

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 23, 2019

Findings Date: December 23, 2019

Project Analyst: Celia C. Inman

Assistant Chief: Lisa Pittman

Project ID #: R-11791-19

Facility: Edenton Dialysis

FID #: 955811

County: Chowan

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add no more than 4 stations for a total of no more than 19 dialysis stations upon project completion and Project ID #R-11595-18 (relocate 2)

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 DaVita) proposes to add four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 61, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is no deficit or surplus of stations in Chowan County; therefore, there is no county need determination for new dialysis stations for Chowan County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Edenton Dialysis in Table B of the July 2019 SDR is 3.76 patients per station per week, or 94.12%, based on 64 in-center dialysis patients and 17 certified dialysis stations [$64 / 17 = 3.764$; $3.764 / 4 = 0.9412$ or 94.12%]. Therefore, Edenton Dialysis is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to six additional stations may be needed at this facility, as illustrated in the following the table:

Edenton Dialysis

OCTOBER 1 REVIEW-JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		94.12%
Certified Stations		17
Pending Stations*		0
Total Existing and Pending Stations		17
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		64
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		59
Step	Description	Result
	Difference (SDR2 - SDR1)	5
(i)	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1695
	(ii) Divide the result of Step (i) by 12	0.0141
(iii)	Multiply the result of Step (ii) by 12	0.1695
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	74.8475
(v)	Divide the result of Step (iv) by 3.2 patients per station	23.3898
	and subtract the number of certified and pending stations to determine the number of stations needed	6.39

*Include all additional stations approved and previously proposed. Do not subtract stations approved or previously proposed to be relocated to another facility.

Note: in its table on page 10 of the application, the applicant incorrectly subtracted two stations. The deduction of two stations in Table B of the July 2019 SDR is composed of the addition of two stations approved in Project ID #R-11595-18 and the relocation for four stations to Perquimans County Dialysis in Project ID #R-10264-14.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Edenton Dialysis is six stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add four new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.3 (a and d), pages 12-13 and 14, respectively; Section N.2, page 49; Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.3 (b and d), pages 13-14; Section C.7, page 23; Section L, pages 44-45; Section N.2, page 49; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3 (c and d), pages 13-14; Section N.2, page 49; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, 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.

(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 four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

The following table, summarized from data on page 7 of the application and Table B of the July 2019 SDR, illustrates the current and projected number of dialysis stations at Edenton Dialysis.

Edenton Dialysis		
# of Stations	Description	Project ID #
17	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
4	# of stations to be added as part of this project	R-11791-19
	# of stations to be deleted as part of this project	
2	# of stations previously approved to be added but not yet certified	R-11595-18
-4	# of stations previously approved to be deleted but not yet certified	R-10264-14*
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
19	Total # of stations upon completion of all facility projects	

*Per the records in DHSR, Certificate of Need Section, CON Project ID #R-10264-18 was complete with the file closed, as of October 2, 2019. Project ID #R-11595-18 has not yet been designated as complete.

As outlined in the table above, in this application, the applicant proposes to add four dialysis stations at Edenton Dialysis for a total of 19 stations, upon completion of each of the projects outlined above.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” The

facility is located in Chowan County; thus, the service area for this facility is Chowan County. Facilities may serve residents of counties not included in their service area.

Edenton Dialysis provides only in-center (IC) dialysis. In Section C.2, page 18, the applicant provides the patient origin for Edenton Dialysis patients as of December 31, 2018, as summarized in the table below.

**Edenton Dialysis
1/1/2018/-12/31/2018**

COUNTY	# IC PATIENTS	% IC Total
Chowan	43	67.2%
Washington	2	3.1%
Tyrell	4	6.3%
Perquimans	12	18.8%
Hertford	1	1.6%
Other States	2	3.1%
Total	64	100.0%

Totals may not sum due to rounding

The applicant provides the following patient origin for the second full operating year following project completion, in Section C, page 19.

**Edenton Dialysis
Projected Patient Origin
CY2022**

COUNTY	# IC PATIENTS	% IC Total
Chowan	62	84.9%
Washington	4	5.5%
Tyrell	3	4.1%
Perquimans	2	2.7%
Hertford	1	1.4%
Other States	1	1.4%
Total	73	100.0%

Totals may not sum due to rounding

In Section C, pages 19-21, the applicant provides the assumptions and methodology it uses to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to add four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

In Section Q Form C Utilization – Criterion (3), the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that projected utilization begins with the Edenton Dialysis census as of June 30, 2019, as submitted on its ESRD Data Collection Form in August 2019 and summarized below.

**Edenton Dialysis
Patient Origin
As of June 30, 2019**

COUNTY	# IC PATIENTS	% IC Total
Chowan	37	77.1%
Washington	4	8.3%
Tyrell	3	6.3%
Perquimans	2	4.2%
Bertie	1	2.1%
Other States	1	2.1%
Total	48	100.0%

- Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.
- The applicant states that it assumes the 37 patients from Chowan County dialyzing at Edenton Dialysis will increase at a rate equal to the 13.8% Chowan County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR, Table D.
- The applicant assumes that the 11 patients from outside Chowan County being served in Chowan County will continue to dialyze at Edenton Dialysis but does not assume any growth in patients from these counties.

Projected Utilization

In Section Q Form C Utilization – Criterion (3), the applicant provides its projected utilization methodology, based on its stated assumptions. The projected in-center utilization is summarized in the following table.

EDENTON DIALYSIS IN-CENTER PATIENTS

Begin with facility census of Chowan County patients as of June 30, 2019. 48 total patients with 37 from Chowan County.	37
Project this population forward six months to December 31, 2019, using the Chowan County Five Year AACR of 13.8% (13.8% / 12 x 6)	$37 \times 1.069 = 39.553$
Add patients from outside Chowan County projected to continue to dialyze at Edenton Dialysis. This is the ending census on December 31, 2019.	$48.816 + 11 = 50.553$
Project Chowan County patients forward one year to December 31, 2020, using the Chowan County Five Year AACR of 13.8%.	$39.553 \times 1.138 = 45.0113$
Add patients from outside Chowan County projected to continue to dialyze at Edenton Dialysis. This is the ending census on December 31, 2020.	$45.0113 + 11 = 56.1131$
Project Chowan County patients forward one year to December 31, 2021, using the Chowan County Five Year AACR of 13.8%.	$45.01131 \times 1.138 = 51.2228$
Add patients from outside Chowan County projected to continue to dialyze at Edenton Dialysis. This is the ending census on December 31, 2021.	$51.2228 + 11 = 62.2228$
Project Chowan County patients forward one year to December 31, 2022, using the Chowan County Five Year AACR of 13.8%.	$51.2228 \times 1.138 = 58.2916$
Add patients from outside Chowan County projected to continue to dialyze at Edenton Dialysis. This is the ending census on December 31, 2022.	$58.2916 + 11 = 69.2916$

Source: Table in Section Q

Based on the applicant’s methodology and assumptions, at the end of OY1 (CY2021) Edenton Dialysis is projected to serve 62 in-center patients (rounded down) on 19 stations; and at the end of OY2 (CY2022) the facility is projected to serve 69 in-center patients on 19 stations.

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

- OY1: 3.26 patients per station per week, or 81.6% utilization [$62 / 19 = 3.26$; $3.26 / 4 = 0.8158$].
- OY 2: 3.36 patients per station per week, or 90.8% utilization [$69 \text{ patients} / 19 \text{ stations} = 3.63$; $3.63 / 4 = 0.9079$].

The projected utilization of 3.26 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- Edenton Dialysis was operating at 94.12% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects growth in the Chowan County patient population using the Chowan County Five Year AACR of 13.8%.

- The applicant does not project growth for patients residing outside of Chowan County.
- Projected IC utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C.7, page 23, 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.

...

Edenton 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, handicapped persons, elderly and other under-served persons.”

In Section L, page 46, 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.

**Edenton Dialysis
Projected Payor Mix CY 2022**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	0.0%	0.0%	0.0%
Commercial Insurance*	6.3%	0.0%	0.0%
Medicare*	84.1%	0.0%	0.0%
Medicaid*	4.8%	0.0%	0.0%
Other (specify)	4.8%	0.0%	0.0%
Total	100.0%	100.0%	100.0%

Totals may not sum due to rounding

*Including any managed care plans

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 four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

In Section E, page 28, the applicant states that it considered the following alternatives related to serving the needs of the patients in the area:

1. Maintain the status quo – the applicant states this alternative was dismissed given the growth of the facility.
2. Relocate stations from another DaVita facility – the applicant states that Edenton Dialysis is the only operational dialysis facility in Chowan County and relocating stations from a contiguous county is not possible.

On page 28, the applicant states that the proposed project is a more effective alternative as it ensures that the facility will proactively address the issues of growth and access at the facility. Continuing to operate at the current capacity could create a situation where the patients using the facility as projected in Section C would have a third shift as their only option of dialyzing

at Edenton Dialysis or even no option at all to choose Edenton Dialysis if the patient population maxed out the facility's capacity.

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 provided 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, 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 July 2019 SDR, DVA Healthcare Renal Care, Inc. shall develop no more than four additional dialysis station at Edenton Dialysis for a total on no more than 19 dialysis stations, upon completion of this project and Project ID #R-11595-18 (relocate two stations), which shall include any home hemodialysis training or isolation stations.**
 - 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 four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects a total capital cost of \$71,160 for medical equipment.

In Section Q, following F.1a Capital Cost, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 30, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 29, the applicant states that the capital cost of \$71,160 will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita	Total
Loans		
Accumulated reserves or OE *	\$71,160	\$71,160
Bonds		
Other (Specify)		
Total Financing	\$71,160	\$71,160

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 13, 2019 from the DaVita Chief Accounting Officer and signed by Esther Fleming, authorizing and committing \$71,160 of accumulated reserves of DaVita, the parent company for DVA Healthcare Renal Care, Inc., for the capital costs of the project. The exhibit also documents that DaVita's Form 10-K reflects more than \$323,038,000 in cash and cash equivalents, and total current assets exceeding \$8 billion.

Financial Feasibility

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

Edenton Dialysis Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total Treatments	8,744	9,724
Total Gross Revenue (charges)	\$2,745,553	\$3,053,215
Total Net Revenue	\$2,608,013	\$2,900,263
Average Net Revenue per Treatment	\$298	\$298
Total Operating Expenses (costs)	\$1,989,879	\$2,121,560
Average Operating Expense per Treatment	\$228	\$218
Net Income / Profit	\$618,134	\$778,702

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 the availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates the availability of 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 four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning*

Area, each of the 94 remaining counties is a separate dialysis station planning area.” The facility is located in Chowan County; thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, Edenton Dialysis, a DaVita related facility, is the only dialysis facility operating in Chowan County.

Chowan County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Edenton Dialysis	17	94.12%	3.7647

Source: July 2019 SDR, Table B.

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

“In Section B-1 and Section C of this application, we demonstrate the need that Edenton Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Chowan 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 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 at Edenton Dialysis, as calculated using the methodology in the July 2019 SDR, for up to six additional dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing and/or approved dialysis stations.

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.

- (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 Form H Staffing, the applicant provides a table illustrating current and projected OY2 staffing in full time equivalents (FTEs) for Edenton Dialysis, as summarized below.

POSITION	FTE Positions as of 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
RN	3.00	3.00	3.00
Patient Care Technician	7.00	8.00	8.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	14.00 [13.50]	15.00 [14.50]	15.00 [14.50]

Source: Section Q Form H

The assumptions and methodology used to project existing staffing are provided in Section Q. As the table above shows, the applicant's total number of FTE positions is 0.50 FTE positions more than the total for each FTE position listed in the table; therefore, the applicant's projected cost for salaries exceeds the projected salary needs. More than adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Forms F.2 Income Statement and F.4 Operating Costs. 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. Exhibit H contains supporting documentation. In Section H.4, page 37, the applicant identifies the current medical director for the facility as Dr. Ravi Ramsamooj. In Exhibit H-4, the applicant provides a letter from Ravi Ramsamooj, MD, indicating his intent to continue to serve as medical director for the proposed services.

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, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis maintenance	On site
Self-care training	On site
Hemodialysis	Albemarle Dialysis
Peritoneal dialysis	Albemarle Dialysis
Accessible follow-up program	Albemarle Dialysis
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Vidant Chowan Hospital
Emergency care	Vidant Chowan Hospital
Blood bank services	Vidant Chowan Hospital
Diagnostic and evaluation services	Vidant Chowan Hospital
X-ray services	Vidant Chowan Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Vidant Chowan Hospital
Vascular surgery	Vidant Chowan Hospital
Transplantation services	Vidant Medical Center (per Exhibit I-1)
Vocational rehabilitation & counseling	Chowan Social Services
Transportation	Inter County Public Transportation Authority

Source: Table in Section I, page 38

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

The applicant adequately demonstrates 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 does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 45, the applicant provides the historical payor mix during CY2018 for its existing services, as shown in the table below.

**Edenton Dialysis
Historical Payor Mix CY 2018**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	0.0%	0.0%	0.0%
Commercial Insurance*	6.3%	0.0%	0.0%
Medicare*	84.1%	0.0%	0.0%
Medicaid*	4.8%	0.0%	0.0%
Other (specify)	4.8%	0.0%	0.0%
Total	100.0%	100.0%	100.0%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 44, the applicant provides comparison of the demographical information on Edenton Dialysis patients and the service area patients during CY2018, as summarized below.

	Percentage of Total Edenton Dialysis Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations will be Located*
Female	46.0%	52.4%
Male	54.0%	47.6%
Unknown	0.0%	0.0%
64 and Younger	51.6%	24.6%
65 and Older	48.4%	75.4%
American Indian	0.0%	0.4%
Asian	0.0%	0.8%
Black or African-American	81.0%	34.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	17.5%	62.6%
Other Race	1.6%	1.4%
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, the applicant states in Section L, page 45, that it has no obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities.

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

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.

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

**Edenton Dialysis
Projected Payor Mix CY 2022**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	0.0%	0.0%	0.0%
Commercial Insurance*	6.3%	0.0%	0.0%
Medicare*	84.1%	0.0%	0.0%
Medicaid*	4.8%	0.0%	0.0%
Other (specify)	4.8%	0.0%	0.0%
Total	100.0%	100.0%	100.0%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 0.0% of in-center dialysis services will be provided to self-pay patients, 84.1% to Medicare patients, and 4.8% to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Edenton Dialysis.

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.

- (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 46, the applicant adequately describes the range of means by which patients will have access to 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.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

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

C

The applicant proposes to add four dialysis stations to Edenton Dialysis, an existing facility, for a total of 19 dialysis stations upon completion of this project and Project ID #R-11595-18 (relocate two stations).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The facility is located in Chowan County; thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, Edenton Dialysis, a DaVita related facility, is the only dialysis facility operating in Chowan County.

Chowan County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Edenton Dialysis	17	94.12%	3.7647

Source: July 2019 SDR, Table B.

Per the July 2019 SDR, as of December 31, 2018, Edenton Dialysis is well-utilized, operating above 3.7 patients per station.

In Section N, pages 49-50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The expansion of Edenton will have no effect on competition in Chowan 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.

...

The expansion of Edenton 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.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

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.

- (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 over 100 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, one facility, Waynesville Dialysis Center, had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. The applicant further states that Waynesville Dialysis Center is currently in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius 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 .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- Edenton Dialysis is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section Q Form C, the applicant projects that Edenton Dialysis will serve 62 in-center patients on 19 stations, or a rate of 3.26 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patient per station per week.

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

- C- In Section Q Form C Utilization – Criterion (3), the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.