

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2021

Findings Date: June 25, 2021

Project Analyst: Gregory F. Yakaboski

Acting Chief: Lisa Pittman

Project ID #: N-12049-21

Facility: Southeastern Dialysis Center-Elizabethtown

FID #: 955448

County: Bladen

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than five dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10)

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

Total Renal Care of North Carolina, LLC, hereinafter TRC or the applicant, operates a dialysis facility, Southeastern Dialysis Center-Elizabethtown (SEDC-Elizabethtown), in Elizabethtown, Bladen County. In this application, the applicant proposes to add no more than 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10). DaVita, Inc. (DaVita) is the ultimate parent company of TRC.

SEDC-Elizabethtown provides in-center (IC) dialysis and a peritoneal dialysis (PD) program, however, the facility does not offer a home hemodialysis (HH) program.

Need Determination

Chapter 9 of the 2021 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 9B, page 133, the county need methodology shows there is not a county need determination for additional dialysis stations in Bladen 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 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 119, the utilization rate reported for the facility is 77.88 percent or 3.115 patients per station per week, based on 81 in-center dialysis patients and 26 certified dialysis stations ($81 \text{ patients} / 26 \text{ stations} = 3.115$; $4.3125 / 4 = 0.7788$ or 77.88%).

As shown in Table 9D, page 138, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 10 additional stations; thus, the applicant is eligible to apply to add up to 10 stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 5 new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 10 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 SMFP, states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 17-18; Section N, page 63; Section O, pages 65-67; 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, pages 18-19; Section C, pages 27-28; Section L, pages 56-60; Section N, page 63; 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, page 19; Section F, pages 36-37; Section N, page 63; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

The applicant proposes to add no more than 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

Patient Origin

On page 113, the 2021 SMFP defines the service area for county need methodology for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancy counties.” SEDC-Elizabethtown is in Bladen County. Thus, the service area for this facility is Bladen County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 21, the applicant provides the IC, HH and PD historic patient origin for SEDC-Elizabethtown for CY2020, as summarized in the following table:

SEDC-Elizabethtown: Last Full FY 1/1/2020 to 12/31/2020						
County	IC		HH		PD	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Bladen	62.00	91.20%	0.00	0.00%	7.00	58.33%
Columbus	1.00	1.50%	0.00	0.00%	5.00	41.67%
Cumberland	1.00	1.50%	0.00	0.00%	0.00	2.00%
New Hanover	1.00	1.50%	0.00	0.00%	0.00	0.00%
Sampson	3.00	4.40%	0.00	0.00%	0.00	0.00%
Total	68.00	100.00%	0.00	0.00%	12.00	100.00%

Source: Table on page 21 of the application.

In Section C.3, page 22, the applicant provides the projected IC, HH, and PD projected patient origin of SEDC-Elizabethtown for the second full operating year following project completion, January 1, 2024 – December 31, 2024 (CY2024), as summarized in the following table:

SEDC-Elizabethtown: Second FY 1/1/2024 to 12/31/2024						
County	IC		HH		PD	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Bladen	62.00	91.20%	0.00	0.00%	11.00	68.75%
Columbus	1.00	1.50%	0.00	0.00%	5.00	31.25%
Cumberland	1.00	1.50%	0.00	0.00%	0.00	0.00%
New Hanover	1.00	1.50%	0.00	0.00%	0.00	0.00%
Sampson	3.00	4.40%	0.00	0.00%	0.00	0.00%
Total	68.00	100.00%	0.00	0.00%	16.00	100.00%

Source: Table on page 22 of the application.

In Section C.3, pages 22-24, the applicant provides the assumptions and methodology used to project its patient origin. On page 22 the applicant states:

“Projections for patient utilization begin with the patient population at SECD-Elizabethtown as of December 31, 2020. The census, as reported in the facility’s December 2020 ESRD Data Collection form, included 68 in-center patients. Of these 68 patients, 62 lived in the service area, Bladen County and 6 lived outside the service area.”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on the facility census as of December 31, 2020. Sixty-two of the in-center patients reside in Bladen County and 6 reside out of the service area.
- To project the patient census forward the applicant projects a 0.00% growth rate based on the fact that while the Bladen County Five-Year Average Annual Change Rate (AACR) is 3.7%, as published in the 2021 SMFP, Table 9B, page 133, utilization at SEDC-Elizabethtown has experienced a recent decline in growth primarily as a result of relocation of patients to a new facility in the county, Bladenboro Dialysis. However, based on the census reported in the December 2020 ESRD Data Collection form, SEDC-Elizabethtown still has a high utilization rate of 89.47% [68 patients/19 stations = $3.5789/4 = 0.8947$ or 89.47%]
- The applicant assumes that the 6 in-center patients residing outside of the Bladen County will continue to dialyze at the facility and does not project any growth for this group.

Analysis of Need

In Section C, page 15 and pages 22-23, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 15, the applicant states that the proposed services are needed based on Condition 2 of the facility need methodology; demonstrating a need for a five-station expansion.

The information is reasonable and adequately supported based on the following:

- According to the 2021 SMFP, Table 9A, as of December 31, 2019, SEDC-Elizabethtown was operating at a rate of 3.115 in-center patients per station per week, or at a utilization rate of 77.88 percent [81 patients / 26 stations = 3.115; $4.3125/4 = 0.7788$ or 77.88%].
- Based on the census data reported in the December 2020 ESRD Data Collection form SEDC-Elizabethtown was operating at rate of 3.5789 in-center patients per station per week, or a utilization rate of 89.47% [68 in-center patients/ 19 stations = $3.5789/4 = 0.89947$ or 89.47%].
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In-Center Projected Utilization

In Section C, page 23, and Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

The applicant begins with the IC patients as of January 1, 2021	68
The applicant projects IC patients forward one year to December 31, 2021 assuming a 0.0% growth rate.	$68 \times 1.0 = 68$
The applicant projects IC patients forward one year to December 31, 2022 assuming a 0.0% growth rate.	$68 \times 1.0 = 68$
The applicant projects IC patients forward one year to December 31, 2023 assuming a 0.0% growth rate. This is the projected ending census for Operating Year 1 (CY2023) .	$68 \times 1.0 = 68$
The applicant projects IC patients forward one year to December 31, 2024 assuming a 0.0% growth rate. This is the projected ending census for Operating Year 2 (CY2024) .	$68 \times 1.0 = 68$

Projected patients for Operating Year (OY)1 and OY2 are rounded to the nearest whole number. Therefore, at the end of OY1 (CY2023) the facility is projected to serve 68 in-center patients and at the end of OY2 (CY2024) the facility is projected to serve 68 in-center patients.

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

- OY1: 2.83 patients per station per week or 70.83% utilization ($68 \text{ patients} / 24 \text{ stations} = 2.833/4 = 0.7083$ or 70.83%)
- OY2: 2.83 patients per station per week or 70.83% utilization ($68 \text{ patients} / 24 \text{ stations} = 2.833/4 = 0.7083$ or 70.83%)

The projected utilization of 2.83 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).

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

- The applicant projects the first two full operating years of the project will be January 1, 2023–December 31, 2023 (CY2023) and January 1, 2024–December 31, 2024 (CY2024).
- The applicant begins its projections with the facility census as of December 31, 2020. This information is reported in the ESRD Data Collection forms submitted to the Agency. The facility reported 68 in-center patients receiving dialysis services at SEDC-Elizabethtown. Of the 68 patients, 62 reside in Bladen County and 6 are non-Bladen County residents.
- The applicant applied a projected annual growth rate of 0.00% based on the fact that while the Bladen County Five-Year Average Annual Change Rate (AACR) is 3.7%, as published in the 2021 SMFP, Table 9B, page 133, utilization at SEDC-Elizabethtown

has experienced a recent decline in growth primarily as a result of relocation of patients to a new facility in the county, Bladenboro Dialysis. However, based on the census reported in the December 2020 ESRD Data Collection form, SEDC-Elizabethtown still has a high utilization rate of 89.47% [68 patients/19 stations = 3.5789/4 = 0.8947 or 89.47%]

- The applicant does not project growth for the 6 patients residing outside of the Bladen County service area.

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant applied a projected annual growth rate of 0.00% based on the fact that while the Bladen County Five-Year Average Annual Change Rate (AACR) is 3.7%, as published in the 2021 SMFP, Table 9B, page 133, utilization at SEDC-Elizabethtown has experienced a recent decline in growth primarily as a result of relocation of patients to a new facility in the county, Bladenboro Dialysis. However, based on the census reported in the December 2020 ESRD Data Collection form, SEDC-Elizabethtown still has a high utilization rate of 89.47% [68 patients/19 stations = 3.5789/4 = 0.8947 or 89.47%]
- The applicant does not project growth for its IC patients who do not reside in Bladen County.
- Projected utilization for the in-center patients at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

PD Projected Utilization

SEDC-Elizabethtown- PD Program: Historical and Projected Utilization

	Last Full Operating Year: 12/31/2020	End of OY2: 12/31/2024
PD Patients	12.00	16

Source: Table on page 23 in Section C of the application and Section Q.

The applicant started with the historical number of PD patients as of 12/31/2020 and applied an annual growth rate of at least one patient per year.

	Start Date	# of Patients at start of year	# of Patients at end of year	Average # of Patients during year
Interim	1/1/2021	12	13	12.5
Interim	1/1/2022	13	14	13.5
OY1	1/1/2023	14	15	14.5
OY2	1/1/2024	15	16	15.5

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

- The applicant bases the future utilization of services upon the facility’s historical PD patient utilization, and
- In 2020 the SEDC-Elizabethtown home program trained 6 PD patients. The applicant conservatively bases the future need for services upon a growth rate of one PD patient per year.
- Federal focus and emphasis on home dialysis pursuant to the Presidential Executive Order of July 10, 2019.

Access to Medically Underserved Groups

In Section C.6, pages 27-28, 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, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.

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

SEDC Elizabethtown 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.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	94.1%
Racial and ethnic minorities	80.6%
Women	41.9%
Persons with Disabilities	100.0%
Persons 65 and older	46.8%
Medicare beneficiaries	80.9%
Medicaid recipients	10.3%

Source: Section C, page 28.

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 based on the following reasons:

- ESRD patients are afforded protections under the Americans with Disabilities Act.

- DaVita corporate policy commits to providing dialysis services to all residents in the service area without qualifications.

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 all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to add no more than 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

In Section E, page 35, 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 this alternative would not address the utilization at SEDC-Elizabethtown. Therefore, the applicant determined that this was not the most effective alternative.
- Relocate Stations from another DaVita facility-The applicant states that Bladenboro Dialysis, the only other DaVita facility in Bladen County, is a new facility with only a 10-

stations. Furthermore, the applicant states relocating any dialysis stations from Bladenboro would negatively impact the patients currently being served and the facility's operations. Therefore, the applicant determined that this was not the most effective alternative.

Based on the explanations above, the applicant states that its proposal is the most effective alternative as the utilization at SEDC-Elizabethtown dictates the need for additional dialysis stations and there are no dialysis stations at the only other DaVita dialysis facility in Bladen County that can be relocated to SEDC-Elizabethtown to address the utilization.

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

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

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. Total Renal Care of North Carolina, LLC (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 2021 SMFP, the certificate holder shall develop no more than 5 additional in-center dialysis stations for a total of no more than 24 in-center stations at Southeastern Dialysis Center-Elizabethtown upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**

- c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.**
- 4. 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 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$88,694
Total	\$88,694

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following reasons:

- DaVita’s Project Manager for North Carolina partnered with Finance to develop the capital cost of this project.
- To ensure reasonable project costs a regional data base and corporate model were utilized along with inputs from DaVita’s operations and regional Real Estate team. DaVita has a team of Project Managers which are all part of DaVita’s Team Genesis Project Management.
- The information provided in Form F.1a Capital Cost projections and assumptions.

In Section F, page 37, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility that is already operational.

