

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 30, 2018

Findings Date: November 30, 2018

Project Analyst: Gregory F. Yakaboski

Chief: Martha J. Frisone

Project ID #: R-11595-18

Facility: Edenton Dialysis

FID #: 955811

County: Chowan

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add 2 stations for a total of 15 stations upon completion of this project and Project ID #R-10264-14 (relocate 4 stations to Perquimans County Dialysis)

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. (DVA or the applicant) d/b/a Edenton Dialysis proposes to add two stations to Edenton Dialysis for a total of 15 stations upon completion of this project and Project ID# R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Edenton Dialysis does not currently offer either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program. The parent company of DVA is DaVita, Inc. (DaVita).

Need Determination

The 2018 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 the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there

is no county need determination for Chowan County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Edenton Dialysis in the July 2018 SDR is 3.3529 patients per station per week. This utilization rate was calculated based on 57 in-center dialysis patients and 17 certified dialysis stations as of December 31, 2017 (57 patients /17 stations = 3.3529 patients per station per week). Application of the facility need methodology indicates that 4 additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		83.8%
Certified Stations		17
Pending Stations		0
Total Existing and Pending Stations		17
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		57
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		52
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	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 6/30/17	0.1923
(ii)	Divide the result of Step (i) by 12	0.0160
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.1923
(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	67.9615
(v)	Divide the result of Step (iv) by 3.2 patients per station	21.2380
	and subtract the number of certified and pending stations to determine the number of stations needed	4.2380

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 4 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. 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 2 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles* on page 233 of the 2018 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section K.1(g), page 39, Section N, page 49, Section O, page 50, and Exhibits O-2 and O-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 15, Section L, pages 43-47, Exhibit L-3 and Section N, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), page 11, Section C, pages 13-15, Section F, pages 23-27, Section K, pages 38-42 and Section N, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

DVA proposes to add two stations to the Edenton Dialysis facility for a total of 15 stations upon completion of this project and Project I.D. #R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Edenton Dialysis does not currently offer either a peritoneal dialysis program or a home hemodialysis program.

Patient Origin

On page 365, the 2018 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.*” Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC) patients.

Edenton Dialysis: Historical Utilization as of 12/31/17

County	IC Patients
Chowan	36
Perquimans	14
Tyrrell	3
Durham	1
Gates	1
Pasquotank	1
Washington	1
Total	57

Source: Table on page 18 of the application.

Edenton Dialysis: Projected Utilization

County	OY1	OY2	County Patients as a % of Total	
	IC Patients	IC Patients	OY1	OY2
Chowan	44	48	88.0%	88.9%
Tyrrell	3	3	6.0%	5.6%
Durham	1	1	2.0%	1.9%
Gates	1	1	2.0%	1.9%
Washington	1	1	2.0%	1.9%
Total	50	54	100.0%	100.0%

Source: Table on page 13 of the application.

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 13-14, the applicant states:

- The first two full operating years (OYs) of the project will be
OY1: January 1, 2020 – December 31, 2020 (CY2020), and
OY2: January 1, 2021 – December 31, 2021 (CY2021).
- 57 patients were receiving in-center dialysis treatments at Edenton Dialysis as of December 31, 2017.
- As of December 31, 2017 Edenton Dialysis had 17 certified dialysis stations and was at 83.82% utilization [57 patients/ 17 stations = 3.3529/4 = 0.8382 or 83.82%]. Upon completion of Project ID# R-10264-14 Edenton Dialysis will have 13 dialysis stations and 15 in-center patients from Perquimans County who currently dialyze at Edenton Dialysis will transfer their care to Perquimans County Dialysis.

In Section B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January and July 2018 SDR. The facility need methodology shows a need for 4 dialysis stations and the proposed project is for 2 dialysis stations.

The information is reasonable and adequately supported because the proposed project is consistent with the facility need methodology.

Projected Utilization

In Section C.1, pages 13 – 15, the applicant describes its assumptions and the methodology used to project utilization, which are summarized below:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021.
- As of December 31, 2017, Edenton Dialysis had 57 in-center patients, consisting of 36 residents of Chowan County and 21 patients residing in other counties.
- 15 in-center patients from Perquimans County will transfer their care from Edenton Dialysis to Perquimans County Dialysis as of January 1, 2019 (Project ID #R-10264-14)

- Utilization by Chowan County residents is projected to grow at 7.5%, the Five-Year Average Annual Change Rate (AACR) for Chowan County, as shown in Table D in the July 2018 SDR.
- The applicant projects no growth for the remaining patients.

