

## 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-11082-15

Facility: Southeastern Dialysis Center-Wilmington

FID #: 956055

County: New Hanover

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

Project: Add 2 dialysis stations for a total of 34 stations upon completion of this project and Project ID#O-10324-14 (relocate 10 stations), Project ID #O-10346-14 (add 10 stations), and Project ID #O-11018-15 (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-Wilmington (SEDC-Wilmington) proposes to add two dialysis stations to the existing facility for a total of 34 stations upon completion of this project and Project ID#O-10324-14 (relocate 10 stations), Project ID #O-10346-14 (add 10 stations), and Project ID #O-11018-15 (add 3 stations).

#### **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. According to the Table B in the July 2015 Semiannual Dialysis Report (SDR), the county need methodology

shows there is a surplus of one dialysis station in New Hanover County; therefore, the applicant is ineligible to apply for additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in this facility based on the facility need methodology, because the utilization rate reported for SEDC-Wilmington in the July 2015 SDR is 5.0 patients per station, or 125% (5.0 / 4 patients per station = 1.25). This utilization rate was calculated based on 145 in-center dialysis patients and 29 certified dialysis stations (145 patients / 29 stations = 5.0 patients per station).

Application of the facility need methodology indicates 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 12/31/14		125.0%
Certified Stations		29
Pending Stations		13
<b>Total Existing and Pending Stations</b>		<b>42</b>
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		145
In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1)		141
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	4
	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 6/30/14	0.0567
(ii)	Divide the result of Step (i) by 12	0.0047
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.0567
(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	153.2270
(v)	Divide the result of Step (iv) by 3.2 patients per station	47.8834
	and subtract the number of certified and pending stations to determine the number of stations needed	5.8834

On February 25, 2015, the applicant was approved to add ten stations to SEDC-Wilmington (Project ID #O-10346-14); and on July 31, 2015, the applicant was approved to add three stations to SEDC-Wilmington (Project ID #O-11018-15). Both certificates of need were issued after the data for the July 2015 SDR was submitted; thus, the data is reflected in the table above.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six stations, rounded up from 5.8834. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations, therefore the application is consistent with the facility need determination for dialysis stations.

## Policies

There is one policy in the 2015 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology applies. 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.”*

### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 9-10 and Section O, page 55. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality in the delivery of dialysis services.

### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, page 10, Section C, page 17, Section I, pages 38 - 41, Section L, pages 48 - 51 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access to dialysis services.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 11, Section F, page 29, and Section N, page 54. 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. Therefore, the application is consistent with Policy GEN-3.

**Conclusion**

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2015 SDR and with Policy GEN-3. 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 proposes to add two dialysis stations to the existing facility for a total of 34 dialysis stations at SEDC-Wilmington upon completion of this project, Project ID#O-10324-14 (relocate 10 stations), Project ID #O-10346-14 (add 10 stations), and Project ID #O-11018-15 (add 3 stations).

**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 New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 22, the applicant provides a table showing the historical patient origin for in-center (IC), peritoneal dialysis (PD), and home hemodialysis (HHD) patients served by SEDC-Wilmington, as shown below:

COUNTY	# IC PATIENTS	# HHD PATIENTS	# PD PATIENTS
New Hanover	117	6	41
Brunswick	19	6	11
Columbus	4	1	1
Other States	2	0	0
Pender	1	2	11
Onslow	1	0	0
Bladen	1	1	2
South Carolina	0	2	0
Cherokee	0	0	1
Total	145	18	67

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	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
New Hanover	111	9	36	119	10	39	70.3%	71.8%
Brunswick	19	6	11	19	6	11	16.2%	15.4%
Columbus	4	1	1	4	1	1	2.7%	2.6%
Other States	2	0	0	2	0	0	0.9%	0.9%
Pender	1	2	11	1	2	11	6.3%	6.0%
Onslow	1	0	0	1	0	0	0.5%	0.4%
Bladen	1	1	2	1	1	2	1.8%	1.7%
South Carolina	0	2	0	0	2	0	0.9%	0.9%
Cherokee	0	0	1	0	0	1	0.5%	0.4%
Total	139	21	62	147	22	65	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 13-16.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

The applicant projects to serve 120 in-center dialysis patients on 34 in-center stations at the end of the first operating year, which is 3.53 patients per station per week or an 88% utilization rate. In addition, the applicant projects to serve 21 home hemodialysis patients and 53 peritoneal dialysis patients at the end of the first operating year.

In Section C-2, page 17, the applicant refers the reader to Section B-2, page 7 where the facility need methodology is discussed, which supports a need for two additional dialysis stations. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

**Projected Utilization**

In Section C, pages 13-16, the applicant provides the assumptions and methodology it uses to demonstrate the need that this population has for the in-center, home hemodialysis and home peritoneal dialysis services proposed at SEDC-Wilmington. The applicant’s assumptions and methodology are summarized below:

**In-Center Dialysis Patients**

- Based on Table A in the July 2015 SDR, SEDC-Wilmington was dialyzing 145 in-center patients on 29 certified stations yielding a station utilization rate of 125% (145 / 29 = 5.0; 5.0 / 4 = 1.25 or 125%) as of December 31, 2014.

- 117 of the in-center patients were residents of New Hanover County, and the other 28 patients resided outside of New Hanover County, including Brunswick County.
- In Project ID #O-10324-14, the applicant was approved to develop a new 12-station facility, New Hanover Dialysis, by relocating ten existing stations from SEDC-Wilmington and two from Cape Fear Dialysis Center. Within that application, the applicant projected that 28 New Hanover County residents who currently dialyze at SEDC-Wilmington would transfer their care to New Hanover Dialysis upon certification of the facility (January 1, 2016).
- In Project ID #O-10305-14, the applicant was approved to develop Leland Dialysis Center (Brunswick County), by relocating eight existing stations from Southeastern Dialysis Center-Shallotte and two existing dialysis stations from Southport Dialysis. Within that application, the applicant projected that 19 Brunswick County residents who currently dialyze at SEDC-Wilmington would transfer their care to Leland Dialysis upon certification of that facility (January 2016). (This would leave nine in-center patients residing outside of New Hanover County who would remain at SEDC-Wilmington.)
- The applicant projects in-center patient utilization based on the 7.3% five year average annual change rate (AACR) for New Hanover County, found in Table B in the July 2015 SDR. See the following calculations, based on 117 New Hanover County in-center patients at SEDC-Wilmington as of December 31, 2014:

DATE	# SERVICE AREA PTS.	GROWTH RATE	TOTAL SERVICE AREA PTS.	# OUT OF SERVICE AREA PTS.	TOTAL IN-CENTER PATIENTS
As of 12/31/2014	117				
Current (CY 2015)	117	x 1.073	125.41	+ 28	153.541
Interim (CY 2016)	97 (125 – 28)	x 1.073	104.08	+ (28 – 19) = 9	113.081
OY 1 (CY 2017)	104	x 1.073	111.68	+ 9	120.679
OY 2 (CY 2018)	111	x 1.073	119.83	+ 9	128.832

- The applicant projects that the facility will have 120 in-center patients by the end of operating year one (OY1) for a utilization rate of 88%, or 3.53 patients per station per week. The applicant further projects that the facility will have 128 in-center patients by the end of operating year two (OY2), for a utilization rate of 94%, or 3.78 patients per station per week.
- OY1 is Calendar Year 2017.
- OY2 Calendar Year 2018.
- In Section C, page 14, the applicant states the calculations include a deduction of 28 in-center patients projected to transfer their care to New Hanover Dialysis in January 2016 (projected certification date for Project ID #O-10324-14). In addition, the calculations

include a deduction of nine in-center patients projected to transfer their care to Leland Dialysis in January 2016 (projected certification date for Project ID#O-10305-14).

Therefore, at the end of OY 2 (CY 2018), the applicant projects an in-center patient census of 128 patients, which is a utilization rate of 94% or 3.76 patients per station per week. The projected utilization of 3.52 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant currently provides home hemodialysis (HHD) and peritoneal dialysis (PD) at SEDC-Wilmington, but this project proposes additional in-center dialysis stations. See Section C, pages 15 - 17 for the applicant's discussion of its HHD and PD services.

### **Access**

In Section C, page 16, 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 52, the applicant provides its historical payor mix for SEDC-Wilmington, which indicates that Medicare and Medicaid represented 62.2% 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.

NA

- (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 26, 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. 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 two stations to the existing facility to ensure adequate access for the dialysis patients of New Hanover 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-Wilmington shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall add no more than two dialysis stations at Southeastern Dialysis Center-Wilmington for a total of no more than 34 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**
  - 3. Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall submit a letter documenting that the funds necessary for the capital costs of the project will be committed to development of the project.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington 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.

CA

TRC proposes to add two dialysis stations to SEDC-Wilmington, for a total of 34 dialysis stations at the facility upon completion of this project, Project ID#O-10324-14 (relocate 10 stations), Project ID #O-10346-14 (add 10 stations), and Project ID #O-11018-15 (add 3 stations).

**Capital and Working Capital Costs**

In Section F, page 27, the applicant projects the capital cost for the proposed project as summarized in the table below:

SEDC-WILMINGTON PROPOSED PROJECT CAPITAL COSTS	
Dialysis Machines	\$13,000
Equipment/Furniture	\$ 7,733
<b>Total Capital Cost</b>	<b>\$20,733</b>

In Section F, pages 29 - 30, the applicant states that there are no working capital needs for the proposed project since SEDC-Wilmington is an existing facility.

In Section F, page 28, the applicant states that the accumulated reserves of TRC will be used to finance the proposed project.

**Availability of Funds**

The applicant states on page 28 that Exhibit F-5 contains a letter documenting the availability of funds for the proposed project; however, Exhibit F contains the audited financial statements of DaVita Healthcare Partners for years ending December 31, 2012, 2013 and 2014, as well as a table listing TRC projects currently under development in North Carolina. There is no letter in Exhibit F that documents the commitment of funds for the proposed project.

In Section F, page 29, the applicant refers to Exhibit F-7 [sic] for a copy of the most recent audited financial statements for DaVita HealthCare Partners, Inc. (years ended December 31, 2014 and 2013). As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project, subject to Condition # 3 found at the end of Criterion (4).

**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-WILMINGTON</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	\$12,144,328	\$12,810,475
Deductions from Gross Patient Revenue	\$ 118,374	\$ 125,174
Net Patient Revenue	\$12,025,953	\$12,685,301
Operating Expenses	\$ 4,420,029	\$ 4,616,476
<b>Net Profit</b>	<b>\$ 7,605,925</b>	<b>\$ 8,068,825</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 it has sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. However, the applicant does not adequately demonstrate that the funds will be committed to development of the project. Therefore, the application is conforming to this criterion, subject to Condition # 3 found at the end of Criterion (4).

- (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 two dialysis stations to SEDC-Wilmington, for a total of 34 dialysis stations at SEDC-Wilmington upon completion of this project, Project ID#O-10324-14 (relocate 10 stations), Project ID #O-10346-14 (add 10 stations), and Project ID #O-11018-15 (add 3 stations).

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 New Hanover 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 New Hanover County, as follows:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Cape Fear Dialysis	32	116	3.62	90.6%
SEDC-Wilmington	29	145	5.00	125.0%

Data reported in the July 2015 SDR, as of 12/31/14.

In addition, the applicant was approved to develop a new 12-station facility, New Hanover Dialysis, in Project ID #O-10324-14, by relocating existing certified dialysis stations. The applicant operates all of the existing and approved New Hanover County dialysis facilities listed above. Both of the existing dialysis facilities are operating above 80% utilization.

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	OPERATING YEAR ONE (CY 2017)			OPERATING YEAR TWO (CY 2018)			COUNTY PTS AS % OF TOTAL	
	IC	HHD	PD	IC	HHD	PD	OY 1	OY 2
New Hanover	111	9	36	119	10	39	70.3%	71.8%
Brunswick	19	6	11	19	6	11	16.2%	15.4%
Columbus	4	1	1	4	1	1	2.7%	2.6%
Other States	2	0	0	2	0	0	0.9%	0.9%
Pender	1	2	11	1	2	11	6.3%	6.0%
Onslow	1	0	0	1	0	0	0.5%	0.4%
Bladen	1	1	2	1	1	2	1.8%	1.7%
South Carolina	0	2	0	0	2	0	0.9%	0.9%
Cherokee	0	0	1	0	0	1	0.5%	0.4%
<b>Total</b>	<b>139</b>	<b>21</b>	<b>62</b>	<b>147</b>	<b>22</b>	<b>65</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the table above, at the end of OY1 (CY 2017), the applicant projects an in-center patient census of 120 patients, for a utilization rate of 88% or 3.52 patients per station per week [120 patients / 34 stations = 3.52; 3.52 / 4 = 0.882, or 88%]. At the end of OY2 (CY 2018), the applicant projects an in-center patient census of 128 patients for a utilization rate of 94% or 3.76 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 the New Hanover County Five Year Average Annual Change Rate published in the July 2015 SDR.

The applicant adequately demonstrates the need to add two stations to SEDC-Wilmington based on the number of in-center patients it proposes to serve. The discussion on 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 New Hanover 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 34, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for SEDC-Wilmington. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	5.0	1.0	6.0
Technician (Patient Care)	12.0	1.0	13.0
Administrator	1.0	-	1.0
Dietician	1.0	-	1.0
Social Worker	1.0	-	1.0
Home Training RN	2.0	-	2.0
Bio-med Technician	1.0	-	1.0
Reuse Technician	1.0	-	1.0
Administrative Assistant	1.0	-	1.0
<b>Total</b>	<b>25.0</b>	<b>2.0</b>	<b>27.0</b>

In Section H, page 37, the applicant provides the projected direct care staff for SEDC-Wilmington 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	6.0	2,080	12,480	3,120	4.0
Technician	13.0	2,080	27,040	3,120	8.7
<b>Total</b>	<b>19.0</b>	<b>2,080</b>	<b>39,520</b>	<b>3,120</b>	<b>12.7</b>

In Section I, page 35, the applicant identifies Dr. Jonathan Woods as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by Dr. Woods of Southeastern Nephrology Associates, supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 35 - 36, 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 39, the applicant lists the providers of the necessary ancillary and support services that are being provided and will continue to be provided at the existing facility. The applicant discusses coordination with the existing health care system on page 41. Also on page 41, the applicant states that the clinical staff at SEDC-Wilmington has established relationships with other 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. Woods (Medical Director), 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 48, the applicant states, “*SEDC-Wilmington, 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.*”

*SEDC-Wilmington 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 49 - 51, the applicant discusses its financial policies to help underserved groups. In Section L, page 52, the applicant states that Medicare/Medicaid represented 62.2% of all dialysis treatments at SEDC-Wilmington in calendar year 2014. The following table illustrates the historical payor sources for SEDC-Wilmington, as follows:

PAYOR TYPE	PERCENT PATIENTS
Private Pay	0.0%
Commercial Insurance	10.0%
Medicare	6.1%
Medicaid	17.4%
Medicare/ Medicaid	38.7%
VA	24.8%
Other	3.0%
<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 New Hanover and Brunswick counties and statewide [the other counties which comprise a portion of the applicant’s service area are not included, since the majority of the patients are from New Hanover and Brunswick counties].

<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>
New Hanover	13%	5.7%	20.4%
Brunswick	7%	2.8%	19.8%
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 51, the applicant states:

*“SEDC-Wilmington 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 51, 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, page 17, 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, page 51, the applicant states:

*“SEDC-Wilmington 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, page 49, the applicant projects that 62.2% of all patients who will receive dialysis treatment at SEDC-Wilmington will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below.

<b>PAYOR TYPE</b>	<b>PERCENT PATIENTS</b>
Private Pay	0.0%
Commercial Insurance	10.0%
Medicare	6.1%
Medicaid	17.4%
Medicare/ Medicaid	38.7%
VA	24.8%
Other	3.0%
<b>Total</b>	<b>100.0%</b>

On page 49, the applicant also states that the projected payor mix for SEDC-Wilmington is based upon the experience of the facility and no change is anticipated.

The applicant demonstrates that medically underserved populations 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, page 51, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at SEDC-Wilmington. ... 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 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, page 53, the applicant states that SEDC-Wilmington has been offered as a clinical training site for student nurses attending Miller Motte College.

Exhibit M-2 contains a copy of the applicant’s existing agreement with Miller Motte College for student nurse clinical rotations at SEDC-Wilmington. The information provided in Section M and referenced exhibits is 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

The applicant proposes to add two stations to SEDC-Wilmington using the facility need methodology. There will be 34 certified dialysis station at SEDC-Wilmington upon completion of this project and Project ID#O-10324-14 (relocate 10 stations), Project ID #O-10346-14 (add 10 stations), and Project ID #O-11018-15 (add 3 stations).

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 New Hanover 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 New Hanover County, as follows:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Cape Fear Dialysis	32	116	3.62	90.6%
SEDC-Wilmington	29	145	5.00	125.0%

Data reported in the July 2015 SDR, as of 12/31/14.

In addition, the applicant was approved to develop a new 12-station facility, New Hanover Dialysis, in Project ID #O-10324-14, by relocating existing certified dialysis stations. The applicant operates or will operate all of the existing and approved New Hanover County dialysis facilities listed above. Both of the existing dialysis facilities are operating above 80% utilization.

In Section N, page 54, 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:

*“The expansion of SEDC-Wilmington will have no effect on competition in New Hanover County. This project 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 and not any other providers in the service area.*

*The expansion of SEDC-Wilmington 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 others 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 cost-effective alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that SEDC-Wilmington will continue to provide quality dialysis services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that SEDC-Wilmington will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (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 55, 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 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	Yes	7/29/2014
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 57, the applicant refers to Section G, page 33 for the historical utilization rates for SEDC-Wilmington. The December 31, 2014 utilization rate was reported as 125% with 145 in-center patients dialyzing on 29 stations.

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

-C- In Section P, page 54, the applicant refers to Section C-9, page 22 where it provides the SEDC-Wilmington mortality rates, as follows:

SEDC-WILMINGTON	BEGINNING IN-CENTER PATIENTS	ENDING IN-CENTER PATIENTS	AVERAGE	DEATHS	% GROSS MORTALITY
2014	131	145	138	21	15.2%
2013	82	131	106.5	23	21.6%
2012	80	82	81	20	24.7%

.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 22 and provides the following home training and home dialysis data for the SEDC-Wilmington facility.

RESIDENCE	# IC PATIENTS	# HHD PATIENTS	# PD PATIENTS
New Hanover	117	6	41
Brunswick	19	6	11
Columbus	4	1	1
Other States	2	0	0
Pender	1	2	11
Onslow	1	0	0
Bladen	1	1	2
South Carolina	0	2	0
Cherokee	0	0	1
<b>Total</b>	<b>145</b>	<b>18</b>	<b>67</b>

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

- C- In Section P, page 57, the applicant refers the reader to Section C-10, page 23, and states that SEDC-Wilmington 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 57, the applicant refers the reader to Section C-10, page 23, and states that SEDC-Wilmington had 37 patients 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 57, the applicant refers to Section C-11, page 23 and reports hospital admission rates as follows: Dialysis related - 38 or 12.2%; Non-dialysis related - 273 or 87.8%.

.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 58, the applicant refers the reader to Section C-10, page 23 and states that at SEDC-Wilmington, there was one person with infectious disease and no patients converted to an infectious status 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 add 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 add 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 add 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 add 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 44, the applicant states: “*SEDC-Wilmington 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-Wilmington, 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 - 16. 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 add 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 51, the applicant states, “*SEDC-Wilmington 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 add 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 120 in-center patients on 34 stations at the end of the first operating year, which is 3.53 patients per station per week, or a utilization rate of 88%. 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 - 17, 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 39, the applicant states that diagnostic and evaluation services will be referred to New Hanover Regional Medical Center (NHRMC).

*.2204(2) Maintenance dialysis;*

-C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that in-center maintenance dialysis will be provided by SEDC-Wilmington.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that self-care training will be provided by SEDC-Wilmington.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that an accessible follow-up program for support of patients dialyzing at home will be provided by SEDC-Wilmington.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that patients in need of x-ray services will be referred to New Hanover Regional Medical Center.

*.2204(6) Laboratory services;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where 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 P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that patients in need of blood bank services will be referred to New Hanover Regional Medical Center.

*.2204(8) Emergency care;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that patients in need of emergency care will be referred to New Hanover Regional Medical Center.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that patients in need of acute dialysis services will be referred to New Hanover Regional Medical Center.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 36, where the applicant states that patients in need of vascular surgery services will be referred to Wilmington Surgical Associates.

*.2204(11) Transplantation services;*

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where 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. Woods, the medical director at SEDC-Wilmington, which documents the provision of transplantation services.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 39, where 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 P-1, page 57, the applicant refers the reader to Section I-1, page 39, where the applicant states that transportation services will be provided by Wave Transit.

**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 P-1, page 57, the applicant refers the reader to Section H-2, page 35, where the applicant states that it will comply with *42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494)*. In Section H-1, page 34, 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 P-1, page 60, the applicant refers the reader to Section H-4, page 36, where the applicant discusses its training at TRC facilities. See also Exhibit H-4, which contains DaVita's in-service training calendar and a training outline of DaVita's continuing education program courses.