

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 20, 2016

Findings Date: January 20, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: O-11257-16-16

Facility: Southeastern Dialysis Center – Wilmington

FID #: 956055

County: New Hanover

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 4 dialysis stations to existing facility for a total of 38 stations upon completion of this project, Project ID# O-10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-10346-14 (add 10 stations), Project ID# O-11018-15 (add 3 stations), and Project ID# O-11082-15 (add 2 stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington (“SEDC Wilmington”) proposes to add four stations to the existing facility for a total of 38 in-center stations upon completion of this project and the following projects: Project ID# O10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-10346-14 (add 10 stations), Project ID# O-11018-15 (add three stations), and Project ID# O-11082-15 (add 2 stations).

**Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of four dialysis stations in New Hanover County; thus, there is no need for any additional dialysis stations in New Hanover County pursuant to the county need methodology. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for SEDC-Wilmington in the July 2016 SDR is 5.03 patients per station. This utilization rate was calculated based on 146 in-center dialysis patients and 29 certified dialysis stations as of December 31, 2015 (146 patients / 29 stations = 5.03 patients per station). Application of the facility need methodology indicates that 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 12/31/15		125.9%
Certified Stations		29
Pending Stations		15
<b>Total Existing and Pending Stations</b>		<b>44</b>
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		146
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		143
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.0420
(ii)	Divide the result of Step (i) by 12	0.0035
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.0420
(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	152.1259
(v)	Divide the result of Step (iv) by 3.2 patients per station	47.5393
	and subtract the number of certified and pending stations to determine the number of stations needed	3.5393

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

## **Policies**

*Policy GEN-3: Basic Principles*, page 39, of the 2016 SMFP is applicable to this review. *Policy GEN-3* states:

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

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Exhibits B-4 and K-1(g) and Section N.1, page 53. 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.4(b), page 10, Section C.3, page 17, Section L, pages 47 - 50, Exhibit L-3, and Section N.1, page 53. 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.4(c), page 11, Section G, page 32, and Section N.1, page 53. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value for dialysis services.

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

## **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2016 SDR and with *Policy GEN-3: Basic Principles*. 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 d/b/a Southeastern Dialysis Center – Wilmington (“SEDC Wilmington”) proposes to add four stations to the existing facility for a total of 38 in-center stations upon completion of this project and the following projects: Project ID# O-10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-10346-14 (add ten stations), Project ID# O-11018-15 (add three stations), and Project ID# O-11082-15 (add 2 stations).

**Patient Origin**

On page 369, the 2016 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 counties is a separate dialysis station planning area. Thus, the service area for this facility is New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 21, the applicant provides the in-center patient origin for SEDC-Wilmington as of December 31, 2015, as summarized in the following table:

**SEDC-Wilmington  
Historical Patient Origin as of 12/31/15**

COUNTY	# OF IN CENTER PTS.	# HOME HEMO DIALYSIS PTS.	# OF PERITONEAL DIALYSIS PTS.
New Hanover	116	3	39
Brunswick	21	6	6
Columbus	6	2	0
Onslow	1	0	1
Pender	0	2	9
Bladen	0	2	1
South Carolina	0	1	0
Other States	2	0	0
<b>Total</b>	<b>146</b>	<b>16</b>	<b>56</b>

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**SEDC-Wilmington  
 Projected Patient Origin OY 1 and 2**

COUNTY	OY 1 (CY 2018)			OY 2 (CY 2019)			COUNTY PTS. AS % OF TOTAL	
	IN-CTR.	HHD	PD	IN-CTR.	HHD	PD	OY 1	OY 2
New Hanover	113	6	30	122	7	31	81.9%	82.9%
Brunswick	2	6	0	2	6	0	4.4%	4.1%
Columbus	6	2	0	6	2	0	4.4%	4.1%
Onslow	1	0	1	1	0	1	1.1%	1.0%
Pender	0	2	7	0	2	7	4.9%	4.7%
Bladen	0	2	1	0	2	1	1.6%	1.6%
South Carolina	0	1	0	0	1	0	0.5%	0.5%
Other States	2	0	0	2	0	0	1.1%	1.0%
<b>Total</b>	<b>124</b>	19	39	133	20	40	100.0%	100.0%

Totals may not foot due to rounding.

See pages 13 - 16 for the assumptions and methodology used to project patient origin.

The applicant adequately identifies the population to be served.

**Analysis of Need**

*In-Center Patients*

In Section B.2, page 7, the applicant provides a table to show the application is filed pursuant to the facility need methodology outlined in the 2016 SMFP, utilizing data from the July 2016 SDR. The applicant proposes to add four dialysis stations to SEDC-Wilmington for a total of 38 certified stations upon completion of this project and the following projects: Project ID# O10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-11018-15 (add three stations), and Project ID# O-11082-15 (add 2 stations).

In Section C.1, pages 13 – 15, the applicant provides the assumptions and methodology it used to project growth of the in-center patient population. The assumptions are summarized below:

- The applicant notes the facility was dialyzing 146 in-center patients as of December 15, 2015, as reported in the July 2016 SDR.
- The applicant states 116 of those patients were residents of New Hanover County.
- The applicant states 47 existing patients will transfer their care from SEDC-Wilmington to either New Hanover Dialysis or Leland Dialysis (Project ID# O-10324-14 and Project ID# O-10305-14); 28 of those patients are projected to be residents of New Hanover County and 19 are projected to be residents of Brunswick County.
- The applicant projects growth in the in-center patient population using an 8% growth rate that is higher than the 5.4% New Hanover County Five Year Average Annual Change Rate (AACR) reported in the July 2016 SDR, but is less than one-half of the

actual Five Year AACR (18.4%) at SEDC-Wilmington, as calculated by the applicant on page 14.

- The applicant adds the patients who reside outside of New Hanover County after projecting growth of the New Hanover County patient population, and repeats this for each interim and project year.
- The other projects that involve the transfer of patients are projected to be certified in 2017, so that the first project year for this project will begin with 97 New Hanover County in-center patients.
- The applicant states Operating Year one is projected to begin January 1, 2018, and Operating Year two is projected to begin January 1, 2019. Operating Years are calendar years, as reported by the applicant on page 13.
- The applicant projects growth beginning January 1, 2016 and ends December 31, 2019.

Projected Utilization

In Section C.1, page 14, the applicant projects the following in-center utilization for SEDC-Wilmington:

	DATE	# SA PTS.	GROWTH RATE	# SA YEAR END PTS	# PTS FROM OUT OF SA	TOTAL # PTS YEAR END	DATE
Current Year	1/1/16	116	1.08	125.28	30	155.28	12/31/16
Interim	1/1/17	125 – 28 = 97	1.08	104.76	30 – 19 = 11	115.76	12/31/17
OY 1	1/1/18	104.76	1.08	113.14	11	124.14	12/31/18
OY 2	1/1/19	113.14	1.08	122.19	11	133.19	12/31/19

The applicant rounds down to the nearest whole number and projects to serve 124 in-center patients on 38 stations or 3.26 patients per station per week [124 / 38 = 3.26] by the end of Operating Year 1, and 133 in-center patients or 3.5 patients per station per week [133 / 38 = 3.5] by the end of Operating Year 2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

*Home Hemodialysis Patients*

In Section C-1, page 15, the applicant provides assumptions and methodology for the growth of the home hemodialysis (HHD) patient population. The applicant states SEDC-Wilmington had 16 HHD patients as of December 31, 2015. The applicant projects that the HHD patient population will increase by at least one patient per year, as illustrated in the following table:

YEAR	START DATE	# PTS. BEGIN	# PTS. END
Current Year	1/1/2016	16	17
Interim Year	1/1/2017	17	18
OY 1 (CY 2018)	1/1/2018	18	19
OY 2 (CY 2019)	1/1/2019	19	20

Source: Application page 15

### *Peritoneal Dialysis Patients*

In Section C-1, page 15, the applicant states SEDC-Wilmington had 56 peritoneal dialysis (PD) patients as of December 31, 2015. On pages 15 – 16, the applicant provides assumptions and methodology for the growth of the PD patient population and projects that 20 PD patients will transfer their care to other TRC facilities by the beginning of OY 1 of this project (January 1, 2018). Thereafter, the applicant projects that the PD patient population will increase by at least one patient per year, as illustrated in the following table:

YEAR	START DATE	# PTS. BEGIN	# PTS. END
Current Year	1/1/2016	56	57
Interim Period	1/1/2017	57 – 20 = 37	38
OY 1 (CY 2018)	1/1/2018	38	39
OY 2 (CY 2019)	1/1/2019	39	40

The applicant adequately demonstrates that projected utilization of in-center, HHD and PD patients is based on reasonable and adequately supported assumptions regarding continued growth of the patient population at the facility.

### **Access to Services**

In Section C.3, page 17, the applicant states that by policy, the proposed services will be available to all persons without regard to race, sex, age or handicap. The applicant further states services will be available to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, and “*other underserved persons.*”

In addition, in Section L.1, page 48 the applicant projects that 90.6% of the in-center patients, 77.0% of the home hemo-dialysis patients and 91.5% of the peritoneal dialysis patients who will receive dialysis services at SEDC-Wilmington will be covered by either Medicare or Medicaid. In Section L.1, page 48, the applicant states that its projected payor mix is based on the payor mix for the last full operating year for SEDC-Wilmington. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, 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 proposed project 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.1, page 25, the applicant discusses the one alternative it considered prior to submitting this application, which is summarized as follows:

- Maintain the Status Quo – the applicant states that this alternative was dismissed considering the growth rate at SEDC-Wilmington.

After considering the above alternative, the applicant states that applying for four stations at SEDC-Wilmington pursuant to the facility need methodology is the most effective alternative to meet the identified need for additional stations to continue to serve the growing dialysis patients in 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 four dialysis stations to the existing facility for a total of 38 dialysis stations upon completion of this project and the following projects: Project ID# O-10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID # L-10346-14 (add ten stations), Project ID# O-11018-15 (add three stations), and Project ID# O-11082-15 (add 2 stations).**
- 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall install plumbing and electrical wiring through the walls for no more than four dialysis stations, which shall include any isolation or home hemodialysis stations.**

**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.

C

The applicant proposes to add four stations to the existing facility for a total of 38 stations upon completion of this project and the following projects: Project ID# O-10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-10346-14 (add 10 stations), Project ID# O-11018-15 (add 3 stations), and Project ID# O-11082-15 (add 2 stations).

**Capital Costs and Working Capital Costs**

In Section F.1, page 26, the applicant states there is no capital cost associated with this project. In Section F.10 and Section F.11, pages 28 - 29, the applicant states there will be no start-up or initial operating expenses associated with this project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

**SEDC Wilmington  
Projected Revenues and Expenses**

	<b>OY 1 (CY 2018)</b>	<b>OY 2 (CY 2019)</b>
Total Treatments	17,710	19,044
Total Gross Revenues (Charges)	\$7,898,289	\$8,368,809
Total Net Revenue	\$7,681,546	\$8,156,926
Total Operating Expenses (Costs)	\$6,160,264	\$6,501,410
<b>Net Profit</b>	<b>\$1,521,282</b>	<b>\$1,655,517</b>

Source: Application Section R, Forms B and C

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

### **Conclusion**

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding utilization and revenues (charges 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

The applicant, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington (“SEDC Wilmington”) proposes to add four stations to the existing facility for a total of 38 in-center stations upon completion of this project and the following projects: Project ID# O10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-10346-14 (add 10 stations), Project ID# O-11018-15 (add 3 stations), and Project ID# O-11082-15 (add 2 stations).

On page 369, the 2016 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 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.

The July 2016 SDR indicates there are two operational dialysis facilities and one approved but not yet operational dialysis facility in New Hanover County, all of which are owned and operated by Total Renal Care of North Carolina, LLC, as shown in the table below:

FACILITY	LOCATION	# STATIONS	# APPROVED STATIONS*	# PATIENTS	% UTILIZATION
Cape Fear Dialysis	Wilmington	32	0	127	99.22%
SEDC-Wilmington	Wilmington	29	5	146	125.86%
New Hanover Dialysis*	Wilmington	-	12	-	0.00%

\*Stations approved but not yet certified. The July 2016 SDR shows three stations pending certification; however, Project ID #O-11082-15 approved two additional stations. Therefore, there are a total of five stations pending certification.

Source: Table A, July 2016 SDR

New Hanover Dialysis is not yet certified and has been approved to operate 12 stations. The July 2016 SDR reports that as of December 31, 2015, Cape Fear Dialysis Center was operating at 99.22% with 127 in-center patients on 32 stations; and SEDC-Wilmington was operating at 125.85%, with 146 in-center patients on 29 stations. Both facilities were operating above capacity as of December 31, 2015. In Section G-1, page 32, the applicant states that while it does propose to increase the inventory of dialysis stations in New Hanover County, the increase in stations meets the need of the individual facility's growing patient population. Therefore, the addition of stations serves to increase needed capacity rather than duplicate any existing or approved services in the county.

In Section C.1, pages 13 - 16, the applicant provides reasonable projections for the in-center, home hemo-dialysis and peritoneal dialysis patient population it proposes to serve. The applicant's growth projections are based on a rate calculated by the applicant that is less than one-half of the historical growth rate of the facility.

The applicant adequately demonstrates the need to add four stations to the existing facility. The discussion on analysis of need found in Criterion (3) 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.1, page 33, the applicant provides the current staffing for the facility and the projected staffing following the addition of four dialysis stations. The following table illustrates current and projected staffing at SEDC-Wilmington:

**SEDC-Wilmington Current and Projected Staffing**

POSITION	CURRENT FTES	# FTES TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	5.0	1.0	6.0
Patient Care Technician	11.0	4.0	15.0
Administrator	1.0	1.0	2.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Home Training RN	2.0	0.0	2.0
Administrative Assistant	1.0	0.0	1.0
Biomedical Technician	1.0	0.0	1.0
<b>Total</b>	<b>23.0</b>	<b>6.0</b>	<b>29.0</b>

Source: Application page 33

In Section H.2, page 34, the applicant states that the Medical Director for Sandhills Dialysis will be Dr. Jonathan Woods. In Exhibit I-3, the applicant provides a letter signed by Dr. Woods, dated August 15, 2016, confirming his commitment to continue to serve as Medical Director.

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, pages 37 - 39, the applicant includes a list of providers of the necessary ancillary and support services to be provided for the patients who dialyze at SEDC-Wilmington. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-3, including letters from DaVita Laboratory Services, Inc. and several nephrologists. The information in Section I and Exhibits I-1 and I-3 is reasonable and adequately supports a finding of conformity with 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.7, page 51, the applicant provides the historical payor mix for SEDC-Wilmington for the last full operating year (CY 2015), as follows:

**SEDC-Wilmington  
 Payor Mix CY 2015**

PAYOR TYPE	% IN-CENTER PTS.	% HHD PATIENTS	% PD PATIENTS	% OF TOTAL PATIENTS
Medicare	15.8%	30.8%	18.6%	17.6%
Medicaid	8.6%	0.0%	3.4%	6.6%
Commercial Insurance	6.5%	15.4%	6.8%	7.1%
Medicare/Commercial	29.5%	30.8%	50.9%	35.6%
Medicare/Medicaid	36.7%	15.4%	18.6%	30.0%
VA	2.9%	7.6%	1.7%	2.8%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not foot due to rounding

As the table above indicates, 90.6% of SEDC-Wilmington’s in-center patients were covered by Medicare or Medicaid, and 89.8% of the total patient population was covered by Medicare or Medicaid in CY 2015. In addition, the applicant describes its admission and financial policies in Section L.3, pages 48 - 50, and provides a copy of its admission policy which states that patients will be admitted “without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability” in Exhibit L-3.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
New Hanover	16%	52%	23%	18%	9%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

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

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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 applicants;

C

In Section L.3(d) page 50, 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.6, page 50, the applicant states that there have been no civil rights equal access complaints filed within the last five years against the existing facility or any facilities owned by the parent corporation.

The application is conforming to this criterion.

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

C

In Section L.1(b), page 48, the applicant states that the projected payor mix is based on historical payor mix for SEDC-Wilmington for the last full operating year, illustrated as follows:

**SEDC-Wilmington  
Projected Payor Mix OY 2**

PAYOR TYPE	% IN-CENTER PTS.	% HHD PATIENTS	% PD PATIENTS	% OF TOTAL PATIENTS
Medicare	15.8%	30.8%	18.6%	17.6%
Medicaid	8.6%	0.0%	3.4%	6.6%
Commercial Insurance	6.5%	15.4%	6.8%	7.1%
Medicare/Commercial	29.5%	30.8%	50.9%	35.6%
Medicare/Medicaid	36.7%	15.4%	18.6%	30.0%
VA	2.9%	7.6%	1.7%	2.8%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not foot due to rounding

The applicant projects that 90.6% of its in-center patients and 89.8% of the total patient population will be covered by Medicare or Medicaid.

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.4, page 50, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients who contact the facility directly or indirectly will be referred to "a qualified nephrologist for evaluation and subsequent admission if

*it were found to be medically necessary.*” In Exhibit I-3, the applicant provides letters of support from area Nephrologists.

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 52, the applicant states that it has offered SEDC-Wilmington as a clinical training site for nursing students from Miller-Motte College. A copy of an existing Student Training Agreement between DaVita and Miller-Motte College is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately supports a finding of conformity with 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, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Wilmington (“SEDC Wilmington”) proposes to add four stations to the existing facility for a total of 38 in-center stations upon completion of this project and the following projects: Project ID# O10324-14 (relocate 10 stations to New Hanover Dialysis), Project ID# O-10346-14 (add 10 stations), Project ID# O-11018-15 (add 3 stations), and Project ID# O-11082-15 (add 2 stations).

On page 369, the 2016 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 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.

The July 2016 SDR indicates there are three dialysis facilities in New Hanover County, all of which are owned and operated by Total Renal Care of North Carolina, LLC. New Hanover Dialysis is an approved but not yet certified 12-station dialysis facility. The July 2016 SDR reports that as of December 31, 2015, Cape Fear Dialysis Center was operating at 99.22% with 127 in-center patients on 32 stations; and SEDC-Wilmington was operating at 125.85%, with 146 in-center patients on 29 stations. Both facilities were operating above capacity as of December 31, 2015.

In Section N.1, page 53, the applicant states that addition of the four stations proposed in this application will have no effect on competition in New Hanover County. TRC is the only provider of dialysis services in New Hanover County. Furthermore, the applicant states the expansion of SEDC-Wilmington will enhance access to dialysis services for its patients, and thus will enhance quality and access to those services for its patients and their family members.

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

The information provided by the applicant in the sections referred to 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 a cost-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 DaVita will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that DaVita 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 54, the applicant describes the methods by which SEDC-Wilmington will ensure the provision of quality care in the delivery of dialysis services. In Exhibit O-3, the applicant provides a list of four dialysis facilities operated by the applicant that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. In Exhibit O, the applicant provides documentation dated June 23, 2016 to confirm that each facility is back in compliance as of the date of the application.

Based on a review of the certificate of need application and publicly available data, 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant is not proposing to establish a new end stage renal disease facility.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

- C- In Section C-1, pages 13 – 15 the applicant demonstrates the need for four additional in-center dialysis stations at SEDC-Wilmington based on 124 in-center patients dialyzing on 38 in-center stations as of the end of the first operating year [ $124 / 38 = 3.26$ ;  $3.26 / 4 = 81.6\%$ ]. 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 – 16, the applicant provides the assumptions and methodology used to project in-center, home hemo-dialysis and peritoneal dialysis utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.