The following table illustrates application of these assumptions and the methodology used.

Edenton Dialysis	In-Center Patients
As of January 1, 2018 there were 36 Chowan County IC patients	36
Project the Chowan County IC patients forward to December 31, 2018, using the Five Year AACR for Chowan County.	$36 \times 1.075 = 38.7$
Project the Chowan County IC patients forward to December 31, 2019, using the Five Year AACR for Chowan County.	$38.7 \times 1.075 = 41.6025$
Project the Chowan County IC patients forward to December 31, 2020, using the Five Year AACR for Chowan County.	$41.6025 \times 1.075 = 44.723$
Add the 6 patients from other counties currently dialyzing at Edenton Dialysis ($21 - 15 = 6$). This is the patient census at the end of OY1.	$44.723 + 6 = \mathbf{50.723}$
Project the Chowan County IC patients forward to December 31, 2021, using the Five Year AACR for Chowan County.	$44.723 \times 1.075 = 48.077$
Add the 6 patients from other counties currently dialyzing at Edenton Dialysis. This is the patient census at the end of OY2.	$48.077 + 6 = \mathbf{54.077}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 50 and 54 in-center patients, respectively.

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

- OY1: 3.333 patients per station per week, or 83.3% ($50 \text{ patients} / 15 \text{ stations} = 3.3333 / 4 = 0.8333$ or 83.3%).
- OY2: 3.4615 patients per station per week, or 83.25% ($54 \text{ patients} / 15 \text{ stations} = 3.6 / 4 = 0.900$ or 90.00%).

The projected utilization of 3.333 patients per station per week at the end of OY1 meets 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:

- The applicant starts with the 36 existing Chowan County IC patients.
- The Chowan County patients are projected to increase 7.5% per year which is the Five Year AACR for Chowan County as reported in Table D of the July 2018 SDR.

- The six non-Chowan County patients are existing patients and no growth is projected.

Access

In Section C.3, page 15, 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.” In Section L.1, page 44, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix

Payor Category	Edenton Dialysis Percent of Total Treatments
Medicaid	7.1%
Medicare	28.6%
Medicare/Medicaid	25.0%
Medicare/Commercial	21.4%
Commercial Insurance	5.4%
VA Insurance	12.5%
Total	100.0%

Source: Table, page 44 of the application.

On page 44, the applicant states the projected payor mix is based on the payor mix during the last year of operation. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 or eliminate a service, nor does the applicant propose to 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

DVA proposes to add two stations to the Edenton Dialysis facility for a total of 15 stations upon completion of this project and Project I.D. #R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Edenton Dialysis does not currently offer either a peritoneal dialysis program or a home hemodialysis program.

In Section E, page 22, 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.

On page 22, the applicant states that its proposal is the most effective alternative because the proposed project will address both the issues of growth and access to the facility. Developing a third shift is inconvenient for patients and if a facility is at its maximum capacity that eliminates patient choice.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. 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 2018 SDR, DVA Healthcare Renal Care, Inc. shall develop no more than 2 additional dialysis stations for a total of no more than 15 certified stations at Edenton Dialysis upon completion of this project and Project I.D. #R-10264-14 (relocate four stations to Perquimans County Dialysis), 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

DVA proposes to add two stations to the Edenton Dialysis facility for a total of 15 stations upon completion of this project and Project I.D. #R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Edenton Dialysis does not currently offer either a peritoneal dialysis program or a home hemodialysis program.

Capital and Working Capital Costs

In Section F, pages 23 and 25-26, the applicant states that the proposed project will not involve any capital expenditures, start-up or initial operating expenses.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	7,188	7,706
Total Gross Revenues (Charges)	\$1,981,422	\$2,123,305
Total Net Revenue	\$1,886,778	\$2,021,841
Average Net Revenue per treatment	\$262.49	\$262.37
Total Operating Expenses (Costs)	\$1,860,470	\$1,970,560
Average Operating Expense per treatment	\$258.83	\$255.72
Net Income	\$26,307	\$51,281

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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 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

DVA proposes to add two stations to the Edenton Dialysis facility for a total of 15 stations upon completion of this project and Project I.D. #R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Edenton Dialysis does not currently offer either a peritoneal dialysis program or a home hemodialysis program.

