

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 31, 2020

Findings Date: July 31, 2020

Project Analyst: Misty L. Piekaar-McWilliams

Co-Signer: Fatimah Wilson

Project ID #: F-11890-20

Facility: Huntersville Dialysis

FID #: 130490

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add no more than 3 dialysis stations pursuant to facility need for a total of no more than 21 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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., herein referred to as “the applicant” or “DVA”, proposes to add no more than three (3) dialysis stations pursuant to facility need for a total of no more than 21 stations upon project completion.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 170, the county need methodology shows there is no 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 2020 SMFP, if the utilization rate for the dialysis center, as reported in the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Huntersville Dialysis (HD) in Table 9B on page 160 of the 2020 SMFP, is 92.86% or 3.714 patients per station per week, based on 52 in-center dialysis patients and 14 certified dialysis stations as of December 31, 2018 [$52 / 14 = 3.7142$; $3.7142 / 4 = 0.92855$]. Note, the 2020 SMFP Table 9B rounded up to obtain the 92.86% utilization rate. 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 9E, page 172 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at HD is up to three (3) additional stations; thus, the applicant is eligible to apply to add up to three (3) additional dialysis stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three (3) new stations to HD pursuant to facility need, which is consistent with the 2020 SMFP calculated facility need determination for up to three (3) dialysis stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

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

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

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5(a), pages 13-16, referencing

other application sections and exhibits with specific details with a general goal to create a “Culture of Safety”. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), pages 14-15, referencing other application sections and exhibits, Section L, pages 44-47 and Section N.2(c), page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section N, page 49 and Section B.5(c), page 15, by “negot[ing] national contracts with numerous vendors in order to secure the best product available at the best price” in addition to conducting preventative maintenance on the dialysis machines to extend the life of the dialysis machines. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value. The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The application is consistent with Condition 2 of the facility need methodology for dialysis stations.
 - The applicant adequately demonstrates that the application is consistent with Policy GEN-3, promoting safety and quality, equitable access, and maximizing healthcare value.
- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than three (3) dialysis stations to HD pursuant to facility need for a total of no more than 21 stations upon project completion.

The following table, summarized from data on page 7 of the application and page 160 of the 2020 SMFP, shows the projected number of stations at HD upon project completion.

HD		
Stations	Description	Project ID #
18	Total number of existing certified stations in the SMFP in effect on the day the review will begin	
+3	Number of stations to be added as part of this project (adding three (3) stations pursuant to facility need)	F-11890-20
21	Total number of stations upon completion of proposed project and previously approved projects	

As outlined in the table above, in this application, the applicant proposes to add three (3) additional dialysis stations for a total of 21 stations upon project completion.

Patient Origin

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

In Sections C.2 and C.3, pages 19 and 20, the applicant provides the historical and projected in-center (IC) patient origin for HD during the last full operating year, CY2019, and the projected patient origin for the second full operating year following project completion, January 1, 2023 - December 31, 2023 (CY 2023), as summarized in the following table:

HD Historical & Projected Patient Origin				
	Historical (CY 2019)		Projected (CY 2023)	
	# of Patients	% of Patients	# of Patients	% of Patients
Mecklenburg	49	77.8%	57.7652897	80.5%
Cabarrus	3	4.8%	3	4.2%
Catawba	1	1.6%	1	1.4%
Iredell	4	6.3%	4	5.6%

Lincoln	4	6.3%	4	5.6%
South Carolina	1	1.6%	1	1.4%
Other States	1	1.6%	1	1.4%
Total	63	100.00%	71.7652897	100.00%

As shown in the table above and stated on page 19, HD does not offer home hemodialysis training and support services.

In Section C, page 19, the applicant provides the assumptions and methodology used to project HD's patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.3(b), page 20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need based on HD's and Mecklenburg County's patient growth rate over the last year. The applicant states:

- HD's projected patient population for Second Full Operating Year (01/01/2023 to 12/31/2023) is projected to increase to 71.7652897 in-center patients.
- The Second Full OY projection for patient population is based upon the 4.2% Mecklenburg County's Five Year Average Annual Change Rate (AACR) as indicated in Table 9C of the 2020 SMFP.
- The applicant does not project growth in the patient population from Cabarrus, Catawba, Iredell, and Lincoln counties but adds them to the projections where appropriate.

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

- According to the 2020 SMFP, as of December 31, 2018, HD was operating at a rate of 3.71 patients per station per week, or 92.86 percent of capacity.
- The applicant adequately demonstrates the need to add three (3) dialysis stations pursuant to facility need based on its existing and future patient population.

Projected Utilization

In Section C, page 21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census on December 31, 2019. On page 20, the applicant states that on December 31, 2019, it was serving 49 Mecklenburg County patients and 14 patients who lived outside of Mecklenburg County. Specifically, HD served three (3) Cabarrus County patients, one (1)

Catawba County patient, four (4) Iredell County patients, four (4) Lincoln County patients, one (1) South Carolina patient and one (1) patient from another state.

- The applicant projects growth of the Mecklenburg County patient population at an annual growth rate of 4.2 percent, which is Mecklenburg County’s Five Year AACR as published in the 2020 SMFP.
- The applicant projects no growth calculations for patients living outside of Mecklenburg County.
- The project is scheduled for completion on December 31, 2021. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 21, and in the Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for OY1 and OY2, as summarized in the table below.

HD Projected Utilization		
	IC Stations	IC Patients
The applicant begins with the 63 patients [at] dialyzing on 18 stations at the facility as of 1/1/2020.	18	63
The facility’s Mecklenburg County patient census is projected forward a year to 12/31/2020 and is increased by the Five Year AACR of 4.2% for Mecklenburg County.		$49 \times 1.042 = 51.0580$
The 14 patients from outside Mecklenburg County are added to the facility’s census. This is the ending census as 12/31/2020.		$51.0580 + 14 = 65.06$
The facility’s Mecklenburg County patient census is projected forward a year to 12/31/2021 and is increased by 4.2%.		$51.0580 \times 1.042 = 53.20244$
The 14 patients from outside Mecklenburg County are added to the facility’s census. This is the ending census as 12/31/2021.		$53.20244 + 14 = 67.20$
The proposed project [and] is projected to be certified on 1/1/2022. This is the station count at the beginning of OY1. The facility’s Mecklenburg County patient census is projected forward a year to 12/31/2022 and is increased by 4.2%.	$18+3=21$	$53.20244 \times 1.042 = 55.43694$
The 14 patients from outside Mecklenburg County are added to the facility’s census.		$55.43694 + 14 = 69.44$

This is the ending census as of the end of OY1.		
The facility's Mecklenburg County patient census is projected forward a year to 12/31/2023 and is increased by 4.2%.		$55.43694 \times 1.042 = 57.76529$
The 14 patients from outside Mecklenburg County are added to the facility's census. This is the ending census as of the end of OY2.		$57.76529 + 14 = 71.77$

The applicant projects to serve 69 patients on 21 stations, which is 3.285 patients per station per week ($69 \text{ patients} / 21 \text{ stations} = 3.285$), by the end of OY1 and 72 patients on 21 stations, which is 3.4285 patients per station per week ($72 \text{ patients} / 21 \text{ stations} = 3.4285$), by the end of OY2. Note, whereas the applicant rounded up the patient census from 71.77 patients to 72 patients for OY2 given that a patient constitutes a whole person and, thus, cannot be adequately described using a fraction, even with the applicant rounding up from 71.77 patients to 72 patients, 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) ($71.77 \text{ patients} / 21 \text{ stations} = 3.4176$).

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

- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the Mecklenburg County patient population using the Five Year AACR for Mecklenburg County of 4.2 percent as published in the 2020 SMFP.
- The applicant projects no growth for patients residing outside of Mecklenburg County and adequately supports the decisions to include or exclude patients residing outside of Mecklenburg County who were dialyzing at the facility on December 31, 2019.

Access

In Section C.7, pages 22-23, the applicant discusses access to services at HD. On page 23, the applicant states:

“We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patients shifts per day to accommodate patient need. 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.”

Exhibits L-4 and L-5 contain the facility’s Charity/Reduced Cost Care and Referral/Admissions Policies, respectively. The applicant projects payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.3, page 46.

**Projected Payor Mix
CY2023**

Payor Source	# of IC Patients	% of IC Patients	# of HH/PD Patients	% of HH/PD Patients
Self-Pay	1.1	1.6%	0.0%	0.0
Insurance	11.4	15.9%	0.0%	0.0
Medicare	52.4	73.0%	0.0%	0.0
Medicaid	2.3	3.2%	0.0%	0.0
Other (VA)	4.6	6.3%	0.0%	0.0
Total	71.765	100.0%	0.0%	0.0

In Section L, page 46, the applicant provides the assumptions for projecting payor mix, stating that the projected payor mix is based on the sources of patient payment that has been received (in the last full operating year) by the existing facility and no adjustment rate has been applied to the projected payor mix. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to add no more than three (3) dialysis stations pursuant to facility need for a total of no more than 21 stations upon project completion.

In Section E, page 28, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- Maintain the status quo - the applicant states that this alternative was dismissed given the growth rate at the facility.
- Policy ESRD-2, Mecklenburg County Station Relocation – the applicant states that HD, through its parent company DaVita, has two (2) other dialysis facilities in Mecklenburg County and operating at less than 75% capacity from which stations might be relocated pursuant to Policy ESRD-2; Mint Hill Dialysis (MHD) and Sugar Creek Dialysis (SCD). The applicant states that if MHD relocated stations to HD, the current patients at MHD would be negatively impacted since stations are already projected to be relocated from MHD (Project ID # F-11846-20). Similarly, the applicant states that if SCD relocated stations to HD, the current patients at SCD would be negatively impacted since

SCD is a new facility with only 10 stations. Thus, relocation of stations within the same service area is not an effective alternative.

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application and
- 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. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the 2020 SMFP, DVA Healthcare Renal Care, Inc. shall add no more than three (3) additional in-center dialysis stations for a total of no more than 21 in-center stations at Huntersville Dialysis upon completion of this project.**
 - 3. DVA Healthcare Renal Care, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than three (3) dialysis stations pursuant to facility need for a total of no more than 21 stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Medical Equipment	\$44,550.00
Non-Medical Equipment	\$2,579.00
Furniture	\$4,200.00
Total Capital Cost	\$51,329.00

The applicant provides the assumptions used to project the capital cost in Section Q including the use of a corporate model and regional database to ensure project costs are reasonable.

In Section F, pages 30-31, the applicant shows that there will be no start-up or initial operating expenses because HD is an existing facility.

Availability of Funds

In Section F, page 29, the applicant states that the capital cost will be funded by the parent company, DaVita, Inc., as shown in the table below.

Sources of Capital Cost Financing	
Type	DaVita
Loans	
Accumulated reserves or OE *	\$51,329.00
Bonds	
Other (Specify)	
Total Financing	\$51,329.00

In Exhibit F-2, the applicant provides a letter dated March 15, 2020, from DaVita's Chief Accounting Officer, authorizing and committing accumulative reserves of DaVita, Inc. for the capital cost of the project.

In Exhibit F-1, the applicant provides corporate financial statements and a copy of the applicant's United States Securities and Exchange Commission Form 10-K for the fiscal year ending December 31, 2019, showing DaVita, Inc. with approximately \$1.1 billion in cash and cash equivalents, total assets exceeding \$17.3 billion and equity exceeding \$2.3 billion, which is sufficient to cover the development cost of the project.

Financial Feasibility

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

Huntersville Dialysis Revenue and Expenses		
	CY2022	CY2023
In-Center Patients*	69	72
Total # of Treatments	10,125	10,463
Total Gross Revenue**	\$4,192,062	\$4,332,049
Total Gross Revenue per Treatment	\$414	\$414
Total Adjustments to Revenue	\$224,106	\$231,590
Total Net Revenue	\$3,967,956	\$4,100,460
Total Net Revenue per Treatment	\$392	\$392
Total Operating Costs	\$2,819,131	\$2,893,280
Net Income	\$1,148,825	\$1,207,180

*Source: Methodology for Criterion 3 including Mecklenburg County 4.2% Average Annual Change Rate for the Past Five Years

**Includes total patient services gross revenue and other revenue

Totals may not sum due to rounding

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, and
- 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.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

- 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 costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than three (3) dialysis stations pursuant to facility need for a total of no more than 21 stations upon project completion.

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

There are 27 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 27 of these dialysis facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%

Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
Renaissance Park Dialysis*	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis***	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis***	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

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

***Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the 2020 SMFP lists both the existing operational facility and the replacement facility.

In Section G, pages 34-35, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“In Section B, Question 2 and Section C, Question 3 of this application, we demonstrate the need that Huntersville Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Mecklenburg County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- Huntersville Dialysis, the only dialysis facility located in Huntersville, North Carolina, is currently operating at or above the ESRD performance standard of 2.8 patients per station per week.
- The applicant adequately demonstrates that HD will be operating above 2.8 patients per station per week in its projected utilization, which is based on historical patient utilization increased by the Five Year AACR of 4.2% for Mecklenburg County.
- The applicant adequately demonstrates that the proposed addition of three (3) stations is needed in addition to the existing and approved dialysis services in Mecklenburg County.

Conclusion

The Agency reviewed the:

- application, and

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

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

- (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

In Section Q, Form H Staffing, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions, as summarized in the following table.

POSITION	CURRENT FTE POSITIONS CY2019	PROJECTED FTE POSITIONS CY2021	PROJECTED FTE POSITIONS CY2022
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	3.00	3.00	3.00
Licensed Practical Nurses (LPNs)	0.00	0.00	0.00
Home Training Nurse	0.00	0.00	0.00
Technicians (PCT)	7.00	8.00	8.00
Medical Records	0.00	0.00	0.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Administration/Business Office	1.00	1.00	1.00
Other- Biomedical Technician	0.50	0.50	0.50
Total	13.50	14.50	14.50

Source: Section Q Form H of the application.

Housekeeping and maintenance are provided through independent contractors whereas Dr. Kimberly Yates will continue to serve as Medical Director for the facility pursuant to her letter of support dated March 12, 2020 and received by the Agency on June 22, 2020.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 37, the

applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating her support for the proposed project and her intent to continue serving as medical director for the facility. In Exhibits H-1 and H-3 respectively, the applicant provides supporting documentation of its Medical Records Custodian and Maintenance policy, employee benefits and Annual In-Service Training calendar.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 38, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 38, as summarized below.

**Huntersville Dialysis
 Ancillary and Support Services**

Services	Provider
Self-care training (performed in-center)	On Premises
Home Hemodialysis Training & Follow Up Program	Charlotte East Dialysis
Peritoneal Dialysis Training & Follow-Up Program	Charlotte East Dialysis
Isolation-Hepatitis B	On Site
Psychological counseling	On Site by RN
Nutritional counseling	On Site by RD
Social work services	On Site by MSW
Acute dialysis in an acute care setting	Carolinas Medical Center Novant Health Presbyterian Medical Center
Emergency care	Carolinas Medical Center Novant Health Presbyterian Medical Center
Blood bank services	Carolinas Medical Center Novant Health Presbyterian Medical Center
Diagnostic and evaluation services	Carolinas Medical Center Novant Health Presbyterian Medical Center
X-ray services	Carolinas Medical Center Novant Health Presbyterian Medical Center
Pediatric nephrology	Carolinas Medical Center Novant Health Presbyterian Medical Center
Vascular surgery	Carolinas Medical Center Novant Health Presbyterian Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation counseling & services	NC DHHS Division of Vocational Rehab Services
Transportation	Mecklenburg Transportation System (MTS)

In Section I, pages 38-39, the applicant describes HD’s existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- 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 projects 2.8% of the proposed population in OY2 will come from outside the Health Service Area. Consequently, 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.

C

In Section K, page 41, the applicant states that the project will involve no new construction, but renovation of existing square footage. The proposed floor plan is provided in Exhibit K-2.

On pages 41-42, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal and provides supporting documentation in Exhibit K-2.

On page 42, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 42, the applicant discusses any applicable energy saving features that are/will be incorporated into the construction/renovation plans.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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 handicapped persons, 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.1(b), page 45, the applicant provides the facility's historical payor mix for CY2019, as summarized in the table below.

Payor Source	# of IC Patients	% of IC Patients	PD & HH Patients
Self Pay	1.0	1.6%	0.0%
Commercial Insurance	10.0	15.9%	0.0%
Medicare	46.0	73.0%	0.0%
Medicaid	2.0	3.2%	0.0%
Other (VA)	4.0	6.3%	0.0%
Total	63	100.0%	0.0%

In Section L.1(a), page 44, the applicant provides comparison of the demographical information on HD patients and the service area patients during the last full operating year, is summarized below.

	Percentage of Total HD Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations Will be Located or Services Offered*
Female	46.7%	51.9%
Male	53.3%	48.1%
Unknown	0.0%	0.0%
64 and Younger	51.7%	88.8%
65 and Older	48.3%	11.2%
American Indian	0.0%	0.8%
Asian	0.0%	6.4%
Black or African-American	51.7%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	40.0%	46.4%
Other Race	8.3%	2.4%
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.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information 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 handicapped persons 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.2(a), page 45 of the application, the applicant states that while the facility is not required or obligated to provide uncompensated care or community service; but as a Medicare Participating Provider, it is at a minimum subject to Federal laws and regulations regarding equal access and non-discrimination.

In Section L, page 45, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- application, and
- 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 46, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix
CY 2023**

Payor Source	Total # of IC Patients	Total % of IC Patients	PD & HH Patients
Self Pay	1.1	1.6%	0.0%
Insurance	11.4	15.9%	0.0%
Medicare	52.4	73.0%	0.0%
Medicaid	2.3	3.2%	0.0%
Other (VA)	4.6	6.3%	0.0%
Total	71.765	100.0%	0.0%

*Including any managed care plans

As shown in the table above, during the second full calendar year of operation, the applicant projects that 1.6% of IC patients will be self pay patients, 73.0% will have all or part of their services paid for by Medicare and 3.2% will have all or part of their services paid for by Medicaid.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant's projected payor mix is based on the sources of patient payment that have been received (in the last full operating year) by the existing facility, and
- no adjustment rate has been applied to this payor mix so the projected payor mix is the same as that found in Section L.1, page 45.

The Agency reviewed the:

- application, and
- 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 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- 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 48 of the application, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides documentation in Exhibit M-2.

The Agency reviewed the:

- application, and
- exhibit to the application.

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than three (3) dialysis stations pursuant to the facility need for a total of no more than 21 stations upon project completion.

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

There are 27 existing or approved dialysis facilities in Mecklenburg County, 23 of which are operational. Information on all 27 dialysis facilities is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
Renaissance Park Dialysis*	DaVita	Charlotte	0	0.00%
South Charlotte Dialysis***	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis***	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

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

***Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the 2020 SMFP lists both the existing operational facility and the replacement facility.

Regarding the expected effects of the proposal on competition in the service area, in Section N, pages 49-50, the applicant states that it does not expect the addition of stations to have any effect on the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. On page 49, the applicant further states:

“Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita..”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 49, the applicant states:

“The expansion of Huntersville Dialysis will enhance accessibility to dialysis for our 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.”

Regarding the impact of the proposal on quality, in Section N, page 49, the applicant states:

“DaVita is committed to providing quality care to the ESRD population and, by policy, works [through] every reasonable effort to accommodate all of its patients. . . Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 49, the applicant states:

“DaVita is committed to providing quality care to the ESRD population and, by policy, works [through] every reasonable effort to accommodate all of its patients.” The applicant also provides data on pages 44-45 which illustrate the percentage of total patients served by HD who are medically underserved organized by gender, age, race and payor source.

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would be a positive impact on:

- Cost-effectiveness (see Sections B, C, F, N and Q of the application and any exhibits).
- Quality (see Sections B, C, N and O of the application and any exhibits).
- Access to medically underserved groups (see Sections B, C, D, L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

- (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, the applicant identifies the dialysis facilities located in North Carolina and owned, operated or managed by the applicant's parent company or a related entity. The applicant identifies a total of 110 DaVita, Inc. dialysis facilities located in North Carolina.

In Section O, page 51, the applicant states the entity is an "industry leader in clinical outcomes". During the 18 months immediately preceding the submittal of the application, one (1) facility operated by DaVita, Inc., Waynesville Dialysis Center, received an immediate jeopardy citing on May 8, 2019, for not entering potassium bath change orders into the facility's electronic medical record system. At the time of this application, the applicant states Waynesville Dialysis Center is in compliance at the time of application submittal. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 110 operational 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.
- (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. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- The applicant is not proposing to establish a new ESRD facility.

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

-C- In Section C, page 21, the utilization methodology proposed by the applicant achieves a projection of 69 in-center patients by the end of the first operating year, CY2022, for a utilization rate of 3.285 in-center patients per station per week or 82.1% ($69 \text{ patients} / 21 \text{ stations} = 3.285 \text{ patients per station} / 4 = 0.8214$). The projected utilization of 3.285 patients per station per week exceeds the 2.8 in-center patients per station per week threshold in the first full year following project completion, as required by 10A NCAC 14C .2203(b)(2). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C, pages 20-21, and in Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.