

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 25, 2019

Findings Date: July 25, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: P-11711-19

Facility: Southeastern Dialysis Center - Kenansville

FID #: 945251

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Relocate entire facility and relocate one station from Wallace Dialysis for a total of 20 stations upon completion of this project and Project# P-11680-19 (add two stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

The applicant, Total Renal Care of North Carolina, LLC (TRC) proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville and relocate no more than one existing dialysis station from Wallace Dialysis Center for a total of no more than 20 dialysis stations at Southeastern Dialysis Center - Kenansville (SEDC-Kenansville) upon completion of this project and Project ID #P-11680-19 (add two stations). The new site for the facility will be 133 Limestone Road in Kenansville.

#### **Need Determination**

The applicant proposes to relocate the entire facility and relocate one dialysis station from Wallace Dialysis Center; therefore, neither the county need methodology nor the facility

need methodology in the 2019 State Medical Facilities Plan (SMFP) are applicable to this review.

### **Policies**

There are two policies in the 2019 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

### **Policy ESRD-2**

Policy ESRD-2 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant, TRC, proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville. Both the existing facility and the proposed site are in Duplin County. Additionally, the applicant proposes to relocate one existing dialysis station from Wallace Dialysis Center, also in Duplin County. There will be no change in the dialysis station inventory for Duplin County as a result of this project. Therefore, the application is consistent with Policy ESRD-2.

### **Policy GEN-4**

Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.4, pages 15 - 16, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **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.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville and relocate no more than one existing dialysis station from Wallace Dialysis Center for a total of no more than 20 dialysis stations at SEDC-Kenansville upon completion of this project and Project ID #P-11680-19 (add two stations).

**Patient Origin**

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

In Section C.2, page 18, C.3, page 19 and clarifying information submitted on July 11, 2019, the applicant provides the historical and projected patient origin for in-center (IC) patients, respectively, as illustrated in the tables below:

SEDC-Kenansville Historical Patient Origin (CY 2018)

COUNTY	# PATIENTS	% OF TOTAL
Duplin	61	91.0%
Greene	1	1.5%
Lenoir	1	1.5%
Onslow	1	1.5%
Wake	1	1.5%
Other States	2	3.0%
<b>Total</b>	<b>67</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

SEDC-Kenansville Projected Patient Origin (CY 2022)

COUNTY	# PATIENTS	% OF TOTAL
Duplin	67	91.8%
Greene	1	1.4%
Lenoir	1	1.4%
Onslow	1	1.4%
Wake	1	1.4%
Other States	2	2.7%
<b>Total</b>	<b>73</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

The applicant does not currently offer home hemodialysis (HHD) training or peritoneal dialysis (PD) training and support services at SEDC - Kenansville, nor does the applicant propose to offer those services as a part of this application.

In Section C, pages 19 - 20, the applicant provides the assumptions and methodology used to project patient origin for in-center patients.

The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, pages 19 - 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 21, the applicant states:

*“The proposed project is to relocate SEDC Kenansville to a new location due to the condition of the current facility. While there are no deficiencies in facility-related quality of care metrics at SEDC Kenansville, the age and condition of [the] facility’s physical plant and infrastructure make renovations cost-prohibitive, including the need for a significant mold remediation for the second time in five years. Providing current and projected patients the updates and upgrades that we’ve been able to make in other DaVita facilities and capacity for projected growth requires that we move this facility to a new location.*

...

*Additionally, the relocation of 1 station from Wallace Dialysis would increase the capacity at SEDC Kenansville and allow it to better address the significant growth it has recently experienced.”*

In Section C, pages 19 - 20, the applicant provides assumptions and methodology used to project the number of patients to project utilization, summarized as follows:

- The applicant states that as of December 31, 2018, SEDC Kenansville had 67 in-center patients. Of those in-center patients, 61 were residents of Duplin County and six resided outside the county.
- As of December 31, 2018, SEDC Kenansville was certified for 17 in-center dialysis stations.
- Page 19 of the application references Project ID #P-11601-18, stating that the applicant was approved to add dialysis stations to SEDC Kenansville, with a projected certification date of January 1, 2021. However, the applicant incorrectly references the wrong project. In Project ID #P-11680-19, the applicant was approved to add two dialysis stations to the existing facility with a projected certification date of January 1, 2021.
- In this application, the applicant also proposes to relocate one in-center dialysis station from Wallace Dialysis Center to SEDC Kenansville.

- The projected certification date for the stations as proposed in this application is January 1, 2021, which would leave SEDC Kenansville with a total of 20 dialysis stations as of that date.
- The applicant states the Five-Year Average Annual Change Rate (AACR) for Duplin County which is 1.4%, as published in Table D of the January 2019 SDR; however, the applicant states the Five Year AACR for SEDC Kenansville was 11.0%, as shown in the table below:

**SEDC-Kenansville Five Year AACR**

12/31/2014	48	
12/31/2015	45	-6.3%
12/31/2016	47	4.4%
12/31/2017	44	-6.4%
12/31/2018	67	52.3%
<b>Five Year AACR</b>		<b>11.0%</b>

- The applicant projects growth in the patient population by a 2.5% rate, which it states is conservative given the Five Year AACR growth at the facility.
- The applicant does not project an increase in the patient population for patients residing outside of Duplin County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2021  
Operating Year 2 (OY2) = Calendar Year (CY) 2022

The information is reasonable and adequately supported.

#### Projected Utilization

The applicant's methodology begins with the Duplin County in-center patient census as of December 31, 2018 and applies the 2.5% Five Year AACR discussed above, as illustrated in the following table, summarized from page 20 of the application:

**Projected Patients, SEDC Kenansville**

	# STATIONS	# PATIENTS/CALCULATIONS
Begin with the facility census as of December 31, 2018.	17	67
Project Duplin County patients forward one year to December 31, 2019 by 2.5%.	--	$61 \times 1.025 = 62.53$
Add six patients from outside Duplin County.	--	$62.53 + 6 = 68.53$
Project Duplin County patients forward one year to December 31, 2020 by 2.5%.	--	$62.53 \times 1.025 = 64.09$
Add six patients from outside Duplin County.	--	$64.09 + 6 = 70.09$
Add two stations pursuant to Project ID #P-11680-19 on January 1, 2021.	$17 + 2 = 19$	--
Relocate one station from Wallace Dialysis Center as proposed in this application	$19 + 1 = 20$	--
Project Duplin County patients forward one year to December 31, 2021 by 2.5%.	--	$64.09 \times 1.025 = 65.69$
Add six patients from outside Duplin County.	--	$65.69 + 6 = 71.69$
Project Duplin County patients forward one year to December 31, 2022 by 2.5%.	--	$65.69 \times 1.025 = 67.33$
Add six patients from outside Duplin County.	--	$67.33 + 6 = 73.33$

The applicant rounded down to the nearest whole number for OY 1 and OY 2. The applicant projects to serve 71 in-center patients at the end of OY 1 and 73 in-center patients at the end of OY 2. Thus, the applicant projects that SEDC - Kenansville will have a utilization rate of 88.75% or 3.55 patients per station per week ( $71 \text{ patients} / 20 \text{ stations} = 3.55$ ;  $3.55 / 4 = 0.8875$  or 88.75%) at the end of OY 1. The projected utilization of 3.55 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- the applicant begins with the in-center patient population as of December 31, 2018.
- the applicant uses a 2.5% growth rate to project utilization, which is higher than the Five-Year AACR for Duplin County, but lower than the 11.0% growth the facility has experienced over the last five years.
- the applicant holds the patient population from outside Duplin County constant, and
- the utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

**Access**

In Section B.3, page 13, the applicant states that, by policy, the proposed services will be available to all patients in need of dialysis, without regard to race, sex, age, handicap, socioeconomic status or the ability to pay. In Section L.1, page 47, the applicant provides the projected payor mix during OY 2, as illustrated below.

