

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 24, 2021

Findings Date: June 24, 2021

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: F-12050-21

Facility: Huntersville Dialysis

FID #: 130490

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add no more than 6 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 Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

DVA Healthcare Renal Care, Inc. (hereinafter referred to as “DVA” or “the applicant”) proposes to add 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations upon project completion.

Need Determination

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 137, 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 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. Table 9A on page 127 of the 2021 SMFP shows the utilization rate reported for Huntersville Dialysis is 87.5 percent or 3.5 patients per station per week based on 63 in-center dialysis patients and 18 certified dialysis stations (63 patients / 18 stations = 3.5; $3.5 / 4 = 87.5\%$).

As shown in Table 9D on page 139 of the 2021 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Huntersville Dialysis is up to 6 additional stations; thus, the applicant is eligible to apply to add up to 6 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 stations to Huntersville Dialysis, which is consistent with the 2021 SMFP calculated facility need determination for up to six dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 SMFP, states:

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

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.*

..., established policy and procedure will continue to guide this commitment.”

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 2 of the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates how Huntersville Dialysis'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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following project completion.

The 2021 SMFP shows that as of 12/31/2019, Huntersville Dialysis had 18 licensed dialysis stations and was approved to add three more (pursuant to Project I.D. #F-11890-20). According to the Acute and Home Care Licensure and Certification Section, DHSR, the three stations approved pursuant to Project I.D. #F-11890-20 were certified as of October 18, 2020.

In Section C, page 21, the applicant states it currently provides peritoneal dialysis (PD) training and support in addition to in-center dialysis. On page 22, the applicant projects it will continue to provide PD training and support during the first two full operating years following project completion.

In Section A, page 11, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with DVA to refer to itself or its facilities. References to DaVita should be interpreted to mean DVA unless otherwise specified.

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.” 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.

Huntersville Dialysis – Current (as of 12/31/2020) and Projected (OY 2) Patient Origin								
County	Current (as of 12/31/2020)				Projected – OY 2 (CY 2024)			
	In-Center Patients		PD Patients		In-Center Patients		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	50	75.8%	3	60.0%	69.29	81.2%	7	77.78%
Cabarrus	6	9.1%	0	0.0%	6	7.0%	0	0.00%
Catawba	1	1.5%	0	0.0%	1	1.2%	0	0.00%
Gaston	1	1.5%	0	0.0%	1	1.2%	0	0.00%
Iredell	1	1.5%	1	20.0%	1	1.2%	1	11.11%
Lincoln	7	10.6%	1	20.0%	7	8.2%	1	11.11%
Total	66	100.0%	5	100.0%	85.29	100.0%	9	100.00%

Source: Section C, pages 21-22

In Section C, pages 22-25, 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 clearly explains how it projected growth in the Mecklenburg County patient population.
- The applicant did not project growth in the number of patients at Huntersville Dialysis who do not live in Mecklenburg County.

Analysis of Need

In Section C, pages 22-25 and 27-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The historical growth of the in-center patient population at Huntersville Dialysis is higher than the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 3.1 percent as published in the 2021 SMFP. The applicant states that, based on the patient population between December 31, 2016 and December 31, 2020, the 4-year CAGR for the in-center patient population at Huntersville Dialysis was 15.9 percent.
- Even with the certification of three additional stations, utilization remained high at Huntersville Dialysis in 2020. The applicant states that it ended 2020 with 66 in-center

patients and 21 certified stations, which is a utilization rate of 3.14 patients per station per week or 78.5 percent (66 patients / 21 stations = 3.14 patients per station per week; 3.14 / 4 = 0.785 or 78.5%).

- The applicant states that, even with using a lower growth rate for the in-center patient population than the historical growth rate, the facility’s utilization could go as high as 95 percent.
- The applicant states its projected utilization demonstrates the proposed six stations will be well-utilized.
- The applicant states its parent organization, DaVita, services more home dialysis patients than any other provider in the United States and growth of DaVita’s home dialysis programs is four times higher than growth of in-center patient populations.

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

- The applicant uses publicly available information it has reported to the Agency in the past to demonstrate the historical growth rate at the facility.
- The applicant demonstrates the need for the additional six stations even while using a lower growth rate than the historical growth rate for the facility.
- The applicant provides information about the need to continue to offer home dialysis services.

