

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 24, 2020

Findings Date: November 24, 2020

Project Analyst: Mike McKillip

Team Leader: Gloria Hale

Project ID #: R-11925-20

Facility: Edenton Dialysis

FID #: 955811

County: Chowan

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis 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 DaVita) proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis stations).

Need Determination (Condition 2)

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 Chowan 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 Edenton Dialysis on page 153 of the 2020 SMFP is 94.12 percent or 3.76 patients per station per week, based on 64 in-center dialysis patients and 17 certified dialysis stations (64 patients / 17 stations = 3.76; $3.76 / 4 = 94.12\%$).

As shown in Table 9E on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Edenton Dialysis is up to 7 additional stations; thus, the applicant is eligible to apply to add up to 7 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than one new station to Edenton Dialysis, which is consistent with the 2020 SMFP calculated facility need determination for up to 7 dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 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.5 (a) and (d), pages 13-16, Section N.2(b), 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.5 (b) and (d), pages 14-16, Section C.7, page 23; Section L, pages 44 and 46; Section N.2(c), 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.5 (c) and (d), pages 15-16; Section N.2(a), 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
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates how Edenton Dialysis' projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

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 no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis stations). Effective January 1, 2019, in Project I.D. # R-11595-18, the applicant was approved to add two dialysis stations to Edenton Dialysis. That project was completed on December 1, 2019. Effective January 23, 2020, in Project I.D. # R-11791-19, the applicant was approved to add four dialysis stations to Edenton Dialysis. That project was completed on February 28, 2020. Because the applicant proposes to add one station to the Edenton Dialysis facility within 12 months of development of Project I.D. J-11791-19, this application is considered a change of scope to Project I.D. J-11791-19.

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Edenton Dialysis.

Edenton Dialysis		
# of Stations	Description	Project ID #
13	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
1	# of stations to be added as part of this project	R-11925-20
	# 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
	# of stations previously approved to be deleted but not yet certified	
4	# of stations proposed to be added in an application still under review	R-11791-19
	# of stations proposed to be deleted in an application still under review	
20	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add one dialysis station for a total of 20 stations upon the 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-Graham counties and Avery-

Mitchell-Yancey counties.” Thus, the service area for this facility is Chowan County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients at Edenton Dialysis for the last full operating year (CY2019), as summarized in the table below.

Edenton Dialysis Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Chowan	41	78.8%	0	0.0%	0	0.0%
Perquimans	3	5.8%	0	0.0%	0	0.0%
Tyrell	3	5.8%	0	0.0%	0	0.0%
Washington	3	5.8%	0	0.0%	0	0.0%
Bertie	1	1.9%	0	0.0%	0	0.0%
Other states	1	1.9%	0	0.0%	0	0.0%
Total	52	100.0%	0	0.0%	0	0.0%

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year following project completion, as provided in Section C.3, page 20.

Projected Patient Origin Edenton Dialysis - OY2 CY2023

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Chowan	68	86.1%	0	0.0%	0	0.0%
Perquimans	3	3.8%	0	0.0%	0	0.0%
Tyrell	3	3.8%	0	0.0%	0	0.0%
Washington	3	3.8%	0	0.0%	0	0.0%
Bertie	1	1.3%	0	0.0%	0	0.0%
Other states	1	1.3%	0	0.0%	0	0.0%
Total	79	100.0%	0	0.0%	0	0.0%

Totals may not sum due to rounding

Edenton Dialysis does not provide home therapy services and the applicant does not propose to offer home therapy services as part of the project. In Section C.3, page 20, the applicant provides the assumptions and methodology it used to project in-center patient origin. The applicant states that the in-center patient origin is based upon the facility census as of December 31, 2019. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section Q, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the December 31, 2019 census data. The applicant states that it assumes the patients from Chowan County dialyzing at Edenton Dialysis on December 31, 2019 will continue to dialyze there and will increase at a rate equal to the Chowan County Five Year Average Annual Change Rate (AACR) of 13.8% as published in the 2020 SMFP.
- The applicant assumes the patients from other counties will continue to dialyze at Edenton Dialysis but does not assume any growth in patients from other counties.
- The project is scheduled for completion on December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In-Center Projected Utilization