Availability of Funds

In Section F, page 36, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Total Renal Care of North Carolina, LLC	Total
Loans		
Accumulated reserves or OE *	\$88,694	\$88,694
Bonds		
Other (Specify)		
Total Financing	\$88,694	\$88,694

* OE = Owner’s Equity

In Exhibit F-2c, the applicant provides a letter dated March 3, 2021 from the Chief Accounting Officer of DaVita Kidney Care, the parent company of DVA Healthcare Renal Care, Inc., documenting its commitment to fund the capital costs of the proposed project from cash reserves. Exhibit F-2 also contains a copy of Form 10-K for DaVita, Inc. indicating that the applicant had \$324 million in cash and cash equivalents as of December 31, 2020.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation provided in Section F and Exhibit F-2 and F-2c, as described above.

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 F.2 and clarifying information, the applicant projects that revenues will exceed operating expenses in the first two years following completion of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	12,227	12,375
Total Gross Revenues (Charges)	\$3,479,692	\$3,532,316
Total Net Revenue	\$3,258,038	\$3,307,975
Average Net Revenue per Treatment	\$266	\$267
Total Operating Expenses (Costs)	\$2,713,735	\$2,760,004
Average Operating Expense per Treatment	\$222	\$223
Net Income	\$544,303	\$547,971

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following reasons:

- The applicant's assumptions of charges per treatment by source are based on historical revenue of DaVita's North Carolina facilities.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

On page 113, the 2021 SMFP defines the service area for county need methodology for dialysis stations as "*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancy counties.*" SEDC-Elizabethtown is in Bladen County. Thus, the service area for this facility is Bladen County. Facilities may also serve residents of counties not included in their service area.

There are two (2) dialysis centers in Bladen County. The applicant operates both dialysis centers in Bladen County. Utilization of both dialysis centers is shown in the following table from Chapter 9, Table 9A, page 119 of the 2021 SMFP and page 42 of the application:

Bladen County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
SEDC-Elizabethtown*	DaVita	Elizabethtown	26	77.88%
Bladenboro Dialysis**	DaVita	Bladenboro	0	0.00%

Source: 2021 SMFP, Table 9A.

*Currently SEDC-Elizabethtown is certified for 19 dialysis stations as Project ID# N-11589-18 (add 3) was completed and the stations certified as of October 29, 2020 and Project ID # N-11130-16 (relocate 10) was completed and the stations certified as of November 20, 2020.

**Currently approved for a total of 14 stations.

In Section G, page 42, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Bladen County. The applicant states:

“While adding stations at the facility does increase the number of stations in Bladen County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s 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 in the service area based on the following reasons:

- The applicant adequately demonstrates that the proposed five new in-center dialysis stations at SEDC-Elizabethtown are based on the facility need methodology in the 2021 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

The applicant proposes to add no more than 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

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

Position	Current FTE Staff	Projected FTE Staff
	<i>(Time Period)</i>	2nd Full Fiscal Year <i>(Time Period)</i>
Administrator	1.00	1.00
Registered Nurses (RNs)	3.25	3.00
Home Training Nurse	0.50	0.50
Technicians (PCT)	9.75	9.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Administrator/Business Office	1.00	1.00
Other-Biomedical Tech	0.50	0.50
TOTAL	17.00	16.00

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.4. In Section H, pages 44-45, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following reasons:

- The facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies regarding recruitment, training and continuing education.
- The applicant utilizes three different resources to fill positions. They include DaVita’s Teammate Recruiter, a referral program for current employees, and vocational training through student internship.
- The applicant provides training and continued education through DaVita’s School of Clinical Education.

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 all the reasons described 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

The applicant proposes to add no more than 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

Ancillary and Support Services

In Section I, page 46, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 46-49, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at SEDC-Elizabethtown. SEDC-Elizabethtown is a well-established facility in Bladen County and has long-standing relationships with local healthcare providers and social service agencies in Bladen County.
- The applicant discusses how it provides each necessary ancillary and support service at SEDC-Elizabethtown.
- In Exhibit I.2, the applicant provides a letter of support from the facility administrator ensuring its continuation of established agreements and working relationships in Bladen County.

Coordination

In Section I, page 49, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.

- The letter from the facility administrator in Exhibit I.2.

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 all the reasons described above.

- (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 no applicable to this review.

- (11) Repealed effective July 1, 1987.