Projected Utilization

On Form C and the Form C Utilization subsection in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

Huntersville Dialysis – Historical (as of 12/31/2020) and Projected (OY 2) Utilization									
	Historical (as of 12/31/2020)				Projected – OY 2 (CY 2024)				
	In-Center Patients		PD Patients		In-Center Patients		PD Patients		
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	% of Total
Mecklenburg	50	75.8%	3	60.0%	69.29	81.2%	7	77.78%	
Cabarrus	6	9.1%	0	0.0%	6	7.0%	0	0.00%	
Catawba	1	1.5%	0	0.0%	1	1.2%	0	0.00%	
Gaston	1	1.5%	0	0.0%	1	1.2%	0	0.00%	
Iredell	1	1.5%	1	20.0%	1	1.2%	1	11.11%	
Lincoln	7	10.6%	1	20.0%	7	8.2%	1	11.11%	
Total	66	100.0%	5	100.0%	85.29	100.0%	9	100.00%	

In Section C, pages 22-25 and 27-28, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

In-Center Projected Utilization

- The applicant begins its in-center utilization projections with the patient facility census on December 31, 2020. On page 22, the applicant states that, on December 31, 2020, its in-center patient census was comprised of 50 Mecklenburg County patients and 16 patients from other North Carolina counties.
- The Mecklenburg County AACR published in the 2021 SMFP is 3.1 percent; however, the applicant uses a projected growth rate of 8.5 percent for Mecklenburg County patients. This growth rate is lower than the facility’s 4-year CAGR of 15.9 percent.
- The applicant assumes no population growth for the patients residing in other North Carolina counties dialyzing in-center at Huntersville Dialysis but assumes the patients will continue to dialyze in-center at Huntersville Dialysis and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY 2023. OY2 is CY 2024.

In Section C, page 24, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

Huntersville Dialysis In-Center Projected Utilization	
Starting point of calculations is Mecklenburg County patients dialyzing at Huntersville Dialysis on December 31, 2020.	50
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the applicant’s projected growth rate of 8.5%.	$50 \times 1.085 = 54.25$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the applicant’s projected growth rate of 8.5%.	$54.25 \times 1.085 = 58.861$
The patients from other counties are added. This is the projected census on January 1, 2023 and the starting census for this project.	$58.861 + 16 = 74.86$
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the applicant’s projected growth rate of 8.5%.	$58.86 \times 1.085 = 63.864$
The patients from other counties are added. This is the projected census on December 31, 2023 (OY1).	$63.86 + 16 = 79.86$
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the applicant’s projected growth rate of 8.5%.	$63.86 \times 1.085 = 69.293$
The patients from other counties are added. This is the projected census on December 31, 2024 (OY2).	$69.29 + 16 = 85.29$

The applicant projects to serve 80 patients on 27 stations, which is 3.0 patients per station per week ($80 \text{ patients} / 27 \text{ stations} = 2.96$, which is rounded to 3.0), by the end of OY1 and 85

patients on 27 stations, which is 3.2 patients per station per week (85 patients / 27 stations = 3.15, which is rounded to 3.2), by the end of OY 2. This exceeds 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).

PD Projected Utilization

- The applicant begins its utilization projections with the PD facility census on December 31, 2020. On page 24, the applicant states that, on December 31, 2020, its PD patient census was comprised of three Mecklenburg County patients and two patients from other North Carolina counties.
- The applicant assumes that the PD patient population will increase by one patient per year through the second full operating year following project completion. Based on the projected patient origin on page 22, the applicant projects the new patients will be Mecklenburg County residents.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY 2023. OY2 is CY 2024.

In Section C, pages 24-25, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.

Huntersville Dialysis PD Projected Utilization	
Starting point of calculations is Huntersville Dialysis PD patients as of December 31, 2020.	5
The PD patient population of Huntersville Dialysis is projected forward by one year to December 31, 2021, at a growth rate of one patient per year.	5 + 1 = 6
The PD patient population of Huntersville Dialysis is projected forward by one year to December 31, 2022, at a growth rate of one patient per year.	6 + 1 = 7
The PD patient population of Huntersville Dialysis is projected forward by one year to December 31, 2023, at a growth rate of one patient per year (end of OY1).	7 + 1 = 8
The PD patient population of Huntersville Dialysis is projected forward by one year to December 31, 2024, at a growth rate of one patient per year (end of OY2).	8 + 1 = 9

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

- The applicant projects in-center utilization using a growth rate that is higher than the Mecklenburg County 5-year AACR but which is lower than the facility’s own 4-year CAGR.

- The applicant does not project growth for any of the in-center patients who reside outside Mecklenburg County and makes reasonable assumptions about their continued use of the facility.

Access to Medically Underserved Groups

In Section C, pages 28-29, the applicant states:

“By policy, the proposed services will be made available to all residents in the 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. ...