In Section Q, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Chowan County in-center patients as of December 31, 2019.	41
The applicant projects the Chowan County in-center patients forward to December 31, 2020 using the Chowan County AACR.	$41 \times 1.138 = 46.658$
The applicant adds 11 patients from other counties to calculate the ending census as of December 31, 2020.	$46.658 + 11 = 57.658$
The applicant projects the Chowan County in-center patients forward one year to December 31, 2021 using the Chowan County AACR.	$46.658 \times 1.138 = 53.097$
The applicant adds 11 patients from other counties to calculate the projected census as of December 31, 2021.	$53.097 + 11 = 64.097$
The applicant projects the Chowan County in-center patients forward one year to December 31, 2022 using the Chowan County AACR.	$53.097 \times 1.138 = 60.424$
The applicant adds 11 patients from other counties. This is the projected ending census for Operating Year 1 .	$60.424 + 11 = 71.424$
The applicant projects the Chowan County in-center patients forward one year to December 31, 2023 using the Chowan County AACR.	$60.424 \times 1.138 = 68.762$
The applicant adds 11 patients from other counties. This is the projected ending census for Operating Year 2 .	$68.762 + 11 = 79.762$

The applicant projects to serve 71 in-center patients in OY1 and 80 in-center patients in OY2. Thus, the applicant projects that Edenton Dialysis will have a utilization rate of 90% or 3.6 patients per station per week ($71 \text{ patients} / 20 \text{ stations} = 3.6 / 4 = 0.90$ or 90%) in OY1. The projected utilization of 3.6 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 for the following reasons:

- The applicant begins the projections with the existing Chowan County Edenton Dialysis patient census as of December 31, 2019.

- The applicant projects the Chowan County patient census at Edenton Dialysis will increase by the Chowan County Five Year AACR of 13.8 percent, as reported in the 2020 SMFP.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

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, disabled persons, elderly and other under-served persons.”

In Section C.7, page 23, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as summarized in the following table.

Estimated Percentages of Patients by Group		
a	Low income persons	NA
b	Racial and ethnic minorities	86.0%
c	Women	46.0%
d	Handicapped persons	NA
e	The elderly	58.0%
f	Medicare beneficiaries	80.8%
g	Medicaid recipients	9.6%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 a reduction, elimination or relocation of 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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis stations).

In Section E, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.
- *Relocate stations from other facilities* – The applicant states that this alternative is less effective because Edenton Dialysis is the only facility in Chowan County and the facilities in surrounding counties are highly utilized.

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

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

- 1. DVA Healthcare Renal Care, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than one additional in-center dialysis station for a total of no more than 20 in-center and home hemodialysis stations at Edenton Dialysis upon completion of the project, which shall include any home hemodialysis training or isolation 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

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis stations).

Capital and Working Capital Costs

In Form F.1(a), page 81, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$0
Equipment and Furniture	\$18,827
Miscellaneous Costs	\$0
Total	\$18,827

In Section F.3, pages 31-33, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because Edenton Dialysis is an operational facility.

Availability of Funds

In Section F.2, page 30, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	DAVITA
Loans	\$0
Accumulated Reserves or OE*	\$18,827
Other (Specify)	\$0
Total	\$18,827

*OE = Owner's Equity

Exhibit F-2 contains a letter dated July 31, 2020 from the Chief Accounting Officer for DaVita Kidney Care, parent company of Edenton Dialysis, authorizing and committing cash reserves in the amount of \$18,827 for the capital costs of the project. Exhibit F-2 also contains the Form 10K Annual Report for DaVita, Inc. for the fiscal year ending December 31, 2019 that indicates it currently has \$1.1 billion in cash and cash equivalents and \$17.3 billion in total assets.

Financial Feasibility

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

Edenton Dialysis Projected Revenue and Operating Expenses		
	OY 1 CY2022	OY 2 CY2023
Total Treatments (IC, HH, and PD)	10,042	11,203
Total Gross Revenue (charges)	\$3,083,312	\$3,439,735
Total Net Revenue	\$2,909,182	\$3,245,476
Average Net Revenue per Treatment	\$290	\$290
Total Operating Expenses (costs)	\$2,483,831	\$2,664,512
Average Operating Expense per Treatment	\$247	\$238
Net Income / Profit	\$425,351	\$580,965

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 for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates 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 no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this application is Chowan County. Facilities may serve residents of counties not included in their service area.