On page 365, the 2018 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.*” Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

Edenton Dialysis is the only dialysis facility in Chowan County. As of December 31, 2017, the facility was operating at 83.32% utilization according to the Table B of the July 2018 SDR.

In Section G.2, page 29, 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:

“While adding stations at this facility does not 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 would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of two dialysis stations at Edenton Dialysis is needed in addition to the existing stations.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 H.1, page 30, the applicant provides the current staffing for the facility, and states that Edenton Dialysis is projected to reduce the number of full time equivalent (FTE) positions as a result of this proposal and the previously approved R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Upon completion of both projects, the facility will have two less stations than it does now. The applicant states the facility currently staffs 15 FTE positions and will have a staff of 13 FTEs upon project completion. The facility proposes to have one less RN and one less Technician (PCT) upon project completion. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 33.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 31-32, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3 and H-4, the applicant provides supporting documentation. In Section I.3, page 35, the applicant identifies the medical director. In Exhibit I-3, the applicant provides a letter from the current medical director indicating an interest in continuing 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.1, page 34, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

EDENTION DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Edenton Dialysis
Self-care training (in-center)	Edenton Dialysis
Home training HH PD Accessible follow-up program	Albemarle Dialysis
Psychological counseling	Edenton Dialysis
Isolation – hepatitis	Edenton Dialysis
Nutritional counseling	Edenton Dialysis
Social Work services	Edenton Dialysis
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 Chowan Hospital
Vocational rehabilitation & counseling	NC Div of Vocational Rehabilitation Services
Transportation	Inter-County Public Transportation Services

On page 34, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I, pages 35-36, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

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.

- (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 nor 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.7, page 47, the applicant provides the historical payor mix during calendar year 2017 at Edenton Dialysis, as shown in the table below.

Historical Payor Mix

Payor Category	Edenton Dialysis Percent of Total Treatments
Medicaid	7.1%
Medicare	28.6%
Medicare/Medicaid	25.0%
Medicare/Commercial	21.4%
Commercial Insurance	5.4%
VA Insurance	12.5%
Total	100.0%

Source: Table, page 47 of the application.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Chowan	24%	53%	41%	19%	10%	12%
Tyrrell	20%	46%	49%	27%	13%	17%
Durham	13%	52%	58%	16%	7%	13%
Gates	20%	51%	37%	15%	13%	11%
Washington	24%	53%	55%	26%	17%	13%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 46, the applicant states

“Edenton Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.1, page 44, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix

Payor Category	Edenton Dialysis Percent of Total Treatments
Medicaid	7.1%
Medicare	28.6%
Medicare/Medicaid	25.0%
Medicare/Commercial	21.4%
Commercial Insurance	5.4%
VA Insurance	12.5%
Total	100.0%

Source: Table, page 44 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 75.0% of total services will be provided to Medicare patients and 32.1% to Medicaid patients.

On page 44, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based “*on the sources of patient payment that have been received by the existing facility in the last full operating year.*”

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.4, page 46, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

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

DVA proposes to add two stations to the Edenton Dialysis facility for a total of 15 stations upon completion of this project and Project I.D. #R-10264-14 (relocate 4 stations to Perquimans County Dialysis). Edenton Dialysis does not currently offer either a peritoneal dialysis program or a home hemodialysis program.

On page 365, the 2018 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.”* Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

Edenton Dialysis is the only dialysis facility in Chowan County. As of December 31, 2017, the facility was operating at 83.32% utilization according to the Table B of the July 2018 SDR.

In Section N, page 49, 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. On page 49, the applicant states:

“The expansion of Edenton Dialysis will have no effect on competition in Chowan County. ... This project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Healthcare Renal Care, Inc..

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 F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L 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 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 A, page 5, the applicant states DaVita operates more than 85 dialysis facilities in North Carolina. Exhibit A contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 50, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities: Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided 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

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new 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- The applicant is not proposing to establish a new End Stage Renal Disease 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 C, pages 13-15, the applicant adequately demonstrates that Edenton Dialysis will serve 50 in-center patients at the end of OY1 (CY2020) for a utilization rate of 83.33% or 3.333 patients per station per week ($50 \text{ patients} / 15 \text{ stations} = 3.3333 / 4 = 0.8333$ or 83.3%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.