Huntersville 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	84.8%
Racial and ethnic minorities	63.9%
Women	41.7%
Persons with disabilities	100%
Persons 65 and older	62.5%
Medicare beneficiaries	81.8%
Medicaid recipients	1.5%

Source: Section C, page 29

On page 29, the applicant states ESRD is progressive and limits life and that dialysis patients are eligible for protections under the Americans with Disabilities Act. The applicant states that while it does not collect data to explicitly identify patient disabilities, it assumes all ESRD patients are considered to be persons with disabilities.

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 it assumes the percentages of patients for each group listed above would be consistent with historical utilization at its facility.

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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following project completion.

In Section E, page 36, 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 maintaining the status quo was not an effective alternative because of the high growth rate at the facility.

- Relocate Stations from Another DaVita Facility: the applicant states there are four other DaVita facilities in Mecklenburg County that were operating at less than 75 percent of capacity. The applicant states two of the facilities are small facilities which are used to cohort COVID-19 patients and the other two facilities have either recently relocated stations or have recently been approved to relocate stations; therefore, this is not an effective alternative.

The applicant adequately demonstrates 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 other statutory and regulatory review criteria. Therefore, the application can be approved.

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 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than 6 additional in-center (and home hemodialysis) dialysis stations for a total of no more than 27 in-center (and home hemodialysis) dialysis stations at Huntersville 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.ncdhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**

Balance Sheets from the DaVita Inc. Form 10-K Consolidated Financial Statement, which showed that as of December 31, 2020, DaVita Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

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

- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The applicant provided publicly available documentation of its available cash and assets it will use to fund the projected capital cost of 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 revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
Huntersville Dialysis	Full Fiscal Year 1 CY 2023	Operating Year 2 CY 2024
Total Treatments	12,577	13,498
Total Gross Revenues (Charges)	\$5,058,342.96	\$5,448,083.64
Total Net Revenue	\$5,350,454.06	\$5,761,590.64
Average Net Revenue per Treatment	\$425.42	\$426.85
Total Operating Expenses (Costs)	\$3,139,710.13	\$3,286,317.64
Average Operating Expense per Treatment	\$249.64	\$243.47
Net Income/(Loss)	\$2,210,743.94	\$2,475,273.00

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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following 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 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.

There are 25 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 25 of these dialysis facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Brookshire Dialysis	DaVita	Charlotte	10	45.00%
Charlotte Dialysis	DaVita	Charlotte	34	77.94%
Charlotte East Dialysis	DaVita	Charlotte	34	76.47%
Huntersville Dialysis	DaVita	Huntersville	18	87.50%
Mint Hill Dialysis	DaVita	Mint Hill	22	62.50%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	70.83%
Renaissance Park Dialysis**	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis***	DaVita	Charlotte	23	80.43%
Sugar Creek Dialysis	DaVita	Charlotte	10	70.00%
BMA Beatties Ford	BMA	Charlotte	39	78.85%
BMA Nations Ford	BMA	Charlotte	28	83.04%
BMA of East Charlotte***	BMA	Charlotte	26	85.58%
BMA West Charlotte***	BMA	Charlotte	29	77.59%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	61.46%
DSI Glenwater Dialysis	DSI	Charlotte	42	72.02%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	15	81.67%
FKC Southeast Charlotte	BMA	Pineville	10	32.50%
FMC Aldersgate	BMA	Charlotte	10	72.50%
FMC Charlotte	BMA	Charlotte	45	88.89%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	91.25%
FMC Southwest Charlotte	BMA	Charlotte	16	92.19%
INS Charlotte****	BMA	Charlotte	0	0.00%
INS Huntersville****	BMA	Huntersville	0	0.00%

Source: Table 9A, Chapter 9, 2021 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2021 SMFP.

**On November 13, 2020, the certificate of need to develop Renaissance Park Dialysis was relinquished.

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

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

In Section G, page 45, 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:

“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 2 of the facility need determination in the 2021 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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following 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.

Huntersville Dialysis Current and Projected Staffing		
	Current 12/31/20	Projected – OYs 1-2 (CYs 2023 & 2024)
Administrator	1.00	1.00
Registered Nurses	2.25	3.50
Home Training Nurse	0.50	0.50
Patient Care Technicians	6.75	10.25
Dietician	0.50	1.00
Social Worker	0.50	1.00
Admin/Business Office	1.00	1.00
Biomedical Tech	0.50	0.50
TOTAL	13.00	18.75

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 46-47, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H.1a, H.1b, and H.3.

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 provides examples of its 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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following project completion.

Ancillary and Support Services

In Section I, page 48, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 48-51, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-2. 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 provides a letter from the facility administrator attesting to the availability of the necessary ancillary and support services.

Coordination

In Section I, page 51, 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 identifying existing relationships with specific local health care and social service providers.
- The applicant provides a letter from the medical director of the facility 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 58, the applicant provides the historical payor mix during CY 2019 for its existing services at Huntersville Dialysis, as shown in the table below.

Huntersville Dialysis – Historical Payor Mix (CY 2020)				
	In-Center Patients		PD Patients	
Payor Source	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1	1.5%	0	0.0%
Insurance*	8	12.1%	2	40.0%
Medicare*	54	81.8%	3	60.0%
Medicaid*	1	1.5%	0	0.0%
Other (VA)	2	3.0%	0	0.0%
Total	66	100.0%	5	100.0%

Table may not foot due to rounding.
 *Including any managed care plans

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

Huntersville Dialysis	% of Patients Served During CY 2020	% of the Population of Mecklenburg County
Female	41.7%	51.9%
Male	58.3%	48.1%
Unknown	0.0%	0.0%
64 and Younger	37.5%	88.5%
65 and Older	62.5%	11.5%
American Indian	0.0%	0.8%
Asian	1.4%	6.3%
Black or African-American	59.7%	33.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	36.1%	46.1%
Other Race	2.8%	2.5%
Declined / Unavailable	0.0%	0.0%

Sources: DVA Internal Data, US Census Bureau

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 60, the applicant states it has no such obligation.

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 Huntersville Dialysis.

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 61, 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.

Huntersville Dialysis – Projected Payor Mix (CY 2024)				
	In-Center Patients		PD Patients	
Payor Source	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1.29	1.5%	0.00	0.0%
Insurance*	10.34	12.1%	3.60	40.0%
Medicare*	69.79	81.8%	5.40	60.0%
Medicaid*	1.29	1.5%	0.00	0.0%
Other (VA)	2.58	3.0%	0.00	0.0%
Total	85.29	100.0%	9.00	100.0%

Table may not foot due to rounding.

*Including any managed care plans

As shown in the table above, during the applicant's second full fiscal year following project completion, the applicant projects to provide 1.5 percent of in-center services to self-pay patients; 81.8 percent and 60.0 percent of in-center and PD services, respectively, to Medicare patients; and 1.5 percent of in-center services to Medicaid

patients. On page 61, the applicant states it projects five patients each year will receive charity care in the form of reduced or no payment for services.

On page 61, 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 the historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 62, 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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following project completion.

In Section M, page 64, 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 letter provided by the applicant was sent several years ago and thus indicates the facility has been providing such access prior to this application.

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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following 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 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.

There are 25 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 25 of these dialysis facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Brookshire Dialysis	DaVita	Charlotte	10	45.00%
Charlotte Dialysis	DaVita	Charlotte	34	77.94%
Charlotte East Dialysis	DaVita	Charlotte	34	76.47%
Huntersville Dialysis	DaVita	Huntersville	18	87.50%
Mint Hill Dialysis	DaVita	Mint Hill	22	62.50%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	70.83%
Renaissance Park Dialysis**	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis***	DaVita	Charlotte	23	80.43%
Sugar Creek Dialysis	DaVita	Charlotte	10	70.00%
BMA Beatties Ford	BMA	Charlotte	39	78.85%
BMA Nations Ford	BMA	Charlotte	28	83.04%
BMA of East Charlotte***	BMA	Charlotte	26	85.58%
BMA West Charlotte***	BMA	Charlotte	29	77.59%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	61.46%
DSI Glenwater Dialysis	DSI	Charlotte	42	72.02%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	15	81.67%
FKC Southeast Charlotte	BMA	Pineville	10	32.50%
FMC Aldersgate	BMA	Charlotte	10	72.50%
FMC Charlotte	BMA	Charlotte	45	88.89%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	91.25%
FMC Southwest Charlotte	BMA	Charlotte	16	92.19%
INS Charlotte****	BMA	Charlotte	0	0.00%
INS Huntersville****	BMA	Huntersville	0	0.00%

Source: Table 9A, Chapter 9, 2021 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2021 SMFP.

**On November 13, 2020, the certificate of need to develop Renaissance Park Dialysis was relinquished.

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

****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 65, the applicant states:

“The expansion of Huntersville 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, quality, and access by medically underserved groups, in Section N, page 65, the applicant states:

“The expansion of Huntersville 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. ..., with additional capacity, greater operational efficiency is possible. ..., 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. ..., 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 and, by policy, works to make every reasonable effort to accommodate all of its patients.”

See also Sections C, F, L, 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 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 6 dialysis stations to Huntersville Dialysis pursuant to Condition 2 of the facility need methodology for a total of 27 stations following 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 69, 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 publicly available data 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- Huntersville 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 on Form C in Section Q, the applicant projects that Huntersville Dialysis will serve 80 patients on 27 stations, or a rate of 3.0 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 22-25 and 27-28, and in the Form C Utilization subsection of 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.