellaneous (incl. VA)	2.0	2.6%	0.0	0.0%	2.31	7.7%
Total	77.0	100.0%	23.00	100.0%	30.00	100.0%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 1.3% of in-center dialysis services will be provided to self-pay patients, 75.3% to Medicare patients, and 9.1% to Medicaid patients. In addition, 84.2% and 5.3% of HH services will be provided to Medicare and Medicaid patients, respectively, and 42.3% and 3.8% of PD services will be provided to Medicare and Medicaid patients, respectively.

On page 61, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of Durham West Dialysis.

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.5., pages 62, 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

In Section M, page 64, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. 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 offers the facility as a clinical learning site for students from Durham Technical Community College.
- The applicant provides a copy of the training agreement with Durham Technical Community College in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

On page 113, the 2021 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Durham County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are 13 existing or approved dialysis facilities in Durham County, eight of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2021 SMFP is provided below:

Durham County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Percent Utilization as of 12/31/2019	Patients Per Station as of 12/31/2019
Bull City Dialysis (DaVita)	16	51	79.69%	3.19
Downtown Durham Dialysis (DaVita)	10	11	27.50%	1.10
Durham Dialysis (DaVita)	17	98	144.12%	5.76
Durham Regional Dialysis (DaVita)	10	26	65.00%	2.60
Durham West Dialysis (DaVita)	25	77	77.00%	3.08
FMC Dialysis Services of Briggs Avenue (BMA)	29	91	78.45%	3.14
FMC Dialysis Services West Pettigrew (BMA)	24	73	76.04%	3.04
Freedom Lake Dialysis (BMA)	26	84	80.77%	3.23
Fresenius Kidney Care Eno River (BMA)	0	0	0.00%	0.0
Fresenius Medical Care South Durham Dialysis (BMA)	20	65	81.25%	3.25
Hope Valley Dialysis (DaVita)	0	0	0.00%	0.00
Research Triangle Park Dialysis (DaVita)	10	20	50.00%	2.00
Southpoint Dialysis (DaVita)	16	80	125.00%	5.00
Total	203	676		

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 65, the applicant states:

“The expansion of Durham West Dialysis will have no effect on competition in Durham 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 by DaVita.”

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, page 65, the applicant states:

“The expansion of Durham West 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. As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. As discussed in Section B and Section O, 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. As discussed in Section C, question 6, and documented in Exhibit L.5., 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 B, C, F, L, N, O and Q 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 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 A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 67-69, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of "*Immediate Jeopardy*" occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita 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 with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- Durham West Dialysis 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 24, and Form C in Section Q, the applicant projects that Durham West Dialysis will serve 77 in-center patients on 27 stations, or a rate of 2.9 patients per station per week or 71.3% ($77 / 27 = 2.85/4 = 0.7125$ or 71.3%), as of the end of the first operating year (CY2023) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C, pages 23-24, and in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility.