

## **ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

### **FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2015

Findings Date: December 18, 2015

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: O-11086-15

Facility: Southeastern Dialysis Center-Burgaw

FID #: 945252

County: Pender

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Relocate 3 existing dialysis stations from Wallace Dialysis Center in Duplin County to Southeastern Dialysis Center-Burgaw for a total of 18 dialysis stations at Southeastern Dialysis Center-Burgaw and 13 dialysis stations at Wallace Dialysis Center upon completion of this project, Project ID#O-10125-13 (relocate 10 stations to establish a new facility) and Project ID #O-10348-14 (add 3 stations)

### **REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

G.S. 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

The applicant, Total Renal Care of North Carolina, LLC (TRC) d/b/a Southeastern Dialysis Center-Burgaw (SEDC-Burgaw) proposes to relocate three existing dialysis stations from Wallace Dialysis Center (WDC) to SEDC-Burgaw for a total of 13 dialysis stations at WDC and 18 dialysis stations at SEDC-Burgaw upon completion of this project, Project ID#O-10125-13 (relocate 10 stations to establish a new facility) and Project ID #O-10348-14 (add 3 stations). SEDC-Burgaw is located in Pender County. WDC is located in Duplin County. Pender and Duplin counties are contiguous.

### **Need Determination**

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations, and the Semiannual Dialysis Report (SDR) provides utilization data for dialysis facilities and counties. An applicant is eligible to apply for additional stations based on the county need methodology if the utilization of each facility in the county reported in the most recent SDR is at least 80% and the projected station deficit is 10 or greater. According to Table B in the July 2015 SDR, there is a surplus of five dialysis stations in Pender County; and according to Table A, utilization of the existing certified stations is under 80%; therefore, the applicant is ineligible to apply for additional stations based on the county need methodology.

An applicant is also eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. According to Table A in the July 2015 SDR, utilization of the existing dialysis stations at SEDC-Burgaw is 77.27%; therefore, the applicant is ineligible to apply for additional stations based on the facility need methodology. This utilization rate was calculated based on 68 in-center dialysis patients and 22 certified dialysis stations ( $68 / 28 = 3.09$ ;  $3.09 / 4 = 0.7727$  or 77.27%). Therefore, neither the county nor the facility need methodology in the 2015 SMFP is applicable to this review.

In addition, Basic Principle 6 in Chapter 14, page 362 of the 2015 SMFP states that “*No existing facility may expand unless its utilization is 80 percent or greater.*” In project ID #O-10125-13, the applicant was approved to develop Surf City Dialysis by relocating ten existing stations from SEDC-Burgaw. That project is complete. In Project ID # O-10348-14, the applicant was approved to add three dialysis stations to SEDC-Burgaw. The applicant states on page 13 that nine in-center patients have transferred to Surf City Dialysis, which left SEDC-Burgaw with 15 existing and approved in-center stations and 59 patients, which is a utilization rate of 98.3% [ $59 / 15 = 3.93$ ;  $3.93 / 4 = 0.9833$ ]. The utilization rate of 98% is above the minimum of 80% set forth in Basic Principle 6.

### **Policies**

There is one policy in the 2015 SMFP which is applicable to this review. *POLICY ESRD-2: Relocation of Dialysis Stations* on page 32 of the 2015 SMFP states:

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

- (1) *Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*

- (2) *Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

SEDC-Burgaw is located in Pender County and WDC is located in Duplin County. Duplin County is contiguous to Pender County. The applicant owns and operates both Wallace Dialysis Center and SEDC-Burgaw, which currently serves one Duplin County resident. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy ESRD-2 in the 2015 SMFP. Therefore, the application is conforming to this criterion.

- (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, Total Renal Care of North Carolina, LLC (TRC) d/b/a Southeastern Dialysis Center-Burgaw (SEDC-Burgaw) proposes to relocate three existing dialysis stations from Wallace Dialysis Center (WDC) to SEDC-Burgaw for a total of 18 dialysis stations at SEDC-Burgaw and 13 dialysis stations at WDC upon completion of this project, Project ID#O-10125-13 (relocate 10 stations to establish a new facility) and Project ID #O-10348-14 (add 3 stations). SEDC-Burgaw is located in Pender County. WDC is located in Duplin County. Pender and Duplin counties are contiguous.

### **Population to be Served**

On page 361, the 2015 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pender County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 17, the applicant provides a table showing the historical patient origin for in-center dialysis patients at SEDC-Burgaw, as shown below:

**SEDC-Burgaw Patient Origin  
 as of 12/31/2014**

COUNTY	# IN-CENTER PATIENTS
Pender	67
Duplin	1
<b>Total</b>	<b>68</b>

In Section C, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OY 1 IN CENTER PTS	OY 2 IN CENTER PTS	COUNTY PTS AS % OF TOTAL	
			OY 1	OY 2
Pender	63	65	98.4%	98.5%
Duplin	1	1	1.6%	1.5%
<b>Total</b>	<b>64</b>	<b>66</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology for the projections above on pages 13-15.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

The applicant proposes to relocate three existing dialysis stations from WDC to SEDC-Burgaw. SEDC-Burgaw is located in Pender County and WDC is located in Duplin County. Duplin County is contiguous to Pender County. Both facilities are owned and operated by the applicant and SEDC-Burgaw currently serves one Duplin County resident. Policy ESRD-2 allows for the relocation of stations between contiguous counties. The discussion regarding Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.

*Table B: ESRD Dialysis Station Need Determination by Planning Area* in the July 2015 SMFP indicates that Duplin County, the county in which WDC is located, had a surplus of three dialysis stations as of December 31, 2014. Additionally, Table B indicates that Pender County, the county in which SEDC-Burgaw is located and the county to which the stations are proposed to be relocated, had a deficit of five dialysis stations as of December 31, 2014. Thus, the applicant proposes to relocate three existing stations from a county which has a surplus of three stations to a county which has a deficit of five stations. Therefore, the applicant demonstrates that the proposal to relocate three existing stations from WDC in Duplin County to SEDC-Burgaw in Pender County will not result in a deficit in the number of dialysis stations in Duplin County, the county that would be losing stations. Furthermore, the applicant demonstrates that the proposal will not result in a surplus of dialysis stations in Pender County, the county that would be receiving the relocated stations.

In addition, Basic Principle 6 in Chapter 14, page 362 of the 2015 SMFP states that “*No existing facility may expand unless its utilization is 80 percent or greater.*” In project ID #O-10125-13, the applicant was approved to develop Surf City Dialysis by relocating ten existing stations from

SEDC-Burgaw. That project is complete. In Project ID # O-10348-14, the applicant was approved to add three dialysis stations to SEDC-Burgaw. The applicant states on page 13 that nine in-center patients have transferred to Surf City Dialysis, which left SEDC-Burgaw with 15 existing and approved in-center stations and 59 patients, which is a utilization rate of 98.3% [ $59 / 15 = 3.93$ ;  $3.93 / 4 = 0.9833$ ]. The utilization rate of 98% is above the minimum of 80% set forth in Basic Principle 6.

### Projected Utilization

In Section C, pages 14 and 16, the applicant projects to serve 64 in-center dialysis patients on 18 in-center stations at the end of the first operating year, which is 3.56 patients per station per week or an 88% utilization rate. On page 15, the applicant states the project does not currently provide home hemodialysis or peritoneal dialysis services at this facility.

In Section C, pages 13-16, the applicant provides the assumptions and methodology it uses to demonstrate the need that this population has for three relocated dialysis stations, as summarized below:

- Based on Table A in the July 2015 SDR, SEDC-Burgaw was dialyzing 68 in-center patients on 22 certified stations, yielding a station utilization rate of 77.3% ( $68 / 22 = 3.09$ ;  $3.09 / 4 = 0.7727$  or 77.3%) as of December 31, 2014.
- Of the 68 in-center patients dialyzing at SEDC-Burgaw, 67 were residents of Pender County, and one in-center patient was a resident of Duplin County.
- In Project ID #O-10125-13, the applicant was approved to develop a new facility, Hampstead Dialysis Center, by relocating ten existing stations from SEDC-Burgaw, which left SEDC-Burgaw with 12 in-center dialysis stations. In that application, the applicant also stated that nine in-center patients would transfer from SEDC-Burgaw to the new Hampstead Dialysis facility (Note: Hampstead Dialysis Center received a Declaratory Ruling by the Agency to change the site and the name to Surf City Dialysis. The facility is still located in Pender County). In Section C-1, page 13, the applicant states that Surf City Dialysis has been certified and nine in-center patients from SEDC-Burgaw have transferred.
- In Project ID #O-10348-14, the applicant was approved to add three stations to SEDC-Burgaw, for a total of 15 in-center dialysis stations.
- This project proposes to add three additional stations to SEDC-Burgaw, for a total of 18 stations. The applicant projects in-center patient utilization based on one half of the 6.2% five year average annual change rate (AACR) for Pender County, found in Table B in the July 2015 SDR. The applicant projects growth only for the Pender County patients. See the following calculations, based on 67 Pender County in-center patients at SEDC-Burgaw as of December 31, 2014, from page 14:

DATE	# SERVICE AREA PTS.	GROWTH RATE	TOTAL SERVICE AREA PTS.	# OUT OF SERVICE AREA PTS.	TOTAL IN-CENTER PATIENTS
As of 12/31/2014	67				
Current (CY 2015)	67	x 1.031	69.077	+ 1	70.077
Interim (CY 2016)	69.077	x 1.031	71.218	+ 1	72.218
OY 1 (CY 2017)	(71 – 9) = 62	x 1.031	63.922	+ 1	64.922
OY 2 (CY 2018)	63.922	x 1.031	65.903	+ 1	66.903

- The applicant projects that the facility will serve 65 in-center patients by the end of operating year one (OY1) for a utilization rate of 90%, or 3.61 patients per station per week. The applicant further projects that the facility will serve 67 in-center patients by the end of operating year two (OY2), for a utilization rate of 93%, or 3.72 patients per station per week.
- OY1 is Calendar Year 2017.
- OY2 is Calendar Year 2018.

The projected utilization of 3.56 patients per station per week at the end of OY1 (CY 2017) satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

**Access**

In Section C, page 15, the applicant states:

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

In Section L, page 49, the applicant provides the historical payor mix for SEDC-Burgaw, in which Medicare and Medicaid represented 84.5% of in-center dialysis treatments in calendar year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by TRC and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate three existing dialysis stations from Wallace Dialysis Center in Duplin County to SEDC-Burgaw in Pender County pursuant to Policy ESRD-2 in the 2015 SMFP. According to that policy, an applicant may apply to relocate existing dialysis stations within a county or in contiguous counties, contingent upon a showing that there would not be a deficit of stations in the county that would be losing stations as a result of the relocation; and that there would not be a surplus of stations in the county that would be gaining stations as a result of the relocation.

According to the July 2015 SDR, Table B, Duplin County had a surplus of three dialysis stations as of December 31, 2014. Likewise, Pender County had a deficit of five dialysis stations during the same time. Therefore, the relocation of stations from Duplin County to Pender County would help to decrease the surplus in Duplin County and the deficit of stations in Pender County.

**Utilization at Wallace Dialysis Center**

In Section D, page 20, the applicant states the project proposes to relocate three stations from Wallace Dialysis Center to SEDC-Burgaw. The project does not propose to transfer any patients with those stations. According to the July 2015 SDR, the Wallace Dialysis Center was dialyzing 60 in-center patients on 17 dialysis stations as of December 31, 2014, for a utilization rate of 88% [ $60 / 17 = 3.529$ ;  $3.529 / 4 = 0.8824$ ]. The following table shows projects and station relocations at Wallace Dialysis Center that occurred after December 31, 2014:

FACILITY	PROJECT ID#	# EXISTING STATIONS	DESCRIPTION	END RESULT
Wallace Dialysis Center	O-10348-14	17	Relocate 3 stations to SEDC-Burgaw	14
Wallace Dialysis Center	P-11014-15	14	Add two stations	16
Wallace Dialysis Center	O-11086-15	16	Relocate 3 stations to SEDC-Burgaw	13

On page 20, the applicant states that as of December 31, 2014, there were 49 Duplin County in-center patients and 11 in-center patients from other counties dialyzing at Wallace Dialysis Center. The applicant projects growth of only the Duplin County patients, as stated on page 20:

*“The July 2015 SDR indicated that Duplin County had a five year average annual change rate of 4.1% as indicated in Table B. The following are growth calculations for the Wallace Dialysis Center for the period January 1, 2015 through December 31, 2018, the proposed end of operating year two for the SEDC-Burgaw expansion based on the 49 Duplin County patients.*

- *January 1, 2015 - December 31, 2015 – 49 patients x 1.41 = 51.009*
- *January 1, 2016 - December 31, 2016 – 51.009 patients x 1.041 = 53.104*
- *January 1, 2017 – December 31, 2017 – 53.104 patients x 1.041 = 55.277*
- *January 1, 2018 – December 31, 2018 – 55.277 patients x 1.041 = 57.544*

*Based on the information above, the Wallace Dialysis Center would have 66 in-center patients (55 patients living in Duplin County and 11 patients living in other counties) at the end of operating year one for a utilization rate of [126.9%] or 5.1 patients per station and 68 in-center patients at the end of operating year two for a utilization rate of 130.8% or 5.2 patients per station. The patients at the Wallace Dialysis Center will have an adequate number of stations available since the facility will apply for additional stations on March 15, 2016, well before the three stations are slated to be transferred from the Wallace Dialysis Center to SEDC-Burgaw. The Wallace Dialysis Center has a capacity for up to 20 dialysis stations. These stations will be applied for utilizing the Facility Need Methodology.”*

Thus, when the three stations are initially relocated from Wallace Dialysis Center, the applicant projects that utilization will be well above 3.2 in-center patients per station per week. However, the applicant notes that the facility has the ability to apply for an increase in the number of stations pursuant to the facility need methodology early in 2016 before the stations are transferred.

In Section D, page 21, the applicant states:

*“The relocation of the stations will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care in the Wallace Dialysis Center since additional stations will be secured prior to the transfer of the three stations to SEDC-Burgaw.”*

### **Conclusion**

In summary, the applicant adequately demonstrates that the needs of the population presently served at Wallace Dialysis Center will continue to be adequately met following the relocation of three in-center dialysis stations to SEDC-Burgaw. Furthermore, the applicant adequately demonstrates that the proposed relocation will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain dialysis services at Wallace Dialysis Center. Therefore, the application is conforming to this criterion.

- (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

In Section E, page 22, the applicant discusses the alternatives considered prior to the submission of this application, which includes doing nothing or the proposed project. The applicant stated that continuing to operate the facility without adding stations would necessitate a third shift or turning patients away, because the facility would be at maximum capacity. The applicant stated that a third shift would be inconvenient for patients; and a facility at maximum capacity eliminates patient choice. After considering the alternatives above, the applicant believes the most effective alternative is to add three stations to the existing facility to ensure adequate access for the dialysis patients of Pender County.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC shall add no more than three dialysis stations at Southeastern Dialysis Center-Burgaw for a total of no more than 18 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw 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

TRC proposes to add three dialysis stations to SEDC-Burgaw by relocating three existing stations from Wallace Dialysis Center in Duplin County, for a total of 18 dialysis stations at SEDC-Burgaw upon completion of this project and Project ID#O-10125-13 (relocate 10 stations to establish a new facility) and Project ID #O-10348-14 (add 3 stations). In Section F, pages 23 – 29, the applicant states that there are no capital costs or working capital costs associated with this project.

**Financial Feasibility**

In Section R, Form B, page one, the applicant projects revenues and expenses for the first two full operating years of the project (CYs 2017 - 2018). Additionally, the applicant provides the assumptions used to project revenues and expenses in Section R, Form B, page two, as summarized in the table below.

<b>SEDC-BURGAW</b>		
<b>REVENUE AND EXPENSES - TOTAL FACILITY</b>		
	<b>OPERATING YR 1</b>	<b>OPERATING YR 2</b>
	<b>CY 2017</b>	<b>CY 2018</b>
Gross Patient Revenue	\$3,284,623	\$3,363,454
Deductions from Gross Patient Revenue	\$ 82,460	\$ 84,423
Net Patient Revenue	\$3,202,163	\$3,279,031
Operating Expenses	\$2,724,588	\$2,789,833
<b>Net Profit</b>	<b>\$ 477,575</b>	<b>\$ 489,198</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section H, page 34, the applicant provides projected staffing and salaries. Form A in Section R, page one, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

**Conclusion**

In summary, the applicant adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

- (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

TRC proposes to add three dialysis stations to SEDC-Burgaw by relocating three existing stations at Wallace Dialysis Center, for a total of 18 dialysis stations at Southeastern Dialysis Center-Burgaw and 13 dialysis stations at Wallace Dialysis Center upon completion of this project, Project ID#O-10125-13 (relocate 10 stations to establish a new facility) and Project ID #O-10348-14 (add 3 stations).

In addition, Basic Principle 6 in Chapter 14, page 362 of the 2015 SMFP states that “*No existing facility may expand unless its utilization is 80 percent or greater.*” In project ID #O-10125-13, the applicant was approved to develop Surf City Dialysis by relocating ten existing stations from SEDC-Burgaw. That project is complete. In Project ID # O-10348-14, the applicant was

approved to add three dialysis stations to SEDC-Burgaw. The applicant states on page 13 that nine in-center patients have transferred to Surf City Dialysis, which left SEDC-Burgaw with 15 existing and approved in-center stations and 59 patients, which is a utilization rate of 98.3% [ $59 / 15 = 3.93$ ;  $3.93 / 4 = 0.9833$ ]. The utilization rate of 98% is above the minimum of 80% set forth in Basic Principle 6.

On page 361, the 2015 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pender County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are two existing dialysis facilities in Pender County, as follows:

DIALYSIS FACILITY	EXISTING AND APPROVED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION*
SEDC-Burgaw	15	68	3.09	77.3%
Surf City Dialysis	10	--	--	--

\*The utilization rate is based on the number of certified stations and patients as of December 31, 2014 as reported in the July 2015 SDR.

In Section C, page 13, the applicant provides the total projected patients by county of residence for the proposed project, as shown in the following table:

COUNTY	OY 1 (CY 2017)	OY 2 (CY 2018)	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER	IN-CENTER	OY 1	OY 2
Pender	63	65	98.4%	98.5%
Duplin	1	1	1.6%	1.5%
Total	64	66	100.0%	100.0%

As shown in the table above, at the end of OY1 (CY 2017), the applicant projects a total in-center patient census of 64 patients, for a utilization rate of 89% or 3.55 patients per station per week [ $64 \text{ patients} / 18 \text{ stations} = 3.55$ ;  $3.55 / 4 = 0.888$ , or 89%]. At the end of OY2 (CY 2018), the applicant projects an in-center patient census of 66 patients for a utilization rate of 92% or 3.67 patients per station per week. The projected utilization of 3.52 patients per station per week in OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant states that projected utilization is based on population growth of 3.1%, which is one half of the 6.2% Five Year Average Annual Change Rate published in the July 2015 SDR.

The applicant adequately demonstrates the need to relocate three stations to SEDC-Burgaw based on the number of in-center patients it proposes to serve at the facility. The analysis of

need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Pender County. Consequently, the application is conforming to this criterion.

- (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, page 31, the applicant provides the following table to illustrate current staffing in full time equivalents (FTEs) for SEDC-Burgaw. The table does not reflect that any new FTEs will be added when the three stations are relocated to the facility. The applicant states the Medical Director is not employed by the facility, but is subject to an agreement with the facility.

POSITION	CURRENT AND PROJECTED # FTEs
Registered Nurse	3.0
Technician (Patient Care)	8.0
Administrator	1.0
Dietician	0.5
Social Worker	0.5
Bio-med Technician	0.5
Administrative Assistant	1.0
<b>Total</b>	<b>14.5</b>

In Section H, page 34, the applicant provides the projected direct care staff for SEDC-Burgaw in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.0	2,080	6,240	3,120	2.0
Technician	8.0	2,080	16,640	3,120	5.3
<b>Total</b>	<b>11.0</b>	<b>2,080</b>	<b>22,880</b>	<b>3,120</b>	<b>7.3</b>

In Section I, page 37, the applicant identifies Dr. Brian Donner as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by Dr. Donner of Southeastern Nephrology Associates that confirms his commitment to continue to serve as Medical Director. In Section H, pages 32 - 33, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (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, page 36, the applicant lists the providers of the necessary ancillary and support services that are currently being provided and will continue to be provided following the relocation of three dialysis stations. The applicant discusses coordination with the existing health care system on page 38, and states that the clinical staff at SEDC-Burgaw has established relationships with healthcare providers and social service agencies in the county and that these agencies are aware of and support the proposed project. Exhibits I-1, and I-3 contain supporting documents from Total Renal Laboratories, Inc. d/b/a DaVita Laboratory Services, Inc. and Dr. Donner, respectively. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity 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

- (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

- (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

(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, page 45, the applicant states, “*Southeastern Dialysis Center-Burgaw, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.*”

*Southeastern Dialysis Center-Burgaw makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility provides dialysis six days per week with two patient shifts per day to accommodate patient need.”*

In addition, on pages 47 - 48, the applicant discusses the financial policies the company has in place to ensure dialysis services are provided to all patients in need of dialysis, regardless of the patients’ ability to pay for those services. In Section L, page 52, the applicant states that Medicare/Medicaid represented 84.5% of all dialysis treatments at SEDC-Burgaw in calendar year 2014. The following table illustrates the historical payor sources for SEDC-Burgaw, as follows:

PAYOR TYPE	PERCENT PATIENTS
Private Pay	0.0%
Commercial Insurance	11.3%
Medicare	18.3%
Medicaid	5.6%
Medicare/ Medicaid	36.7%
VA	4.2%
Medicare Commercial	23.9%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Pender and Duplin Counties and statewide:

<b>County</b>	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Pender	17%	7.4%	21.0%
Duplin	20%	7.6%	24.6%
Statewide	17%	6.7%	19.7%
*More current data, particularly with regard to the estimated uninsured percentages, was not available.			

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, provides prevalence data on North Carolina dialysis patients by age, race and gender, and is summarized as follows, on page 59:

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<sup>1</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%
Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report. <sup>2</sup>		

The applicant demonstrates that it currently provides adequate access to medically underserved groups. Therefore, the application is conforming to this criterion.

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

C

In Section L, page 48, the applicant states:

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

In Section L, page 49, the applicant states, *“There have been no civil rights equal access filed within the last five years.”*

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 C-3, page 15, the applicant states:

*“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...*

...

*Payment will not be required upon admission. 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 Section L-3, page 48, the applicant states:

*“Southeastern Dialysis Center-Burgaw makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”*

In Section L-7, page 49, the applicant projects that 84.5% of patients who will receive dialysis treatment at SEDC-Burgaw will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below.

PAYOR TYPE	PERCENT PATIENTS
Private Pay	0.0%
Commercial Insurance	11.3%
Medicare	18.3%
Medicaid	5.6%
Medicare/ Medicaid	36.7%
VA	4.2%
Medicare Commercial	23.9%
<b>Total</b>	<b>100.0%</b>

The applicant demonstrates that medically underserved groups will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 48, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Southeastern Dialysis Center-Burgaw. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. The patient, again, will be referred by a qualified nephrologist for final evaluation and then admission based on the doctor’s orders.”*

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, 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 50, the applicant states that SEDC-Burgaw has been offered as a clinical training site for nursing students from Education Corporation of America.

Exhibit M-2 contains a copy of a March 2015 letter from DaVita to Cape Fear Community College, offering SEDC-Burgaw as a clinical training site for nursing students at the college. There is no agreement or documentation of an agreement between SEDC-Burgaw or DaVita and Education Corporation of America in any of the exhibits. The information provided in Section M and Exhibit M-2 regarding Cape Fear Community College is nevertheless reasonable and supports a finding of conformity 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 three dialysis stations to SEDC-Burgaw by relocating three existing stations at Wallace Dialysis Center, for a total of 13 dialysis stations at Wallace Dialysis Center and 18 dialysis stations at Southeastern Dialysis Center-Burgaw upon completion of this project and Project ID#O-10125-13 (relocate 10 stations to establish a new facility) and Project ID #O-10348-14 (add 3 stations).

In addition, Basic Principle 6 in Chapter 14, page 362 of the 2015 SMFP states that “*No existing facility may expand unless its utilization is 80 percent or greater.*” In project ID #O-10125-13, the applicant was approved to develop Surf City Dialysis by relocating ten existing stations from SEDC-Burgaw. That project is complete. In Project ID # O-10348-14, the applicant was approved to add three dialysis stations to SEDC-Burgaw. The applicant states on page 13 that nine in-center patients have transferred to Surf City Dialysis, which left SEDC-Burgaw with 15 existing and approved in-center stations and 59 patients, which is a utilization rate of 98.3% [ $59 / 15 = 3.93$ ;  $3.93 / 4 = 0.9833$ ]. The utilization rate of 98% is above the minimum of 80% set forth in Basic Principle 6.

On page 361, the 2015 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pender County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there is one existing dialysis facility and one approved dialysis facility in Pender County, as follows:

DIALYSIS FACILITY	EXISTING AND APPROVED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION*
SEDC-Burgaw	15	68	3.09	77.3%
Surf City Dialysis*	10	--	--	--

\*The utilization rate is based on the number of certified stations and patients as of December 31, 2015 as reported in the July 2015 SDR.

There are currently three pending projects which propose to relocate existing dialysis stations in Pender County as noted above. The applicant operates or will operate all of the existing and approved Pender County dialysis facilities listed above.

In Section N, page 51, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

*“Southeastern Dialysis Center-Burgaw is the only dialysis facility in Pender County, the service area. Therefore, this expansion project will have no effect [on] competition. The addition of three stations at this facility 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 expansion of SEDC-Burgaw will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other[s] involved in the dialysis process to receive services.”*

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that SEDC-Burgaw will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that SEDC-Burgaw will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(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 O, page 52, the applicant refers the reader to Section B-4(a) for its discussion regarding the methods it uses to ensure and maintain quality. The discussion is found on pages 9 - 10. In addition, in Exhibit B-4(a), the applicant provides a copy of an article that discusses DaVita's Quality Incentive Program and Five Star Ranking System.

In addition, in Section O, page 52, the applicant states:

*“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look back period. Each facility is currently in compliance.”*

In Exhibit O-3, the applicant lists three facilities that were cited for deficiencies that resulted in a finding of Immediate Jeopardy during the 18-month look back period: Burlington Dialysis, Dialysis Care of Edgecombe County and Dialysis Care of Rowan County. See the table below which shows the survey dates and the dates the facilities were found to be back in compliance with CMS.

TRC QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
		Burlington Dialysis	6/16/2014
Dialysis Care of Edgecombe County	7/1/2014	Yes	7/30/2014
Dialysis Care of Rowan County	9/17/2014	Yes	10/22/2014

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

*(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

*.2202(a)(1) Utilization rates;*

- C- In Section P, page 54, the applicant refers to Section G, page 30 for the historical utilization rates for SEDC-Burgaw. There is no utilization information in Section G. However, in Section C, page 16, the applicant provides the historical utilization rate for SEDC-Burgaw.

*.2202(a)(2) Mortality rates;*

- C- In Section P, page 54, the applicant refers to Section C-9, where it provides SEDC-Burgaw's mortality rates, as follows:

<b>SEDC-BURGAW</b>	<b>BEGINNING IN-CENTER PATIENTS</b>	<b>ENDING IN-CENTER PATIENTS</b>	<b>AVERAGE</b>	<b>DEATHS</b>	<b>% GROSS MORTALITY</b>
2014	70	68	69	7	10.14%
2013	69	70	69.5	6	8.63%
2012	68	69	68.5	4	5.84%

*.2202(a)(3) The number of patients that are home-trained and the number of patients on home dialysis;*

- C- In Section P, page 54, the applicant refers the reader to Section C-8, page 17. The table provided on page 17 indicates that there were no home trained patients at SEDC-Burgaw as of December 31, 2014. In Section I-1, page 35, the applicant states patients who are home trained in either hemodialysis or peritoneal dialysis receive their training at SEDC-Wilmington.

*.2202(a)(4) The number of transplants performed or referred;*

- C- In Section P, page 54, the applicant refers the reader to Section C-10, page 18, and states that SEDC-Burgaw referred three patients for transplants during 2014.

*.2202(a)(5) The number of patients currently on the transplant waiting list;*

- C- In Section P, page 54, the applicant refers the reader to Section C-10, page 18, and states that SEDC-Burgaw had one patient on the transplant waiting list.

*.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

- C- In Section P, page 54, the applicant refers to Section C-11, page 18, and reports hospital admission rates as follows: Dialysis related - 18 or 5.6%; Non-dialysis related - 170 or 94.4%.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section P, page 55, the applicant refers the reader to Section C-10, page 18, and states that there was one person with infectious disease and no patients converted to an infectious status at SEDC-Burgaw during calendar year 2014.

*(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).*

-NA- This application is to relocate existing stations and does not propose a new facility.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This application is to relocate existing stations and does not propose a new facility.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- This application is to relocate existing stations and does not propose a new facility.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- In Exhibit K-1(f), the applicant provides a copy of DaVita HealthCare Partner Inc. policies and procedures for back up electrical service in the event of a power outage.

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- This application is to relocate existing stations and does not propose a new facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section K-1(g), page 41, the applicant states: “*Southeastern Dialysis Center-Burgaw will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements ....*” See also Sections H-2 and K-1(d) and Exhibit K-1(g).
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section C-1, page 13, the applicant provides projected patient origin by county for SEDC-Burgaw, based on the patients who currently dialyze at the facility. The applicant’s assumptions and methodology used to project patient origin are provided on pages 13 - 14. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- This application is to relocate existing stations and does not propose a new facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section L-3(c), page 48, the applicant states, “*Southeastern Dialysis Center-Burgaw makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.*”

## **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- This application is to relocate existing stations and does not propose a new 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 P, page 57, the applicant refers to Section C-1. In Section C-1, pages 13 - 17, the applicant documents the need for the project and demonstrates that it will serve a total of 65 in-center patients on 18 stations at the end of the first operating year, which is 3.61 patients per station per week, or a utilization rate of 90%. The discussion regarding analysis of need 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.1, pages 13 - 14, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

## **10 NCAC 14C .2204 SCOPE OF SERVICES**

*To be approved, the applicant must demonstrate that the following services will be available:*

*.2204(1) Diagnostic and evaluation services;*

-C- In Section I-1, page 36, the applicant states that diagnostic and evaluation services will be referred to New Hanover Regional Medical Center (NHRMC). However, Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which states diagnostic and evaluation services will be provided by Pender Memorial Hospital.

*.2204(2) Maintenance dialysis;*

- C- In Section I-1, page 36, the applicant states that in-center maintenance dialysis is provided at SEDC-Burgaw.

*.2204(3) Accessible self-care training;*

- C- In Section I-1, page 36, the applicant states that self-care training is provided at SEDC-Burgaw.

*.2204(4) Accessible follow-up program for support of patients dialyzing at home;*

- C- In Section I-1, page 36, the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided by SEDC-Wilmington.

*.2204(5) X-ray services;*

- C- In Section I-1, page 36, the applicant states that patients in need of x-ray services will be referred to New Hanover Regional Medical Center. However, Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which states x-ray services will be provided by Pender Memorial Hospital.

*.2204(6) Laboratory services;*

- C- In Section I-1, page 36, the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc. Exhibit I-1 contains a copy of the laboratory agreement.

*.2204(7) Blood bank services;*

- C- In Section I-1, page 36, the applicant states that patients in need of blood bank services will be referred to New Hanover Regional Medical Center. However, Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which states blood bank services will be provided by Pender Memorial Hospital.

*.2204(8) Emergency care;*

- C- In Section I-1, page 36, the applicant states that patients in need of emergency care will be referred to New Hanover Regional Medical Center. However, Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which states emergency care will be provided by Pender Memorial Hospital.

*.2204(9) Acute dialysis in an acute care setting;*

- C- In Section I-1, page 36, the applicant states that patients in need of acute dialysis services will be referred to New Hanover Regional Medical Center. However, Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which states acute dialysis care will be provided by Pender Memorial Hospital.

*.2204(10) Vascular surgery for dialysis treatment patients;*

- C- In Section I-1, page 36, the applicant states that patients in need of vascular surgery services will be referred to New Hanover Regional Medical Center. However, Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which states surgical services will continue to be provided by Wilmington Health-Surgical.

*.2204(11) Transplantation services;*

- C- In Section I-1, page 36, the applicant states that patients in need of transplantation services will be referred to Vidant Medical Center. Exhibit I-3 contains a copy of the August 2015 letter from Dr. Donner, the Medical Director at SEDC-Burgaw which documents the provision of transplantation services at Vidant Medical Center.

*.2204(12) Vocational rehabilitation counseling and services; and*

- C- In Section I-1, page 36, the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

*.2204(13) Transportation*

- C- In Section I-1, page 36, the applicant states that transportation services will be provided by the Pender County Department of Social Services (DSS).

**10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

*.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*

- C- In Section H-2, page 32, the applicant states that it will comply with 42 CFR Section 494. In Section H-1, page 31, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

*.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- In Section H-4, page 33, the applicant discusses training programs that are in place at TRC facilities. See also Exhibit H-4, which contains a copy of DaVita's annual in-service training calendar and a copy of continuing education courses for clinical staff members.