

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2019

Findings Date: December 18, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: P-11789-19

Facility: Southeastern Dialysis Center- Kenansville

FID #: 945251

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 4 stations for a total of no more than 24 stations upon project completion of this project, Project ID# P-11680-19 (add 2 stations) and Project ID# P-11711-19 (relocate entire facility and one station from Wallace Dialysis) which is a change of scope

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina, LLC (the applicant) proposes a change of scope (COS) for the approved, but undeveloped, Project ID # P-11711-19 (relocate entire Southeastern Dialysis Center-Kenansville (SEDC-Kenansville) facility and relocate one station from Wallace Dialysis). SEDC-Kenansville is currently certified for 17 dialysis stations.

In this COS application, the applicant proposes to add four stations at SEDC-Kenansville for a total of 24 stations upon completion of this project, Project ID # P-11711-19 (relocate entire facility and relocate one station from Wallace Dialysis) and Project ID # P-11680-19 (add two

stations). SEDC-Kenansville does not currently offer either a peritoneal dialysis (PD) or a home hemodialysis (HHD) program.

**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 the July 2019 Semiannual Dialysis Report (SDR), Table D, page 62, the county need methodology shows there is a deficit of two stations in Duplin County, but because the deficit is less than 10 stations there is no county need determination for new dialysis stations for 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 July 2019 SDR is 3.9412 patients per station per week. This utilization rate was calculated based on 67 in-center dialysis patients and 17 certified dialysis stations as of December 31, 2018 (67 patients /17 stations = 3.9412 patients per station per week). Application of the facility need methodology indicates that seven additional stations are needed for this facility, as illustrated in the following table.

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		98.5%
Certified Stations		17
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>20</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		67
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		63
Step	Description	Result
	Difference (SDR2 - SDR1)	4
(i)	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1270
(ii)	Divide the result of Step (i) by 12	0.0106
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.1270
(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	75.5079
(v)	Divide the result of Step (iv) by 3.2 patients per station	23.5962
	and subtract the number of certified and pending stations to determine the number of stations needed	3.5962

\*Note: Project Analyst corrected facility need table. In Section B, page 10, of the application, the applicant utilized an incorrect number of existing certified stations in the facility need table (20). The correct number of certified stations is 17. See page 42 of the July 2019 SDR. In addition, three dialysis stations were approved to be added to SEDC-Kenansville [See Project ID#P-11680-19 (add 2 stations) and Project ID#P-11711-19 (add 1 station)] subsequent to the publication of the July 2019 SDR

which have been added as “Pending Stations” in this facility need table. There is no material impact as the facility need table still shows a need for four new dialysis stations at SEDC-Kenansville and the proposed project is to add four new dialysis stations.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add four 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, pages 11-12, Section O, pages 46-47, and Exhibit B-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

**Promote Equitable Access** – The applicant describes how it believes the proposed project would promote equitable access in Section B, page 13, and Section C, page 22. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

**Maximize Healthcare Value** – The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 13, Section K, page 40, and Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

The applicant proposes to add four stations at SEDC-Kenansville for a total of 24 stations upon completion of this project, Project ID # P-11680-19 (add two stations) and Project ID # P-11711-19 (relocate entire facility and relocate one station from Wallace Dialysis) which is a COS.

SEDC-Kenansville does not currently offer either a peritoneal dialysis (PD) or a home hemodialysis (HHD) program. The parent company of Total Renal Care of North Carolina, LLC is DaVita, Inc. (DaVita).

### **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.*” SEDC-Kenansville is in Duplin County. Thus, the service area is Duplin County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected in-center (IC) patient origin.

County	Current (CY2018)		Second Full FY of Operation following Project Completion (CY 2022)	
	IC Patients	% of Total	IC Patients	% of Total
Duplin	61	91.0%	75	92.6%
Greene	1	1.5%	1	1.2%
Lenoir	1	1.5%	1	1.2%
Onslow	1	1.5%	2	2.5%
Pender	0	0.0%	1	1.2%
Wake	1	1.5%	0	0.0%
Wayne	0	0.0%	1	1.2%
Other States	2	3.0%	0	0.0%
Total	67	100.0%	81	100.0%

Source: Section C, pages 17 -18.

In Section C, pages 17-20, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 17-21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.1, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2019 SDR.

- The July 2019 SDR shows that SEDC Kenansville operated at a utilization rate of 98.53 percent (3.9412 patients per station per week) as of December 31, 2018 and had 67 IC patients of which 61 were residents of Duplin County and 6 were residents of other counties/states.
- The applicant states that as of June 30, 2019, SEDC Kenansville had 70 IC patients, 64 of whom were residents of Duplin County with six patients residing in other counties.
- The applicant begins the projections for the future patient population of SEDC-Kenansville by using the ending in-center patient census of 64 patients from Duplin County, as of June 30, 2019.
- The applicant uses a projected annual growth rate of 5.0% which, while above the Five-Year Average Annual Change Rate (AACR) for Duplin County of 0.03%, is conservative as compared to SEDC Kenansville’s 11.0% average growth rate over the past five years due, in part, to the closure of a competitor’s facility. In the table below, the Project Analyst calculated the 5-year compound annual growth rate (CAGR) and the two-year CAGR for IC patients at SEDC-Kenansville.

	6/30/14	6/30/15	6/30/16	6/30/17	6/30/18	6/30/19	5 YR CAGR	2 YR CAGR
# of IC Patients	46	44	41	46	63	70	8.76%	23.36%

Source: ESRD Data Collection Forms for SEDC-Kenansville.

Based on the 5-year CAGR of 8.76% and the 2-year CAGR of 23.36% for SEDC-Kenansville the applicants use of a 5.0% annual growth rate in this application is reasonable and supported.

- The applicant does not project an increase in the six patients who utilize the facility and live in other counties but adds them in at the appropriate time.
- The applicant includes the three stations to be added from Project ID #P-11680-19 (add two stations) and Project ID # P-11711-19 (add one station and relocate the facility) upon certification of the relocated facility projected for January 1, 2021.
- The applicant projects the first full operating year of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year will be January 1, 2022 – December 31, 2022 (CY2022).

The information is reasonable and adequately supported for the following reasons:

- According to the July 2019 SDR, as of December 31, 2018, SEDC-Kenansville was operating at a rate of 3.9412 patients per station per day, or 98.53 percent utilization.
- The applicant demonstrates eligibility to add four dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

*Projected Utilization*

In Section C, pages 17-20, and Section Q, the applicant describes its need methodology and assumptions for projected IC utilization as summarized in the following table.

<b>SEDC-Kenansville</b>	<b>In-Center Patients</b>
As of July 1, 2019, there were 64 Duplin County IC patients	64
Project the Duplin County IC patients forward six months to December 31, 2019, based on an annual growth rate of 5.0%.	$1.025 \times 64 = 65.6$
Project the Duplin County IC patients forward one year to December 31, 2020, based on an annual growth rate of 5.0%.	$1.05 \times 65.6 = 68.88$
Project the Duplin County IC patients forward one year to December 31, 2021, based on an annual growth rate of 5.0%.	$1.05 \times 68.88 = 72.324$
Add the 6 patients from outside Duplin County. This is the ending patient census as of December 31, 2021. <b>This is the IC patient census at the end of OY1.</b>	$72.324 + 6 = \mathbf{78.324}$
Project the Duplin County IC patients forward one year to December 31, 2021, based on an annual growth rate of 5.0%.	$1.05 \times 72.324 = 75.9402$
Add the 6 patients from outside Duplin County. This is the ending patient census as of December 31, 2021. <b>This is the IC patient census at the end of OY2.</b>	$75.9402 + 6 = \mathbf{81.9402}$

The applicant states on page 20 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 78 and 81 in-center patients, respectively.

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

- OY1: 3.25 patients per station per week, or 81.25% (78 patients / 24 stations = 3.25/ 4 = 0.08125or 81.25%).
- OY2: 3.375patients per station per week, or 84.4% (81 patients/24stations = 3.375/4 = 0.844or 84.4%).

The projected utilization of 3.25 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 starts with the 64 existing Duplin County patients utilizing the facility as of June 30, 2019.
- The applicant uses a projected annual growth rate of 5.0% which, while above the Five-Year Average Annual Change Rate (AACR) for Duplin County of 0.03%, is conservative as compared to SEDC Kenansville’s historical average growth rate over the past five years due, in part, to the closure of a competitor’s facility.
- The applicant projects no growth for patients who utilize the facility and live in other counties.
- The utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

**Access**

In Section C, page 22, the applicant states:

*“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*

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

*SEDC Kenansville will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other under-served persons.”*

In the application for Project ID # P-11711-19, in Section L, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>SEDC - KENANSVILLE PROJECTED PAYOR MIX OY2</b>	
<b>PAYMENT CATEGORY</b>	<b>% 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. In Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### Conclusion

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose a reduction or elimination of a service, or the relocation of a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

## CA

The applicant proposes to add four stations at SEDC-Kenansville for a total of 24 stations upon completion of this project, Project ID # P-11680-19 (add two stations) and Project ID # P-11711-19 (relocate entire facility and relocate one station from Wallace Dialysis) which is a COS.

In Section E, page 27, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo- the applicant states that this alternative would not have addressed the growth at the facility and thus was not the least costly or most effective alternative.
- Relocate stations from another DaVita facility- the applicant states that it's other facility in Duplin County, Wallace Dialysis, is already operating at over 80% utilization (based on a patient census of 70 IC patients as of June 30, 2019). The project analyst notes that based on the ESRD Data Collection Form, Wallace Dialysis had 63 IC patients as of June 30, 2019, however, this is immaterial as the utilization rate was still over 80% [63 patients / 19 stations =  $3.3158/4 = 0.82895$  or 82.90%] and relocating stations from Wallace Dialysis would have negatively impacted current patients at Wallace Dialysis, therefore this alternative was not the least costly or most effective alternative

On page 27, the applicant states that its proposal is the most effective alternative because it ensures the facility will proactively address the issues of access and growth at the facility.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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 July 2019 SDR, Total Renal Care of North Carolina, LLC shall develop no more than four additional dialysis stations for a total of no more than 24 certified stations at Southeastern Dialysis Center-Kenansville upon completion of this project, Project ID# P-11680-19 (add 2 stations), and Project ID# P-11711-19 (relocate entire facility and relocate 1 station from Wallace Dialysis), 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 Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add four stations at SEDC-Kenansville for a total of 24 stations upon completion of this project, Project ID # P-11680-19 (add two stations) and Project ID # P-11711-19 (relocate entire facility and relocate one station from Wallace Dialysis) which is a COS.

**Capital and Working Capital Costs**

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

Site Costs	\$0
Construction Costs	\$0
Medical Equipment	\$71,116
<b>Total</b>	<b>\$71,116</b>

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

In Section F, page 30, the applicant states that there are no start-up costs or initial operating expenses since this is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 28, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	DaVita	Total
Loans	\$	\$
Accumulated reserves or OE *	\$71,116	\$71,116
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing</b>	<b>\$71,116</b>	<b>\$71,116</b>

\* OE = Owner's Equity

Exhibit F-2 contains a copy of a letter from the Chief Accounting Officer of DaVita which states that DaVita is the parent and 100% owner of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC and that DaVita has committed cash reserves for the capital costs of the project and will make those funds available to Total Renal Care of North Carolina, LLC. Further, Exhibit F-2 also contains a copy of Form 10K for DaVita, Inc., for year ending December 31, 2018. As shown on page F-6, Consolidated Statements of Cash Flow, Form 10K, DaVita, Inc. had adequate cash and assets to fund the capital and working capital cost of the proposed project.

**Financial Feasibility**

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

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year
Total Treatments	11,263	11,806
Total Gross Revenues (Charges)	\$3,633,811	\$3,808,903
Total Net Revenue	\$3,441,866	\$3,607,731
Average Net Revenue per Treatment	\$306	\$306
Total Operating Expenses (Costs)	\$2,550,617	\$2,637,443
Average Operating Expense per Treatment	\$226	\$223
Net Income	\$891,269	\$970,288

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add four stations at SEDC-Kenansville for a total of 24 stations upon completion of this project, Project ID # P-11680-19 (add two stations) and Project ID # P-11711-19 (relocate entire facility and relocate one station from Wallace Dialysis) which is a COS.

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.” SEDC-Kenansville is in Duplin County. Thus, the service area is Duplin County. Facilities may also serve residents of counties not included in their service area.

According to Table B the July 2019 SDR, there are two existing dialysis facilities in Duplin County. Information on these dialysis facilities, from Table B of the July 2019 SDR, is provided below:

Dialysis Facility	# of Certified Stations as of 12/31/2018	Percent Utilization as of 12/31/2018	Patients Per Station as of 12/31/2018
Southeastern Dialysis Center- Kenansville	17	98.53%	3.9412
Wallace Dialysis	19	78.95%	3.1579

Source: Table B, July 2019 SDR, page 48.

In Section E, page 27, the applicant states, “While the July 2019 SDR reports that Wallace Dialysis is operating at 78.95%, there were 70 patients at the facility as of June 30, 2019 (as reported to DHSR Planning Section) for a utilization rate of 92.1%.” The project analyst notes that based on the ESRD Data Collection Form, Wallace Dialysis had 63 IC patients as of June 30, 2019 not 70 as stated by the applicant, however, this is immaterial as the utilization rate was still over 80% [63 patients / 19 stations = 3.3158/4 = 0.82895 or 82.90%], demonstrating that this facility is also well utilized.

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:

- There is a facility need determination in the 2019 SMFP for the proposed addition of four stations.
- The applicant adequately demonstrates the need patients have for the additional dialysis stations at this specific location in addition to the approved stations.

**Conclusion**

The Agency reviewed the:

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

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

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

C

In Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination except as set forth below.

In Section H, page 34, that applicant states that there were no changes proposed in this application except an updated staffing table as documented in Section Q, Form H, as illustrated below.

Position	Current FTE Positions	OY2 Projected FTE Positions [Project ID # P-11711-19]	OY2 Projected FTE Positions [current application]
RN	3.0	3.0	3.0
Technician (Patient Care)	7.0	8.0	9.0
Administrator	1.0	1.0	1.0
Dietician	0.5	1.0	1.0
Social Worker	0.5	1.0	1.0
Administrative/ Business Office	1.0	1.0	1.0
Bio-med Technician	0.5	0.5	0.5
<b>Total</b>	<b>13.5*</b>	<b>15.5</b>	<b>16.5*</b>

Source: Sections Q, Form H of the application.

\*Note: In Form H, for the current year and OY2, the total FTEs are listed as 14 and 17 respectively. However, the correct totals are 13.5 and 16.5 respectively.

**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 all 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 Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **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.

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **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.

- (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 Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **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.

- (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 Project I.D. #P-11711-19, in Section L, page 47, the applicant provided 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 of Project ID #P-11711-19, 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.

In Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **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.

- (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 Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **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.

- (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 Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add four stations at SEDC-Kenansville for a total of 24 stations upon completion of this project, Project ID # P-11680-19 (add two stations) and Project ID # P-11711-19 (relocate entire facility and relocate one station from Wallace Dialysis) which is a COS.

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.*” SEDC-Kenansville is in Duplin County. Thus, the service area is Duplin County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # P-11711-19, the application was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

### **Conclusion**

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section Q, Form A Facilities, the applicant provides a list of the over 90 dialysis facilities in North Carolina owned and operated by DaVita.

In Section O.2, page 46, the applicant states that, during the 18 months immediately preceding the submittal of the application an incident of immediate jeopardy occurred in one of these facilities, Waynesville Dialysis Center. The applicant provides documentation regarding the deficiency and subsequent measures taken by that facility to ensure compliance with CMS Conditions for Coverage. In Section O, page 47 and in Exhibit O, the applicant states that the deficiency at Waynesville Dialysis Center has been corrected and that Waynesville Dialysis Center was back in compliance as of June 7, 2019. 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

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

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is not proposing to establish a new ESRD facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C, pages 17-20, and Section Q, the applicant demonstrates that SEDC Kenansville will serve a total of 78 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 81.25% or 3.25 patients per station per week (78 patients / 24 stations = 3.25/ 4 = 0.08125or 81.25%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 17-20, and Section Q, the applicant provides the assumptions and methodology used to project utilization of the facility.