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

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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 56, the applicant provides the historical payor mix during the last full fiscal year (CY2020) for the proposed services, as shown in the table below

Payor Category	IC		PD	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	2.0	2.9%	0.0	0.0%
Medicare*	55.0	80.9%	7.0	58.3%
Medicaid*	7.0	10.3%	0.0	0.0%
Insurance*	2.0	2.9%	1.0	8.3%
Other-VA	2.0	2.9%	4.0	33.3%
Total	68.0	100.0%	12.0	100.0%

Source: Table on page 56 of the application.

*Including any managed care plans.

In Section L, page 57, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	41.9%	52.5%
Male	58.1%	47.5%
Unknown	0.0%	0.0%
64 and Younger	53.2%	77.2%
65 and Older	46.8%	22.8%
American Indian	0.0%	3.1%
Asian	0.0%	0.3%
Black or African American	74.2%	34.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	19.4%	54.9%
Other Race	6.5%	1.7%
Declined / Unavailable	0.0%	0.0%

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 and ... persons [with disabilities] 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, page 58, the applicant states that the facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 58, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 59, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2024) following completion of the project, as shown in the table below.

Payor Category	IC		PD	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	2.00	2.90%	0.00	0.00%
Medicare*	55.00	80.90%	9.33	58.30%
Medicaid*	7.00	10.30%	0.00	0.00%
Insurance*	2.00	2.90%	1.33	8.30%
Other (specify)	2.00	2.90%	5.33	33.30%
Total	68.00	100.00%	16.00	100.00%

Source: Table on page 59 of the application.

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.9% of in-center services will be provided to self-pay patients, 80.9% to Medicare patients and 10.3% to Medicaid patients.

On page 59, 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 based on the following reasons:

- The applicant did not apply any adjustment rate when projecting payor mix, therefore, it is expected to be the same as the historical payor mix.
- The applicant's projected payor mix is based upon the sources of patient payment that have been received in the last full operating year by the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 60, 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

The applicant proposes to add no more than 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

In Section M, page 62, 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.2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following reasons:

- In Exhibit M.2, the applicant provides a copy of the student training agreement with UNC Wilmington.

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 all the reasons described above.

- (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 5 in-center dialysis stations at SEDC-Elizabethtown pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon completion of this project, Project ID# N-11589-18 (add 3) and Project ID # N-11130-16 (relocate 10).

On page 113, the 2021 SMFP defines the service area for county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancy counties.”* SEDC-Elizabethtown is in Bladen County. Thus, the service area for this facility is Bladen County. Facilities may also serve residents of counties not included in their service area.

There are two (2) dialysis centers in Bladen County. The applicant operates both dialysis centers in Bladen County. Utilization of both dialysis centers is shown in the following table from Chapter 9, Table 9A, page 119 of the 2021 SMFP and page 42 of the application:

Bladen County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
SEDC-Elizabethtown*	DaVita	Elizabethtown	26	77.88%
Bladenboro Dialysis**	DaVita	Bladenboro	0	0.00%

Source: 2021 SMFP, Table 9A.

*Currently SEDC-Elizabethtown is certified for 19 dialysis stations as Project ID# N-11589-18 (add 3) was completed and the stations certified as of October 29, 2020 and Project ID # N-11130-16 (relocate 10) was completed and the stations certified as of November 20, 2020.

**Currently approved for a total of 14 stations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 63, the applicant states:

“The expansion of SEDC Elizabethtown will have no effect on competition in Bladen 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, page 63, the applicant states:

“The expansion of SEDC Elizabethtown 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. ... with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. ... DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients. ... the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 all the reasons described 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 O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by DaVita, Inc. or a related entity. The applicant identifies a total of 108 of this type of facility located in North Carolina.

In Section O.5, page 67, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of "*Immediate Jeopardy*" occurred in any DaVita-related facility. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 108 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.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 The specific criteria are 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 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, 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 does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*
(1) *an existing dialysis facility; or*
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*
shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.
- C- In Section C, pages 22-23, and Section Q, Form C, the applicant projects that SEDC-Elizabethtown will serve 68 in-center patients on 24 dialysis stations. The projected utilization for OY1 of 2.83 patients per station per week or 70.83% utilization (68 patients / 24 stations = 2.833/4 = 0.7083 or 70.83%) satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 22-23, and Section Q, Form C, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.