The applicant, Edenton Dialysis, currently operates the only dialysis center in Chowan County. The following table shows the utilization information for Edenton Dialysis, from Table 9B, page 153 of the 2020 SMFP:

Chowan County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
Edenton Dialysis (DaVita)	17	64	94.12%

Source: 2020 SMFP, Table 9B.

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Chowan County. The applicant states:

“In Section B, Question 2 and Section C, Question 3 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 addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- There is a facility need determination at Edenton Dialysis, as calculated using the methodology in the 2020 SMFP, for up to seven additional dialysis stations.
- The applicant adequately demonstrates that the one proposed dialysis station is 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 Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Edenton Dialysis, as summarized below.

POSITION	FTE Positions as of 12/31/19	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
Registered Nurses	1.75	2.50	2.50
Technicians	5.00	7.50	7.50
Dietitian	0.50	1.00	1.00
Social Worker	0.50	1.00	1.00
Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	10.25	14.50	14.50

Source: Section Q Form H

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, 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-3 contains documentation of its continuing education programs. In Section H.4, page 37, the applicant identifies the current medical director for the facility. In Exhibit H-4, the applicant provides a letter from the medical director 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
- 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
Self-care training	On site
Home training HH PD Accessible follow-up program	Albemarle Dialysis
Psychological counseling	Onsite by RN
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	Vidant Chowan Hospital
Pediatric nephrology	Vidant Chowan Hospital
Vascular surgery	Vidant Chowan Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	Chowan County Social Services
Transportation	Chowan EMS

Source: Table in Section I, page 38

In Section I, page 39, the applicant describes its existing relationships with other local health care and social service providers.

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.

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 any construction or renovation with this project. 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 for Edenton Dialysis patients during CY2019 for its existing services, as shown in the table below.

**Edenton Dialysis
Historical Payor Mix (CY2019)**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Insurance*	3	5.8%	0		0	
Medicare*	42	80.8%	0		0	
Medicaid*	5	9.6%	0		0	
Other (VA)	2	3.8%	0		0	
Total	52	100.0%	0		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 population during CY2019, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	46.0%	50.8%
Male	54.0%	49.2%
Unknown		
64 and Younger	42.0%	83.5%
65 and Older	58.0%	16.5%
American Indian	0.0%	1.3%
Asian	0.0%	5.9%
Black or African-American	82.0%	13.4%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	14.0%	76.3%
Other Race	4.0%	2.8%
Declined / Unavailable	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
- 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.2, page 45, 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, page 45, 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.3, page 46, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Edenton Dialysis
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Insurance*	4.6	5.8%	0		0	
Medicare*	64.4	80.8%	0		0	
Medicaid*	7.7	9.6%	0		0	
Other (VA)	3.1	3.8%	0		0	
Total	79.8	100.0%	0		0	

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects 80.8% of in-center dialysis services will be provided to Medicare patients and 9.6% 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, stating the payor mix is based upon recent facility history of actual treatment volumes. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Edenton Dialysis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, pages 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 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
- Exhibits to the application

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

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

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations which is a change of scope

for Project I.D. # R-11595-18 (add two dialysis stations) and Project I.D. # R-11791-19 (add four dialysis 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this application is Chowan County. Facilities may serve residents of counties not included in their service area.

The applicant, Edenton Dialysis, currently operates the only dialysis center in Chowan County. The following table shows the utilization information for Edenton Dialysis, from Table 9B, page 153 of the 2020 SMFP:

Chowan County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
Edenton Dialysis (DaVita)	17	64	94.12%

Source: 2020 SMFP, Table 9B.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 49, the applicant states:

“The expansion of Edenton Dialysis 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.”

Regarding the impact of the proposal on cost effectiveness, quality and access by medically underserved groups in Section N.2, page 49, the applicant states:

“As discussed in Section B, DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Edenton Dialysis will enhance accessibility to dialysis for current and projected patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

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

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

In Section O.2, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred at Waynesville Dialysis Center. The applicant states that the facility is back in compliance as of June 7, 2019, and provides documentation in Exhibit O of the application. 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 .2200 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- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility.

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

-C- In Section Q, Form C, the applicant projects that Edenton Dialysis will serve 71 in-center patients on 20 stations, or a rate of 3.6 patients per station per week, as of the end of the first operating year 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 Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility.