

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 14, 2019

Findings Date: June 14, 2019

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: P-11680-19

Facility: Southeastern Dialysis Center - Kenansville

FID #: 945251

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than two dialysis stations for a total of no more than 19 stations upon project completion

### 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

Total Renal Care of North Carolina, LLC (TRC) proposes to add no more than two dialysis stations for a total of no more than 19 dialysis stations at Southeastern Dialysis Center - Kenansville (SEDC - Kenansville) upon project completion.

The applicant previously filed an application, Project I.D. # P-11546-18 to develop Warsaw Dialysis by relocating seven dialysis stations from SEDC - Kenansville and three dialysis stations from Wallace Dialysis Center. However, the applicant relinquished that certificate of need (CON) on May 15, 2019. Thus, the seven stations previously approved to be relocated from the facility will remain at SEDC - Kenansville, resulting in a total of 19 dialysis stations at the facility upon project completion and not 12 dialysis stations as stated throughout the application.

**Need Determination**

The 2019 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 D in the January 2019 Semiannual Dialysis Report (SDR), there is a deficit of four dialysis stations in Duplin County. Therefore, there is no county need determination for new dialysis stations in Duplin County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for SEDC – Kenansville in the January 2019 SDR is 3.7059 patients per station per week. This utilization rate was calculated based on 63 in-center dialysis patients and 17 certified dialysis stations as of June 30, 2018 (63 patients / 17 stations = 3.7059 patients per station per week). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to 11 additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		92.65%
Certified Stations		17
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>17</b>
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		63
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		44
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	19
	Multiply the difference by 2 for the projected net in-center change	38
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.8636
(ii)	Divide the result of step (i) by 12	0.0720
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.4318
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	90.2045
(v)	Divide the result of step (iv) by 3.2 patients per station	28.1889
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>11</b>

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

## Policies

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles* on page 31 of the 2019 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

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

### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a and d), pages 9 and 11, Section K.1(g), page 39, Section N.1, page 49, Section O, page 50 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b and d), pages 10-11, Section C.3, page 15, Section L, pages 43-47, Section N.1, page 49 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Sections B.4(c and d), page 11, Section K.1, pages 38-39, Section N, page 49, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

## **Conclusion**

The Agency reviewed the:

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

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

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

## C

TRC proposes to add no more than two dialysis stations for a total of no more than 19 dialysis stations at SEDC - Kenansville upon project completion.

## **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.8, page 18 and C.1, page 13, the applicant provides the historical and the projected patient origin for in-center (IC) patients, respectively, as illustrated in the tables below.

<b>SEDC - Kenansville Current as of June 30, 2018</b>		
<b>County</b>	<b>In-Center Patients</b>	<b>Percent of Total</b>
Duplin	59.0	93.7%
Greene	1.0	1.6%
Lenoir	1.0	1.6%
Onslow	1.0	1.6%
Wake	1.0	1.6%
<b>Total*</b>	<b>63.0</b>	<b>100.0</b>

\*Note: Totals may not foot due to rounding

<b>County</b>	<b>OY1 CY2021</b>	<b>OY2 CY2022</b>	<b>County Patients as % of Total</b>	
	<b>In-Center Patients</b>	<b>In-Center Patients</b>	<b>OY1</b>	<b>OY2</b>
Duplin	35.0	36.0	89.7%	90.0%
Greene	1.0	1.0	2.6%	2.5%
Lenoir	1.0	1.0	2.6%	2.5%
Onslow	1.0	1.0	2.6%	2.5%
Wake	1.0	1.0	2.6%	2.5%
<b>Total*</b>	<b>39.0</b>	<b>40.0</b>	<b>100.0%</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

The applicant does not currently offer hemodialysis (HHD) training or peritoneal dialysis (PD) training and support services at SEDC - Kenansville, nor does the applicant plan to offer those services as a part of this application. Patients interested in those services are referred to New River Dialysis.

In Section C, pages 13-15, 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 B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2018 SDR and the January 2019 SDR. The facility need methodology shows a need for more than 10 dialysis stations and the proposed project is for two additional dialysis stations.

In Section C.1 pages 13-15, the applicant states:

- The applicant begins the projections for the future patient population of SEDC - Kenansville by using the ending in-center patient census of 63 patients, as of June 30,

2018. Of those in-center patients, 59 were residents of Duplin County and four resided outside the county.

- In Project I.D. # P-11546-18, the applicant was approved to relocate seven dialysis stations from SEDC – Kenansville to help develop a new facility, Warsaw Dialysis, in Duplin County. The applicant also proposed to transfer 25 in-center patients from SEDC - Kenansville to Warsaw Dialysis upon project completion which was projected for January 1, 2020.
- However, the applicant relinquished the CON for Warsaw Dialysis Center on May 15, 2019. Thus, no stations will be relocated, nor will any patients be transferred. The Project Analyst will add the stations and the patients previously proposed to leave the facility back in at the appropriate times in the methodology for projected utilization.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Duplin County which is 1.4%, as published in the January 2019 SDR, to project the Duplin County patient population forward.
- 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 June 30, 2018 and applies the Duplin County AACR of 1.4%, as illustrated in the following table, from page 14 of the application:

Date	# Patients	Growth Rate	End Patients	+ Out of SA Patients	Total Year End Census	Year End Date
7/1/2018	59	1.007	59.413	4	63.413	12/31/2018
1/1/2019	59.413	1.014	60.24478	4	64.24478	12/31/2019
1/1/2020	60 - 25 = 35 [60 +25 = 85]	1.014	35.49 [86.19]	4	39.49 [90.19]	12/31/2020
01/01/2021 <b>OY1</b>	35.49 [86.19]	1.014	35.98686 [87.39666]	4	39.98686 [91.39666]	12/31/2021
01/01/2022 <b>OY2</b>	39.98686 [87.39666]	1.014	36.49068 [88.62021]	4	40.49068 [92.62021]	12/31/2022

Note: The Project Analyst adds back in the seven stations to be relocated and the 25 patients proposed to transfer to Warsaw Dialysis (Project I.D. # P-11546-18).

The applicant rounded down to the nearest whole number for OY1 and OY2. The applicant projects to serve 91 in-center patients at the end of OY1 and 92 in-center patients at the end of OY2. Thus, the applicant projects that SEDC - Kenansville will have a utilization rate of 119.7% or 4.79 patients per station per week (91 patients / 19 stations = 4.79 / 4 = 1.197 or 119.7%) at the end of OY1. The projected utilization of 4.79 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- the applicant begins with the existing in-center patients,
- the applicant grows the Duplin County in-center patients using the Duplin County 5-year AACR (1.4%) and holds the patient population from other counties constant, and
- the utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

The applicant does not currently provide home hemodialysis (HHD) or peritoneal dialysis (PD) nor are those services proposed in this application. In Section I.1, page 34, the applicant states that HHD and PD services will be provided by New River Dialysis.

Access

In Section C.3, page 15, 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 44, the applicant provides the projected payor mix during OY2, as illustrated below.

<b>SEDC - Kenansville Projected Payor Mix OY2</b>	
<b>Payment Category</b>	<b>Percent of Total Revenue</b>
Medicare	26.2%
Medicaid	7.7%
Commercial Insurance	7.7%
Medicare / Commercial	27.7%
Medicare / Medicaid	30.8%
<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.

NA

The applicant does not propose to reduce, eliminate or relocate a facility or a service. The applicant proposes to add two dialysis stations to an existing facility pursuant to the facility need determination. 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

TRC proposes to add no more than two dialysis stations for a total of no more than 19 dialysis stations at SEDC - Kenansville upon project completion.

In Section E.1, page 22, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states that based on the growth rate at SEDC - Kenansville this alternative was dismissed.
- Relocate existing stations from another DaVita facility in Duplin County - The applicant states that both of its operational facilities in Duplin County operated with a utilization above 80%. Therefore, this alternative was rejected.

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 facility is operating above 80% capacity,
- the applicant's application of the facility need methodology, as published in the January 2019 SDR, indicates a need for more than ten additional stations, and



- maintaining the status quo does not address the high utilization and need for additional stations at the 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.**
  - 2. Pursuant to the facility need determination in the January 2019 SDR, the applicant shall develop no more than two additional dialysis stations for a total of no more than 19 certified stations at Southeastern Dialysis Center - Kenansville upon project completion, which shall include any home hemodialysis training or isolation stations.**
  - 3. 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

TRC proposes to add no more than two dialysis stations for a total of no more than 19 dialysis stations at SEDC - Kenansville upon project completion.

### **Capital and Working Capital Costs**

In Section F.1, page 23 and Section F.10, pages 25-26, the applicant states that there will be no capital cost, start-up or initial operating expenses associated with the proposed project as SEDC - Kenansville is an existing facility.

### **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.

	<b>Operating Year 1 CY2021</b>	<b>Operating Year 2 CY2022</b>
Total Treatments	5,780	5,854
Total Gross Revenues (Charges)	\$1,758,078	\$1,781,331
Total Net Revenue	\$1,688,408	\$1,710,739
Average Net Revenue per Treatment	\$292	\$292
Total Operating Expenses (Costs)	\$1,665,962	\$1,694,554
Average Operating Expense per Treatment	\$288	\$289
Net Income	\$22,446	\$16,186

The Project Analyst notes that the applicant’s pro forma financial statement is based on the assumption that seven stations and 25 patients would be leaving the facility pursuant to Project I.D. # P-11546-18, Warsaw Dialysis Center. However, the CON for Warsaw Dialysis Center was relinquished as of May 15, 2019. Thus, no stations or patients will be relocating to that facility. As a result, SEDC - Kenansville will have more stations and patients that are not included in the pro forma financial statements above. However, even with the increase in gross revenue and operating expenses from an increase in total treatments, revenues are reasonably likely to exceed operating expenses in the first two operating years of the project.

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 because 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.

TRC proposes to add no more than two dialysis stations for a total of no more than 19 dialysis stations at SEDC - Kenansville upon project completion.

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	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
Southeastern Dialysis Center - Kenansville	DaVita	Kenansville	17	92.65%
Wallace Dialysis	DaVita	Wallace	16	98.44%
Warsaw Dialysis*	DaVita	Warsaw	0	0.00%

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 29, 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:

*“Both of the operational DaVita facilities in Duplin County were operating at 80% utilization or greater as reported in the January 2019 SDR. Therefore, each facility has the potential for adding stations, given that they show a need. In Section B-2 and Section C of this application, we demonstrate the need that SEDC - Kenansville has for adding stations. While adding stations at this facility does increase the number of stations in Duplin County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

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

- The applicant adequately demonstrates the need for the additional two stations based on the facility need methodology.
- The applicant demonstrates that the proposed stations are needed in addition to the existing or approved stations in Duplin County.

**Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H.1, page 30, the applicant provides 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	2.00
Patient Care Technician	7.00	5.00
Administrator	1.00	1.00
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Administrative Assistant	1.00	1.00
Biomed Technician	0.50	0.50
<b>Total</b>	<b>13.50</b>	<b>10.50</b>

The applicant provides projected direct care staff in OY2 in Section H.7, page 33.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 31, 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 34, 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.3, pages 35-36, and Section I.4, page 36, 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.

NA

The applicant does not propose any new construction or renovation of existing space as part of this project. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
  - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 47, the applicant provides the historical payor mix during CY2018, as shown below.

<b>SEDC - Kenansville Current Payor CY2018</b>	
<b>Payment Category</b>	<b>Percent of Total Revenue</b>
Medicare	26.2%
Medicaid	7.7%
Commercial Insurance	7.7%
Medicare / Commercial	27.7%
Medicare / Medicaid	30.8%
<b>Total*</b>	<b>100.0%</b>

\*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.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
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:

- 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.

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



- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

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

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

In Section L.6, page 46, the applicant states, *“There have been no civil rights equal access complaints filed 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.1, page 44, the applicant provides the projected payor mix during OY2, as illustrated below.

<b>SEDC - Kenansville Projected Payor Mix OY2</b>	
<b>Payment Category</b>	<b>Percent of Total Revenue</b>
Medicare	26.2%
Medicaid	7.7%
Commercial Insurance	7.7%
Medicare / Commercial	27.7%
Medicare / Medicaid	30.8%
<b>Total*</b>	<b>100.0%</b>

\*Note: Totals may not foot due to rounding

As shown in the table above, OY2, the applicant projects 84.7% of total services will be provided to Medicare patients (includes Medicare, Medicare/Commercial and Medicare/Medicaid) and 7.7% to Medicaid patients.

On page 44, the applicant provides the assumptions and methodology used to project payor mix during OY2. 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 46, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M.1, page 48, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

TRC proposes to add no more than two dialysis stations for a total of no more than 19 dialysis stations at SEDC - Kenansville upon project completion.

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	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
Southeastern Dialysis Center - Kenansville	DaVita	Kenansville	17	92.65%
Wallace Dialysis	DaVita	Wallace	16	98.44%
Warsaw Dialysis*	DaVita	Warsaw	0	0.00%

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

*“The 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 Total Renal Care of North Carolina, LLC.”*

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 Section A.11, page 5, the applicant states DaVita Inc. owns and operates over 90 dialysis facilities in North Carolina. In Exhibit A-11, the applicant provides a list of those facilities.

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

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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 13 - 15, the applicant demonstrates that SEDC - Kenansville will serve a total of 39 in-center patients at the end of OY 1 (CY 2021) for a utilization rate of 81.3 or 3.25 patients per station per week (39 patients / 12 stations = 3.25 / 4 = 0.8125 or 81.3%). However, this utilization was based on seven stations and 25 in-center patients being relocated to Warsaw Dialysis Center pursuant to Project I.D. # P-11546-19. The applicant relinquished the CON on May 15, 2019. Thus, no stations will be relocated, nor will any patients be transferred. Therefore, the applicant projects to serve 91 in-center patients at the end of OY1 for a utilization rate of 119.7% or 4.79 patients per station per week (91 patients / 19 stations = 4.79 / 4 = 1.197 or 119.7%) at the end of OY1. 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 13 - 15, 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.