<b>SEDC - KENANSVILLE PROJECTED PAYOR MIX OY 2</b>	
<b>PAYMENT CATEGORY</b>	<b>PERCENT OF TOTAL REVENUE</b>
Medicare	82.1%
Medicaid	9.0%
Commercial Insurance	7.5%
Other	1.5%
<b>Total*</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville and relocate no more than one existing station from Wallace Dialysis Center for a total of no more than 20 dialysis stations at SEDC-Kenansville upon completion of this project and Project ID #P-11680-19 (add two stations).

In Section D, pages 26 - 28, the applicant explains why it believes the needs of the population presently dialyzing at Wallace Dialysis Center will be adequately met following the relocation of one dialysis station to SEDC Kenansville. The applicant states the new facility is “*in close proximity*” to the existing facility; thus the facility will continue to be accessible to the same population, just in a new location.

On page 26 the applicant states Wallace Dialysis was dialyzing 60 in-center patients, 53 of whom were Duplin County residents and seven of whom lived outside of Duplin County. The applicant’s assumptions for projected utilization of Wallace Dialysis Center are summarized as follows:

- The applicant projects growth in the Duplin County in-center patients using the 1.4% Duplin County 5-year AACR as published in the January 2019 SDR.
- The applicant does not project growth in the patients who reside outside of Duplin County.
- The facility was serving 19 home hemo-dialysis patients as of December 31, 2018.
- The applicant projects that the home hemodialysis patient population will increase by one patient per year.
- The period of growth begins January 1, 2019 and projects forward to December 31, 2022, the end of the second project year following completion of this project.

The following table, from page 27, illustrates projected utilization of Wallace Dialysis Center:

**Projected Patients, Wallace Dialysis Center**

	# STATIONS	# PATIENTS/CALCULATIONS
Begin with the facility census as of December 31, 2018.	19	60
Project Duplin County patients forward one year to December 31, 2019 by 1.4%.*	--	$53 \times 1.014 = 53.74$
Add seven patients from outside Duplin County.	--	$53.74 + 7 = 60.74$
Project Duplin County patients forward one year to December 31, 2020 by 1.4%.	--	$53.74 \times 1.014 = 54.49$
Add seven patients from outside Duplin County.	--	$54.49 + 7 = 61.49$
1 station to relocate from Wallace Dialysis	$19 - 1 = 18$	--
Add two stations pursuant to Project ID #P-11601-18. This is the number of stations as of 1/1/21.	$18 + 2 = 20$	--
Project Duplin County patients forward one year to December 31, 2021 by 1.4%. This is the end of OY 1.	--	$54.49 \times 1.014 = 55.26$
Add seven patients from outside Duplin County.	--	$55.26 + 7 = 62.26$
Project Duplin County patients forward one year to December 31, 2022 by 1.4%.	--	$55.26 \times 1.014 = 56.03$
Add seven patients from outside Duplin County. This is the end of OY 2.	--	$56.03 + 7 = 63.03$

\*On page 27, the applicant states the growth is by 3.9%; however, the calculations use 1.4%. The project analyst concludes that the stated 3.9% is thus a typographical error.

Thus, on December 31, 2021, the applicant projects that Wallace Dialysis Center will dialyze 62 patients on 20 in-center stations, which is a utilization rate of 77.5%, or 3.1 patients per station per week [ $62 / 20 = 3.1$ ;  $3.1 / 4 = 0.775$ ]. The needs of the patients currently served at Wallace Dialysis Center will continue to be adequately met following the relocation of one station to SEDC-Kenansville.

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

- The applicant utilizes the 1.4% Duplin County 5-year AACR as published in the January 2019 SDR to project in-center patient utilization at Wallace Dialysis Center following the relocation of one station to SEDC-Kenansville.
- The applicant accounts for the approval of stations pursuant to Project ID# P-11601-18.
- The applicant projects growth only of the Duplin County patient population dialyzing at Wallace Dialysis Center and adds patients who reside in other counties and that choose to dialyze at that facility at the end of the growth projections.

In Section D.2, on page 28, the applicant states the relocation of stations as proposed in this application will have no effect on the ability of low-income persons, racial and ethnic minorities, women, handicapped, elderly and other groups to obtain needed health care.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate the entire 17-station dialysis facility to a new location in Kenansville and relocate no more than one existing station from Wallace Dialysis Center for

a total of no more than 20 dialysis stations at SEDC-Kenansville upon completion of this project and Project ID #P-11680-19 (add two stations).

In Section E.1, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - the applicant states that based on the current facility condition, including the repeated need for mold remediation, this alternative was dismissed.
- Renovate the current facility and develop the previously approved Warsaw Dialysis – the applicant states that because of the existing facility’s age and condition, renovation would be more costly than the proposed project.

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

- the condition of the existing facility is not adequate to continue to meet patient need,
- the applicant’s projected utilization indicates that the facility will be well utilized, and
- maintaining the status quo does not address the demonstrated need for mold remediation at the existing facility.

### **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. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, the applicant shall materially comply with the last made representation.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall relocate one existing dialysis station from Wallace Dialysis Center to Southeastern Dialysis Center – Kenansville, for a total of no more than 20 dialysis stations at Southeastern Dialysis Center – Kenansville upon completion of this project and Project ID #P-11680-19.**

3. **Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than 20 dialysis stations which shall include any isolation stations.**
  4. **Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify one dialysis stations at Wallace Dialysis Center for a total of no more than 20 dialysis stations at Wallace Dialysis Center.**
  5. **Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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, Total Renal Care of North Carolina, LLC (TRC) proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville, and relocate no more than one existing station from Wallace Dialysis Center for a total of no more than 20 dialysis stations at SEDC-Kenansville upon completion of this project and Project ID #P-11680-19 (add two stations).

**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	\$ 85,130
Construction Costs	\$1,100,750
Miscellaneous Costs	\$ 836,002
<b>Total</b>	<b>\$2,021,882</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 31, the applicant states there will be no start-up costs or initial operating expenses associated with this relocation project since SEDC Kenansville is an existing operational facility.

**Availability of Funds**

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

TYPE	DAVITA
Accumulated Reserves/OE*	\$2,021,882
<b>Total</b>	<b>\$2,021,882</b>

Exhibit F-2 contains a letter dated May 5, 2019 from the DaVita Chief Accounting Officer, authorizing and committing accumulated reserves for the capital costs of the project. Exhibit F-7 contains a copy of the Consolidated Financial Statements for DaVita, Inc. for the year ending December 31, 2017. The report indicates that as of December 31, 2017, DaVita had \$508 million in cash and cash equivalents, \$18.9 billion in total assets and \$5.7 billion in net assets (total assets less total liabilities).

**Financial Feasibility**

In Section R, the applicant provided pro forma financial statements for the first two operating years of the project. In the pro forma financial statement (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.

	OPERATING YEAR 1 CY2021	OPERATING YEAR 2 CY2022
Total Treatments	10,448	10,722
Total Gross Revenues (Charges)	\$3,370,838	\$3,459,061
Total Net Revenue	\$3,193,220	\$3,276,795
Average Net Revenue per Treatment	\$305	\$305
Total Operating Expenses (Costs)	\$2,339,479	\$2,395,366
Average Operating Expense per Treatment	\$223	\$223
Net Income	\$853,741	\$881,428

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 that the capital costs are based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville, and relocate no more than one existing station from Wallace Dialysis Center for a total of no more than 20 dialysis stations at SEDC-Kenansville upon completion of this project and Project ID #P-11680-19 (add two stations).

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

According to the January 2019 SDR, there are two operational dialysis facilities and one approved, but not yet operational facility in Duplin County, all of which are operated by DaVita, Inc., the parent company of TRC, as shown in the table below.

DUPLIN COUNTY DIALYSIS FACILITIES					
FACILITY	OWNER	LOCATION	# PATIENTS	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
Southeastern Dialysis Center - Kenansville	DaVita	Kenansville	63	17	92.65%
Wallace Dialysis	DaVita	Wallace	63	16	98.44%
Warsaw Dialysis*	DaVita	Warsaw	0	0	0.00%
<b>Totals</b>			<b>126</b>	<b>33</b>	<b>95.45%</b>

Source: Table B, January 2019 SDR.

\*Projected to be operational in January 2020

Note: The CON for Warsaw Dialysis Center was relinquished as of May 15, 2019.

As illustrated in the table above, both existing facilities operated with a utilization of above 90% with a county utilization of 3.8 patients per station per week, which is based on a total 126 patients dialyzing on 33 stations [126/33=3.8181] or 95.45% [3.8181/4=0.9545], as reported on Table B of the January 2019 SDR.

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

*“As of June 30, 2018 there were two operational dialysis facilities in Duplin County with a total of 33 certified stations. This certificate of need application does not propose to increase the number of stations in Duplin County. Relocating all the existing and pending stations from SEDC Kenansville and one station from Wallace Dialysis to a facility at a different location within the same county will allow DaVita to better serve its current and projected patients, but it will not result in the duplication of existing resources.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates the need to relocate the existing SEDC Kenansville facility and to relocate one station from Wallace Dialysis.

### **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 Form H in Section Q, 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 YEAR 2
Registered Nurse	3.00	3.00
Patient Care Technician	7.00	8.00
Administrator	1.00	1.00
Dietitian	0.50	1.00
Social Worker	0.50	1.00
Administration/Business Office	1.00	1.00
Biomed Technician	0.50	0.50
<b>Total</b>	<b>13.50*</b>	<b>15.50</b>

\*The applicant totaled this column in the application as 14 FTEs; the corrected total is reflected in the table.

The assumptions and methodology used to project staffing are provided in Sections H and Q. 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 Section H, page 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I, the applicant provides a letter from the medical director, Dr. John Herion, indicating his interest in continuing to serve as the medical director of SEDC - Kenansville. In Exhibit H, the applicant provides supporting documentation.

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 38, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>SEDC - KENANSVILLE ANCILLARY AND SUPPORT SERVICES</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	New River Dialysis
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Vidant Duplin Hospital
Emergency care	Vidant Duplin Hospital
Blood bank services	Vidant Duplin Hospital
Diagnostic and evaluation services	Vidant Duplin Hospital
X-ray services	Vidant Duplin Hospital
Laboratory services	DaVita Laboratories Services, Inc.
Pediatric nephrology	Vidant Duplin Hospital
Vascular surgery	Vidant Duplin Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab Services
Transportation	Duplin County Transportation Dept.

In Section I.2, page 39, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant 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. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

C

In Section K, page 41, the applicant states that the project involves constructing 9,000 square feet of new space. Line drawings are provided in Exhibit K-1. The applicant states the project will be developed by Team Genesis Project Management, a team of project managers with DaVita.

On page 41, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 42, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 42 - 43, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 43 - 44, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

### **Conclusion**

The Agency reviewed the:

- Application and
- Exhibits to the application

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

(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.1, page 46, the applicant provides the historical payor mix during CY 2018 for both SEDC Kenansville and Wallace Dialysis, as shown below.

<b>SEDC - KENANSVILLE HISTORICAL PAYOR CY 2018</b>	
<b>Payment Category</b>	<b>Percent of Total Revenue</b>
Medicare	82.1%
Medicaid	9.0%
Commercial Insurance	7.5%
Other	1.5%
<b>Total*</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

<b>WALLACE DIALYSIS HISTORICAL PAYOR CY 2018</b>		
<b>Payment Category</b>	<b>IC % of Total Revenue</b>	<b>PD* % of Total Revenue</b>
Medicare	71.7%	
Medicaid	6.7%	
Commercial Insurance	10.0%	
Other	11.7%	
<b>Total*</b>	<b>100.0%</b>	

\*IC refers to in-center patients and PD refers to peritoneal dialysis patients  
 Note: Totals may not foot due to rounding

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.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial and Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>
Duplin	17%	51%	48%	25%	12%	21%
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 25-26<sup>1</sup>) 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.

**Conclusion**

The Agency reviewed the:

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

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

C

In Section L, page 47, the applicant states it is under no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 47, the applicant states, "*There have been no civil rights equal access complaints filed against SED Kenansville or Wallace Dialysis within the last five years.*"

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 47, the applicant provides the projected payor mix during OY 2, as illustrated below.

SEDC - KENANSVILLE PROJECTED PAYOR MIX OY2	
PAYMENT CATEGORY	% OF TOTAL REVENUE
Medicare	82.1%
Medicaid	9.0%
Commercial Insurance	7.5%
Other	1.5%
<b>Total*</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

As shown in the table above, OY 2, the applicant projects 82.1% of total services will be provided to Medicare patients and 9.0% to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology used to project payor mix during OY 2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at SEDC - Kenansville.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

In Section L.4, page 48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application, and
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 49, 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.

**Conclusion**

The Agency reviewed the:

- Application, and
- Exhibits to the application

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

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

C

The applicant proposes to relocate the entire 17-station dialysis facility to a new location in Kenansville, and relocate no more than one existing station from Wallace Dialysis Center for a total of no more than 20 dialysis stations at SEDC-Kenansville upon completion of this project and Project ID #P-11680-19 (add two stations).

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

According to the January 2019 SDR, there are two operational dialysis facilities and one approved, but not yet operational facility in Duplin County, all of which are operated by DaVita, Inc., the parent company of TRC, as shown in the table below.

DUPLIN COUNTY DIALYSIS FACILITIES					
FACILITY	OWNER	LOCATION	# PATIENTS	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
Southeastern Dialysis Center - Kenansville	DaVita	Kenansville	63	17	92.65%
Wallace Dialysis	DaVita	Wallace	63	16	98.44%
Warsaw Dialysis*	DaVita	Warsaw	0	0	0.00%
<b>Totals</b>			<b>126</b>	<b>33</b>	<b>95.45%</b>

Source: Table B, January 2019 SDR.

\*Projected to be operational in January 2020

Note: The CON for Warsaw Dialysis Center was relinquished as of May 15, 2019.

As illustrated in the table above, both existing facilities operated with a utilization of above 90% with a county utilization of 3.8 patients per station per week, which is based on a total 126 patients dialyzing on 33 stations  $[126/33=3.8181]$  or 95.45%  $[3.8181/4=0.9545]$ , as reported on Table B of the January 2019 SDR.

In Section N.1, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

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

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 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 Form A, Section Q, the applicant provides a table that shows DaVita Inc. owns and operates over 90 dialysis facilities in North Carolina.

In Section O.3, page 52, 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, Waynesville Dialysis Center and Southeastern Dialysis Center - Wilmington. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. The applicant states that the problems in Southeastern Dialysis Center-Wilmington have been corrected and that facility was back in compliance as of March 21, 2018. The applicant states the North Carolina State Survey Agency is projected to return to Waynesville Dialysis in June 2019 following a Plan of Correction submitted by that facility. The applicant states it anticipates the facility will be back in compliance on the date of the return survey. 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

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.2203(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- SEDC - Kenansville is an existing facility.

*.2203(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 19 - 20, the applicant demonstrates that SEDC - Kenansville will serve a total of 71 in-center patients at the end of OY 1 (CY 2021) for a utilization rate of 88.8% or 3.55 patients per station per week (71 patients / 20 stations = 3.55;  $3.55 / 4 = 0.888$  or 88.8%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C, pages 19 - 20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.