

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 19, 2020

Findings Date: November 19, 2020

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Gloria C. Hale

Project ID #: F-11927-20

Facility: Union County Dialysis

FID #: 955953

County: Union

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add no more than 8 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations)

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. (hereinafter referred to as “the applicant” or DVA) proposes to add no more than eight (8) dialysis stations to Union County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations). DVA Healthcare Renal Care, Inc. is a wholly owned subsidiary of DaVita, Inc., the parent company. Union County Dialysis provides in-center (IC) dialysis as well as peritoneal dialysis (PD).

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 not a county need determination for additional dialysis stations in Union 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 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Union County Dialysis on page 163 of the 2020 SMFP is 78.79 percent or 3.15 patients per station per week, based on 104 in-center dialysis patients and 33 certified dialysis stations (104 in-center patients / 33 dialysis stations = 3.15; $3.15 / 4 = 78.79\%$).

As shown in Table 9E, page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Union County Dialysis is up to eight (8) additional stations; thus, the applicant is eligible to apply to add up to eight (8) 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 eight (8) new dialysis stations to Union County Dialysis; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on 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 will promote safety and quality in Section B, pages 13-14; Section N, page 50; Section O, pages 52-53; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 15; Section C, pages 24-25; Section L, pages 45-48; Section N, page 50; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 15; Section F, pages 31-34; Section N, page 50; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- The application is consistent with Condition 2 of the facility need methodology for dialysis stations.
- The application is consistent with Policy GEN-3.

(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.

The applicant proposes to add no more than eight (8) dialysis stations to Union County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations).

The following table, summarized from data on page 7 of the application and page 163 of the 2020 SMFP, shows the projected number of stations at Union County Dialysis upon project completion.

HD		
Stations	Description	Project ID #
33	Total number of existing certified stations as reported in the SMFP in effect on the day the review will begin	
+8	Number of stations to be added as part of this project (adding eight (8) stations pursuant to facility need)	F-11927-20
-4	Number of stations previously approved to be deleted but not yet certified	F-11490-18
37	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 eight (8) additional dialysis stations and relocate four (4) previously approved dialysis stations for a total of no more than 37 dialysis 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Union County Dialysis is in Union County. Thus, the service area for this facility consists of Union County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

In Section C.2, page 20, the applicant provides the patient origin for Union County Dialysis’ IC and PD patients as of December 31, 2019, as summarized in the table below.

**Union County Dialysis
 1/1/2019 to 12/31/2019**

COUNTY	# OF IC PATIENTS	% IC Total	# of HH Patients	% HH Total	# of PD Patients	% PD Total
Union	92.00	89.30%	0.00	0.00%	13.00	92.86%
Anson	2.00	1.90%	0.00	0.00%	1.00	7.14%
Mecklenburg	1.00	1.00%	0.00	0.00%	0.00	0.00%
Stanly	1.00	1.00%	0.00	0.00%	0.00	0.00%
South Carolina	5.00	4.90%	0.00	0.00%	0.00	0.00%
Other States	2.00	1.90%	0.00	0.00%	0.00	0.00%
Total	103.00	100.00%	0.00	0.00%	14.00	100.00%

The following table summarizes projected patient origin for the second full operating year following project completion, as provided in Section C, page 21.

**Union County Dialysis
 1/1/2023 to 12/31/2023**

COUNTY	# OF IC PATIENTS	% IC Total	# of HH Patients	% HH Total	# of PD Patients	% PD Total
Union	104.00	90.40%	0.00	0.00%	17.00	94.44%
Anson	2.00	1.70%	0.00	0.00%	1.00	5.56%
Mecklenburg	1.00	0.90%	0.00	0.00%	0.00	0.00%
Stanly	1.00	0.90%	0.00	0.00%	0.00	0.00%
South Carolina	5.00	4.30%	0.00	0.00%	0.00	0.00%
Other States	2.00	1.70%	0.00	0.00%	0.00	0.00%
Total	115.00	100.00%	0.00	0.00%	18.00	100.00%

Totals may not sum due to rounding

In Section C, pages 21-22, and the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 23, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant in her explanation refers back to Section B, Question 2 which states a total of up to two dialysis stations can be applied for pursuant to Condition 2 of the facility need methodology. Condition 2 of the facility need methodology permits a facility to add stations if the facility's utilization in the current SMFP (2020 SMFP) is at least 75% or 3.0 patients per station per week or greater. Union County Dialysis satisfies Condition 2 of the facility need methodology since Union County Dialysis was operating at a rate of 3.15 patients per station per week, or 78.79 percent of capacity as of December 31, 2018 and, thus, shows why the projected population needs the proposed services.

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

- According to the 2020 SMFP, as of December 31, 2018, Union County Dialysis was operating at a rate of 3.15 patients per station per week, or 78.79 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 2.9 in-center patients per station per week dialyzing at Union County Dialysis as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standard 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 additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203.

Projected Utilization

In-Center Patients

In Section C, pages 20-23, and in Section Q, the applicant provides projected utilization, as illustrated in the following table.

UNION COUNTY DIALYSIS IN-CENTER PATIENTS

	IC Stations	IC Patients
The applicant begins with the 92 patients dialyzing on 33 stations at the facility as of 1/1/2020.	33	92
The facility's Union County patient census is projected forward a year to 12/31/2020 and is increased by the Five Year Average Annual Change Rate (AACR) of 6.8% for Union County.		$92 \times 1.068 = 98.256$
The 11 patients from outside Union County are added to the facility's census. This is the ending census for 12/31/2020.		$98.256 + 11 = 109.256$
Projects ID #F-11742-19 and F-11490-18 are projected to be certified [on] 1/1/2021. Thirteen patients are transferred and four stations are relocated to Marshville Dialysis from Union County Dialysis.	$33 - 4 = 29$	$98.256 - 13 = 85.256$
The facility's Union County patient census is projected forward a year to 12/31/2021 and is increased by 6.8%.		$85.256 \times 1.068 = 91.053$
The 11 patients from outside Union County are added to the facility's census. This is the ending census for 12/31/2021.		$91.053 + 11 = 102.053$
The proposed project is projected to be certified on 1/1/2022. This is the station count at the beginning of OY1. The facility's Union County patient census is	$29 + 8 = 37$	$91.053 \times 1.068 = 97.245$

projected forward a year to 12/31/2022 and is increased by 6.8%.		
The 11 patients from outside Union County are added to the facility's census. This is the ending census as of the end of Operating Year 1 (OY1).		97.245+11=108.245
The facility's Union County patient census is projected forward a year to 12/31/2023 and is increased by 6.8%.		97.245x1.068=103.858
The 11 patients from outside Union County are added to the facility's census. This is the ending census as of the end of Operating Year 2 (OY2).		103.858+11=114.858

Note: The applicant transposed the amount of patients with the amount of stations in their application for the beginning census of 1/1/2020; however, this did not affect their calculations or methodology.

Note: The applicant discussed adding "6 patients from outside Union County" in their calculations but in the applicant's explanation, the applicant added 11 patients as opposed to 6 patients to count for patients who reside outside Union County. It is assumed the applicant added 11 total patients to their calculations to count for the 6 patients who reside outside Union County but reside in North Carolina in addition to the 5 patients who reside in South Carolina to obtain 11 total patients who reside outside Union County.

In both Section C, pages 20-23, and Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the Union County Dialysis patient census as of December 31, 2019, which was 103 total IC patients: 92 Union County patients, two (2) Anson County patients, one (1) Mecklenburg County patient, one (1) Stanly County patient, five (5) patients from South Carolina and two (2) patients from other states.
- The Anson, Mecklenburg, and Stanly County patients in addition to those patients who reside outside North Carolina will be carried forward into projections of future patient census however, the applicant does not project any growth for the Anson, Mecklenburg, and Stanly County patients nor does the applicant project any growth for the patients who reside outside North Carolina.
- The applicant projects the facility patients who reside in Union County will grow at the Five Year Average Annual Change Rate for Union County, 6.8%, as stated in Table 9C, page 169, of the 2020 SMFP.

The applicant states, on page 22, that it rounds its patient projections to the nearest whole number. Thus, at the end of OY1 (CY2022) Union County Dialysis is projected to serve 108 in-center patients on 37 stations; and at the end of OY2 (CY2023) the facility is projected to serve 115 in-center patients on 37 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 2.9 patients per station per week, or 72.5% utilization [$108 / 37 = 2.9$; $2.9 / 4 = 0.725$ or 72.5%].
- OY 2: 3.10 patients per station per week, or 77.5% utilization [$115 \text{ patients} / 37 \text{ stations} = 3.1$; $3.1 / 4 = 0.775$ or 77.5%].

The projected utilization of 2.9 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 6.8 percent for Union County patients which reflects the Union County Five Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Anson, Mecklenburg, and Stanly County patients nor does the applicant project any growth for its patients who reside outside North Carolina.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Peritoneal Dialysis Patients

In Section C, pages 22-23, and in Section Q, the applicant provides projected utilization, as illustrated in the following table.

UNION COUNTY DIALYSIS PD PATIENTS				
PD Patient Projections	Start Date	# of patients- beginning of year	# of patients- end of year	Average # of patients in the year
Interim Period	1/1/2020	14	15	14.5
Interim Period	1/1/2021	15	16	15.5
OY1	1/1/2022	16	17	16.5
OY2	1/1/2023	17	18	17.5

In both Section C, pages 22-23, and Section Q, the applicant provides the assumptions and methodology used to project PD utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).

- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the Union County Dialysis PD patient census as of December 31, 2019, which was:
 - 14 total PD patients: 13 Union County patients and one (1) patient from Anson County.
- The applicant grows its PD census by one patient per year.

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant conservatively grows its PD census by one patient per year.

Access

In Section C.7, page 24, the applicant states,

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

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

Union County 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.”

In Section L, page 47, 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.

**Union County Dialysis
 Projected Payor Mix CY 2023**

Payor Source	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.2	1.9%	0.0	0.0%	0.0	0.0%
Insurance*	11.2	9.7%	0.0	0.0%	6.4	35.7%
Medicare*	83.6	72.8%	0.0	0.0%	9.0	50.0%
Medicaid*	10.0	8.7%	0.0	0.0%	2.6	14.3%
Other (Incl. VA)	7.8	6.8%	0.0	0.0%	0.0	0.0%
Total	114.8	100.0%	0.0	0.0%	18.0	100.0%

*Including any managed care plans

Totals may not sum due to rounding

Note: The application listed total number of IC patients as 114.857702 without explaining how the applicant arrived at that specific number. However, for the purpose of this finding, the total IC center patients is rounded only to the tenth decimal point for this table.

The projected payor mix is reasonable and adequately supported.

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 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 eight (8) dialysis stations to Union County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations).

In Section E, page 30, 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 would not be responsive to the growth of the patient census; therefore, this is not an effective alternative.
- Relocate Stations from Another DaVita Facility: the applicant states of the two (2) DaVita facilities located in Union County, only one (1) is operating at greater than 75% capacity. Relocating stations from Marshville facility (the facility having greater than 75% capacity) would negatively impact the patients served by the facility, given that the facility currently operates three (3) days a week to accommodate patient and physician scheduling; therefore, this is not an effective alternative.

On page 30, the applicant states its proposal is the most effective alternative because the growth of the patient census requires the facility to add stations.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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. Union County Dialysis (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than eight (8) additional in-center dialysis stations for a total of no more than 37 in-center stations at Union County Dialysis upon completion of this project and Project ID #F-11490-18 (relocate 4 stations).**
 - 3. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Union County Dialysis proposes to add no more than eight (8) dialysis stations to Union County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations).

Capital and Working Capital Costs

In Section F, page 31, and Section Q, Form F 1.a, the applicant projects the total capital cost of the project as shown in the table below.

Projected Capital Costs

	Total Costs
Medical Equipment	\$60,000
Non-Medical Equipment	\$10,492
Furniture	\$11,200
Total Capital Cost	\$81,692

In Section Q, the applicant provides the assumptions used to project the capital cost to ensure project costs are reasonable.

In Section F, pages 32-34, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 31, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	DVA Healthcare Renal Care, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$81,692	\$81,692
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$ 81,692	\$81,692

* OE = Owner's Equity

Exhibit F-2 contains a letter dated July 31, 2020, from the Chief Accounting Officer for DaVita, Inc, parent company to DVA Healthcare Renal Care, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-1 contains the Consolidated Financial Statements from DaVita, Inc., for year ending December 31, 2019, showing that DaVita, Inc. had \$1.1 billion in cash and cash equivalents and \$17 billion in total assets.

The letter of financial commitment dated July 31, 2020, stated DaVita, Inc. will commit up to \$81,692 towards the cost of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, 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		
Union County Dialysis	Full Fiscal Year 1 CY 2022	Full Fiscal Year 2 CY 2023
Total Treatments	18,028	19,125
Total Gross Revenues (Charges)	\$6,842,500	\$7,258,700
Total Net Revenue	\$6,436,861	\$6,828,378
Average Net Revenue per Treatment	\$357.05	\$357.04
Total Operating Expenses (Costs)	\$3,721,592	\$3,905,514
Average Operating Expense per Treatment	\$206.43	\$204.21
Net Income/Profit	\$2,715,269	\$2,922,864

Note: The applicant rounded down to the nearest dollar in their application response for average net revenue per treatment.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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

Union County Dialysis proposes to add no more than eight (8) dialysis stations to Union County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations).

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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Union County Dialysis is in Union county. Thus, the service area for this facility consists of Union County. Facilities may serve residents of counties not included in their service area.

There are four dialysis facilities in Union County. The applicant, DVA Healthcare Renal Care, Inc., currently operates one (1) other facility in Union County, Marshville Dialysis Center. The following table shows the existing and approved dialysis facilities in Union County, from Table 9B of the 2020 SMFP:

Union County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	In-Center Patients	Percent Utilization
Fresenius Kidney Care Indian Trail	10	0	20	50.00%
Marshville Dialysis Center*	12	4	29	60.42%
Metrolina Kidney Center	22	0	88	100.00%
Union County Dialysis	33	-4	104	78.79%

Source: 2020 SMFP, Table 9B, page 163

Note: Per the 2020 SMFP, Marshville Dialysis with facility identification (FID) number 800002 will replace Marshville Dialysis Center with FID number 060374.

In Section G, page 36, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Union County. The applicant states the additional stations are needed to support the growing patient census at the facility. The applicant also states the stations are for patients being served by this facility, not for patients being served by another provider.

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

- There is a facility need determination, as calculated using the methodology in the 2020 SMFP, for the proposed dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency.

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

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

C

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 12/31/2019	1 st Full Operating Year (1/1/2022 to 12/31/2022)	2nd Full Operating Year (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	4.25	4.50	4.75
Licensed Practical Nurses (LPNs)	0.00	0.00	0.00
Home Training Nurse	0.50	0.50	0.50
Technicians (PCT)	12.50	14.00	14.00
Medical Records	0.00	0.00	0.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Admin./Business Office	1.00	1.00	1.00
Other: Biomedical Tech.	0.50	0.50	0.50
TOTAL	21.75	23.50	23.75

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 Form F.4, which is found in Section Q. In Section H, pages 37-38, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating his support for the proposed project and his intent to continue serving as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 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, page 39, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

UNION COUNTY DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training (performed in-center)	On site
Home Hemodialysis training & follow up program	Charlotte East Dialysis
Peritoneal dialysis training & follow-up program	On site
Isolation - Hepatitis B	On site
Psychological counseling	On site by RN
Nutritional counseling	On site by RD
Social work services	On site by MSW
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation counseling & services	NC DHHS Division of Vocational Rehab Services
Transportation	Union County DSS

In Section I, pages 39-40, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

In Section K, page 42, the applicant states that the project does not involve construction of new space or renovation of 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 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, page 46, the applicant provides the historical payor mix for Union County Dialysis patients during the last full operating year (CY2019) for the proposed services, as shown in the table below.

**Union County Dialysis
 Historical Payor Mix CY 2019**

Payor Source	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.0	1.9%	0.0	0.0%	0.0	0.0%
Insurance*	10.0	9.7%	0.0	0.0%	5.0	35.7%
Medicare*	75.0	72.8%	0.0	0.0%	7.0	50.0%
Medicaid*	9.0	8.7%	0.0	0.0%	2.0	14.3%
Other (Incl. VA)	7.0	6.8%	0.0	0.0%	0.0	0.0%
Total	103.0	100.0%	0.0	0.0%	14.0	100.0%

*Including any managed care plans
 Totals may not sum due to rounding

In Section L, page 45, the applicant provides the following comparison.

	Percentage of Total Patients Served (All Modalities Combined) CY2019	Percentage of the Population of the Service Area
Female	42.6%	50.7%
Male	57.4%	49.3%
Unknown	0.0%	0.0%
64 and Younger	51.3%	87.0%
65 and Older	48.7%	13.0%
American Indian	0.0%	0.6%
Asian	0.0%	3.6%
Black or African-American	48.7%	12.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	41.7%	71.1%
Other Race	9.6%	2.0%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, the applicant states in Section L.2(a), page 46, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2(c), page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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 47, 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 shown in the table below.

**Union County Dialysis
 Projected Payor Mix CY 2023**

Payor Source	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.2	1.9%	0.0	0.0%	0.0	0.0%
Insurance*	11.2	9.7%	0.0	0.0%	6.4	35.7%
Medicare*	83.6	72.8%	0.0	0.0%	9.0	50.0%
Medicaid*	10.0	8.7%	0.0	0.0%	2.6	14.3%
Other (Incl. VA)	7.8	6.8%	0.0	0.0%	0.0	0.0%
Total	114.8	100.0%	0.0	0.0%	18.0	100.0%

*Including any managed care plans
 Totals may not sum due to rounding

Note: The application listed total number of IC patients as 114.857702 without explaining how the applicant arrived at that specific number. However, for the purpose of this finding, the total IC center patients is rounded only to the tenth decimal point for this table.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.9% of IC services will be provided to self-pay patients, 72.8% to Medicare patients and 8.7% to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project.

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

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 48, 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

In Section M, page 49, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Union County Dialysis proposes to add no more than eight (8) dialysis stations to Union County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 37 dialysis stations upon completion of this project and Project ID #F-11490-18 (relocate 4 stations).

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

There are four dialysis facilities in Union County. The applicant, DVA Healthcare Renal Care, Inc., currently operates one (1) other facility in Union County, Marshville Dialysis Center. The following table shows the existing and approved dialysis facilities in Union County, from Table 9B of the 2020 SMFP:

Union County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	In-Center Patients	Percent Utilization
Fresenius Kidney Care Indian Trail	10	0	20	50.00%
Marshville Dialysis Center*	12	4	29	60.42%
Metrolina Kidney Center	22	0	88	100.00%
Union County Dialysis	33	-4	104	78.79%

Source: 2020 SMFP, Table 9B, page 163

Note: Per the 2020 SMFP, Marshville Dialysis with facility identification (FID) number 800002 will replace Marshville Dialysis Center with FID number 060374.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 50, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 50, the applicant states its proposal will reduce the economic burdens on the facility’s patients by making it easier for them to receive services.

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

Regarding the impact of the proposal on quality, in Section N, page 50, the applicant states that DaVita is committed to providing quality care and further:

“Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meet their needs.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 50, the applicant states,

“DaVita...by policy, works to make every reasonable effort to accommodate all of its patients. The expansion of Union County Dialysis will enhance accessibility to dialysis for current and projected patients....”

See also Section B, C and L of the application and any exhibits.

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 have a positive impact on cost-effectiveness, quality, and access because it adequately demonstrates the following:

- the need the population to be served has for the proposal, the proposal would not result in an unnecessary duplication of existing and approved health services, and the reasonableness of projected revenues and operating costs which collectively results in a cost-effective proposal.
- the quality of the care to 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.
- medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 110 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O.2, pages 52-53, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility: Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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 .2203 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Union County 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, pages 20-23, and in Section Q, Form C, the applicant projects that Union County Dialysis will serve 108 in-center patients on 37 dialysis stations, or a rate of 2.9 patients per station per week or 72.5% utilization rate ($108 / 37 = 2.9$; $2.9 / 4 = 0.725$ or 72.5%), as of the end of the first operating year (CY2022) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

- C- In Section C, pages 20-23, and in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility.