

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

### **FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2016

Findings Date: December 20, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: O-11260-16

Facility: Cape Fear Dialysis

FID #: 080819

County: New Hanover

Applicant: Total Renal Care of North Carolina, LLC

Project: Add eight dialysis stations for a total of 40 stations upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis stations)

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

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

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Cape Fear Dialysis (“the applicant”) proposes to add eight dialysis stations for a total of 40 stations at Cape Fear Dialysis upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis 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 stations in New Hanover County and thus, there is no need for additional dialysis stations in New Hanover County. However, an applicant is eligible to apply for additional dialysis stations in its existing facility 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 because the utilization rate reported for Cape Fear Dialysis in the July 2016 SDR is 3.9688 patients per station, or 99.22% (3.9688 / 4 patients per station = 0.9922). This utilization rate was calculated based on 127 in-center dialysis patients and 32 certified dialysis stations (127 patients / 32 stations = 3.9688 patients per station) as of December 31, 2015.

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

<b>CAPE FEAR DIALYSIS - OCTOBER 1 REVIEW - JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		127.0%
Certified Stations		32
Pending Stations		2
<b>Total Existing and Pending Stations</b>		<b>34</b>
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		127
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		119
Step	Description	Result
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1345
(ii)	Divide the result of Step (i) by 12	0.0112
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1345
(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	144.0756
(v)	Divide the result of Step (iv) by 3.2 patients per station	45.0236
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>11.0236</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 11 stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add eight new stations, therefore the application is consistent with the facility need determination for dialysis stations.

## Policies

There is one policy in the 2016 SMFP which is applicable to this review. Policy GEN-3: Basic Principles on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

### 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, Section N, page 50, Section O, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), page 10, Section C, pages 15-16, Section L, pages 44-47, Section N, page 50 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 11 and Section N, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

**Conclusion**

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and 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 eight new stations at Cape Fear Dialysis, an existing facility located at 3005 Enterprise Drive in Wilmington. Upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis stations), Cape Fear Dialysis will be certified for a total of 40 dialysis 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 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-8, page 19, the applicant provides the historical patient origin for Cape Fear Dialysis as of December 31, 2015, as illustrated below in the table:

<b>CAPE FEAR DIALYSIS As of December 31, 2015</b>	
<b>County</b>	<b># In-Center Dialysis Patients</b>
New Hanover	104
Brunswick	12
Pender	5
Columbus	2
Johnston	1
Onslow	1
Virginia	1
Other States	1
<b>TOTAL</b>	<b>127</b>

In Section C.1, page 13, the applicant provides the projected patient origin for Cape Fear Dialysis for in-center (IC) patients for the first two years of operation following completion of the project as follows:

<b>CAPE FEAR DIALYSIS PROJECTED PATIENT ORIGIN by COUNTY</b>				
	<b>OY1 CY2018</b>	<b>OY1 CY2019</b>	<b>Percent of Total OY1</b>	<b>Percent of Total OY2</b>
<b>County</b>	<b>IC</b>	<b>IC</b>		
New Hanover	110	116	84.6%	85.3%
Brunswick	9	9	6.9%	6.6%
Pender	5	5	3.8%	3.7%
Columbus	2	2	1.5%	1.5%
Johnston	1	1	0.8%	0.7%
Onslow	1	1	0.8%	0.7%
Virginia	1	1	0.8%	0.7%
Other States	1	1	0.8%	0.7%
<b>TOTAL</b>	<b>130</b>	<b>136</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology used to project patient origin on pages 13-15. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section B-2, page 7, the applicant states the need for the proposed project is based on the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR, and it proposes to add eight dialysis stations to Cape Fear Dialysis for a total of 40 stations at that facility. The applicant used the following assumptions in Section C.1, pages 13-14 of the application:

- Based on information in the July 2016 SDR, as of December 31, 2015, the utilization rate for Cape Fear Dialysis was 99.22% or 3.96 patients per station per week. This utilization was based on 127 in-center patients dialyzing on 32 stations. One hundred four of the 127 patients were residents of New Hanover County.
- In Project I.D.# O-10305, the applicant was approved to develop a new dialysis facility – Leland Dialysis in Brunswick County. TRC stated in that application that three in-center patients from Brunswick County would transfer to the new Leland Dialysis Center facility. No stations from Cape Fear Dialysis are being relocated pursuant to this project.
- The applicant proposed in Project I.D.# O-10324-14 to relocate two stations from Cape Fear Dialysis to develop the new New Hanover Dialysis Center facility in New Hanover County, and that 12 New Hanover County in-center patients from Cape Fear Dialysis would transfer their care to New Hanover Dialysis upon project completion. Certification of the New Hanover Dialysis facility is scheduled for January 2017.
- TRC proposed in Project I.D.# O-11022-15 to add two stations to Cape Fear Dialysis.

- The applicant states that Cape Fear Dialysis has experienced a growth rate of 12.2% over the past three years, although New Hanover County’s Five Year Average Annual Change Rate (AACR) was 5.6%, as published in Table B of the July 2016 Semi-Annual Dialysis Report (SDR). Thus, the applicant assumes a 6.0% growth rate for the facility through the second operating year; which is higher than the county’s but lower than the center has experienced (see chart of center growth rate on page 14 of the application).
- The applicant projects that after the growth period beginning January 1, 2016 and ending December 31, 2019, Cape Fear Dialysis will have 104 patients from New Hanover County and projects no growth in patients from other counties.
- The applicant projects that 15 current in-center patients from Cape Fear Dialysis will transfer to the new Leland Dialysis facility and New Hanover Dialysis facility upon certification. After the growth period ending in 2016 Cape Fear Dialysis will have 133 in-center patients, 110 of whom will be from New Hanover County. After subtracting 12 in-center patients who are projected to transfer to New Hanover Dialysis, Cape Fear Dialysis will have 103 New Hanover patients at the beginning of 2018.
- Based on the applicant’s assumptions and methodology, Cape Fear Dialysis is projected to have 130 in-center patients by the end of the first operating year for a utilization rate of 81.3% or 3.25 patients per station, and a minimum of 136 in-center patients by the end of the second operating year for a utilization rate of 85% or 3.4 patients per station.
- OY1 is Calendar Year 2018
- OY2 is Calendar Year 2019

Projected Utilization

The applicant’s methodology is illustrated in the following table.

<b>CAPE FEAR DIALYSIS IN-CENTER PATIENT PROJECTIONS</b>					
	<b>Start Date</b>	<b># SA* Patients x Growth Rate</b>	<b>SA Year End Census + # out of SA existing patients</b>	<b>Total Year End Census</b>	<b>Year End Date</b>
Current Year	1/1/2016	104 x 1.06	110.24 + 23	133.4	12/31/2016
Interim Year	1/1/2017	110-12=98 x 1.06	103.88 + 23-3=20	123.88	12/31/2017
OY1	1/1/2018	103.88 x 1.06	110.1128+ 20	130.1128	12/31/2018
OY2	1/1/2019	110.1128 x 1.06	116.7196 + 20	136.7196	12/31/2019

\*SA = service area = New Hanover County

The applicant projects to serve 130 in-center patients or 3.25 patients per station per week (130/40 = 3.25) by the end of Operating Year 1 and 136 in-center patients or 3.4 patients per station per week (136/40 = 3.4) by the end of Operating Year 2 for the proposed 40-station facility. 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). The July 2016 SDR indicates that

Cape Fear Dialysis operated at a utilization rate of 99.22 percent (3.9 patients per station) as of December 31, 2015. Based on data reported in the SDR, during the period from June 30, 2015 to December 31, 2015, the in-center census at Cape Fear Dialysis increased from 119 (the applicant states 116 patients) to 127 patients, which is an annual rate of growth of 6.7 percent. In this application, the applicant assumes a projected annual rate of growth of 6.0 percent for the in-center patient census at Cape Fear Dialysis, which is slightly more than the New Hanover County Five Year Average Annual Change Rate (2011-2015) of 5.4%, but is less than Cape Fear Dialysis's 12.2 % three year average annual growth rate (page 15 of the application). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

### **Access**

In Section L.1(a), pages 44-45, the applicant states that Cape Fear Dialysis makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.7, page 48, the applicant reports that 83.3% of the in-center patients who received treatments at Cape Fear Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2015. In Section L.1, page 45, the applicant projects 83.3% of its patients will be Medicare or Medicaid recipients; no change from its current payor mix. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for eight additional stations at Cape Fear Dialysis, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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 23, the applicant discusses the three alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Relocate stations from another DaVita facility - the applicant states that both DaVita facilities in the county are operating at more than 80% utilization. Therefore, relocating stations from either of the two existing facilities would negatively impact the patients who receive dialysis there.
3. Apply to add eight stations – the applicant states the eight-station expansion would help to meet the growing demand for dialysis services at Cape Fear Dialysis.

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 Cape Fear Dialysis shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis shall add no more than eight dialysis stations at Cape Fear Dialysis for a total of no more than 40 certified dialysis stations upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis stations), which shall include any include any home hemodialysis training or isolation stations.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis shall install plumbing and electrical wiring through the walls for no more than 40 dialysis stations, which shall include any isolation or home hemodialysis stations.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis 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 eight dialysis stations to Cape Fear Dialysis, for a total of 40 dialysis stations at Cape Fear Dialysis upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis stations).

**Capital and Working Capital Costs**

In the table in Section F-1, page 24, the applicant states the capital costs associated with the proposed project as \$1,464,825. Additionally, in Section F-10, pages 26-27, the applicant states that there are no working capital needs as Cape Fear Dialysis is an existing facility.

**Availability of Funds**

In Section F.2, page 25, the applicant states it will finance the capital costs with accumulated reserves/owner's equity of TRC.

Exhibit F-5 contains a letter dated September 12, 2016, from the Chief Accounting Officer of DaVita, the parent company of Total Renal Care of North Carolina, LLC, which authorizes and commits cash reserves for the project capital costs of \$1,464,825, as well as, "*any other funds that are necessary for development of this project.*" Exhibit F-7 contains the Consolidated Financial Statements for DaVita Healthcare Partners, Inc. which indicates that it had \$965,241 million in cash and cash equivalents as of December 31, 2014, \$17.9 billion in total assets and \$6.1 billion in net assets (total assets less total liabilities). However, the applicant does have 2015 data available and in clarifying information submitted December 15, 2016, states that DaVita Healthcare Partners, Inc. had \$1.5 billion in cash and cash equivalents, \$18.5 billion in total assets and \$5.9 billion in net assets as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the 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.

<b>CAPE FEAR DIALYSIS</b>		
<b>Revenue and Expenses</b>		
	<b>CY2018</b>	<b>CY2019</b>
Total Treatments	18,747	19,711
Total Charges	\$6,610,740	\$6,951,080
Total Net Revenue	\$6,398,229	\$6,727,648
Total Operating Expenses	\$5,021,613	\$5,257,608
<b>Net Income</b>	<b>\$1,376,616</b>	<b>\$1,470,040</b>

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

**Conclusion**

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, 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 proposes to add eight dialysis stations to Cape Fear Dialysis, for a total of 40 dialysis stations at Cape Fear Dialysis upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis 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 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.

The July 2016 SDR indicates that DaVita owns two existing dialysis facilities and one approved new dialysis facility in New Hanover County, as follows:

<b>NEW HANOVER COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of DECEMBER 31, 2015</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Cape Fear Dialysis	DaVita	127	Wilmington	32	0	99.22%
Southeastern Dialysis Center- Wilmington	DaVita	146	Wilmington	29	3	125.86%
New Hanover Dialysis	DaVita	0	Wilmington	0	12	0.00%

As illustrated above, both of the existing facilities owned and operated by the applicant have a utilization rate of 99% or above. A new facility by the applicant has been approved but is not yet operational.

In Section G.2, page 30, the applicant states,

*“... Because this application utilizes the Facility Need Methodology and addresses the specific needs of patients who chose to receive service from DaVita, we will focus on these three facilities for the purposes of examining possible duplication of services.*

*New Hanover Dialysis is not yet certified. Both of the other DaVita facilities in New Hanover County were operating at 80% or greater utilization as of December 31, 2015 as reported in the July 2016 SDR. Therefore, each facility has the potential for adding stations, given that they now show a need. ... While adding stations at this facility does increase the number of stations in New Hanover County, it serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved serves in the area.”*

In Section C-1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis stations), as shown below in the table:

<b>CAPE FEAR DIALYSIS</b>				
<b>Projected Patient Origin by County of Residence</b>				
<b>County</b>	<b>OY1 2018</b>	<b>OY2 2019</b>	<b>County Patients as Percent of Total</b>	
	<b>In- Center Patients</b>	<b>In- Center Patients</b>	<b>OY1</b>	<b>OY2</b>
New Hanover	110	116	84.6%	85.3%
Brunswick	9	9	6.9%	6.6%
Pender	5	5	3.8%	3.7%
Columbus	2	2	1.5%	1.5%
Johnston	1	1	0.8%	0.7%
Onslow	1	1	0.8%	0.7%
Virginia	1	1	0.8%	0.7%
Other States	1	1	0.8%	0.7%
<b>TOTAL</b>	<b>130</b>	<b>136</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the previous table, at the end of OY1 (2018), the applicant is projecting an in-center patient census of 130 patients, for a utilization rate of 81.2% or 3.25 patients per station per week (130 patients / 40 stations = 3.25/4 = 0.8125 or 81.2%). At the end of OY2 (2019), the applicant is projecting an in-center patient census of 136 patients for a utilization rate of 85.0% or 3.4 patients per station per week (136 patients / 40 stations = 3.4/4 = 0.85 or 85.0%). The projected utilization of 3.2 patients per station per week for OY1 meets the 3.2 in-center

patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add eight stations to the Cape Fear Dialysis facility based on the number of in-center patients it proposes to serve. The discussion of 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, page 31, the applicant provides a table as illustrated below, with the current and projected staffing in full time equivalents (FTEs) for Cape Fear Dialysis. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

<b>CAPE FEAR DIALYSIS</b>			
<b>POSITION</b>	<b>CURRENT # FTEs</b>	<b># FTEs TO BE ADDED</b>	<b>PROJECTED # FTEs</b>
Registered Nurse	4.0	1.0	5.0
Technician (Patient Care)	12.0	3.0	15.0
Administrator	1.0	1.0	2.0
Dietician	1.0	-	1.0
Social Worker	1.0	-	1.0
Administrative Assistant	1.0	-	1.0
Bio-med Technician	.5	-	.5
<b>Total</b>	<b>20.5</b>	<b>5.0</b>	<b>25.5</b>

As illustrated in the table above, the applicant projects an increase of 5.0 FTEs in the total number of FTE positions at Cape Fear Dialysis.

In Section H-7, page 34, the applicant provides the projected direct care staff for Cape Fear Dialysis in Operating Year 2, as shown below in the table:

<b>CAPE FEAR DIALYSIS</b>					
<b>DIRECT CARE POSITIONS</b>	<b># FTEs</b>	<b>HOURS PER YEAR PER FTE</b>	<b>TOTAL ANNUAL FTE HOURS</b>	<b>TOTAL ANNUAL HOURS OF OPERATION</b>	<b># FTE HOURS PER HOUR OF OPERATION</b>
Registered Nurse	5.0	2,080	10,400	3,120	3.3
Patient Care Tech	15.0	2,080	31,200	3,120	10.0
<b>Total</b>	<b>20.0</b>	<b>2,080</b>	<b>41,600</b>	<b>3,120</b>	<b>13.3</b>

In Section I-3(a), page 36, the applicant identifies Dr. Douglas Hamerski, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2016 letter signed by Dr. Hamerski, of Southeastern Nephrology Associates, supporting the project and confirming his continued commitment to serve as Medical Director. In Section H-3, pages 32-33, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program. The applicant states on page 33 that DaVita offers a wide range of teammate benefits and maintains a competitive salary structure in order to attract qualified teammates.

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-1, page 35, the applicant lists the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 36-37. Exhibits I-1 and I-3 contain documents from DaVita, DaVita Laboratory Services, Inc., and Dr. Hamerski (Medical Director), respectively, documenting availability of the necessary ancillary and support services. 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.

C

In Section K.2, page 40, the applicant proposes to renovate and expand the existing facility from 6,279 square feet to 7,863 square feet. The applicant provides a line drawing of the facility with the proposed additional stations in Exhibit K. In Section F.1, page 24, the applicant lists the project costs, including \$930,000 for construction, \$534,825 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,464,825. In Section K.1, pages 39-40, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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-1, pages 44-45, the applicant states, “*Cape Fear Dialysis, by policy, makes dialysis services available to all residents in its service area. ... Cape Fear Dialysis helps uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.*”

In addition, on pages 45-47, the applicant discusses its financial policies to help the above named classifications of persons. In Section L-7, page 48, the applicant states that Medicare/Medicaid represented 83.3% of all dialysis services provided at Cape Fear Dialysis in calendar year 2015. The following table illustrates the historical payor sources for Cape Fear Dialysis:

<b>CAPE FEAR DIALYSIS HISTORICAL PAYOR MIX</b>	
<b>PAYOR TYPE</b>	<b>PERCENT OF TOTAL IN-CENTER PATIENTS</b>
Medicare	24.6%
Medicaid	5.3%
Commercial Insurance	12.3%
Medicare/ Commercial	28.8%
Medicare/Medicaid	24.6%
VA	4.4%
<b>Total</b>	<b>100.0%</b>

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 market.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
New Hanover	16%	52%	23%	18%	9%	19%
Brunswick	27%	51%	19%	16%	12%	19%
Pender	17%	50%	26%	15%	13%	20%
Columbus	18%	51%	40%	24%	15%	21%
Johnston	12%	51%	31%	15%	10%	19%
Onslow	8%	45%	33%	14%	11%	16%
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%

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 applicant;

C

In Section L-3(d), page 47, the applicant states:

*“Cape Fear Dialysis 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 47, the applicant states, “*There have been no civil rights equal access filed within the last five years.*”

The application is conforming to this criterion.

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

C

In Section C-3, page 16, the applicant states:

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

*Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

In Section L-3(c), page 47, the applicant states:

*“Cape Fear Dialysis 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-1(b), page 45, the applicant reports that it expects 83.3% of the in-center patients who receive treatments at Cape Fear Dialysis to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

<b>CAPE FEAR DIALYSIS PROJECTED PAYOR MIX PROJECT YEAR 2</b>	
<b>PAYOR TYPE</b>	<b>PERCENT OF TOTAL IN-CENTER PATIENTS</b>
Medicare	24.6%
Medicaid	5.3%
Commercial Insurance	12.3%
Medicare/ Commercial	28.8%
Medicare/Medicaid	24.6%
VA	4.4%
<b>Total</b>	<b>100.0%</b>

On page 45, the applicant states the projected payor mix for Cape Fear Dialysis will remain the same as its historical payor mix.

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 47, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Cape Fear Dialysis. ... 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-1, page 49, the applicant states that Cape Fear Dialysis has been offered as a clinical training site for student nurses attending Cape Fear Community College in Wilmington.

Exhibit M-2 contains a copy of the student training agreement with Cape Fear Community College. 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 eight dialysis stations to Cape Fear Dialysis, for a total of 40 dialysis stations at Cape Fear Dialysis upon completion of this project, Project I.D.# O-10324-14 (relocate two stations to New Hanover Dialysis) and Project I.D.# O-11022-15 (add two dialysis 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 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.

The July 2016 SDR indicates that DaVita owns two existing dialysis facilities and one approved new dialysis facility in New Hanover County, as follows:

<b>NEW HANOVER COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of DECEMBER 31, 2015</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Cape Fear Dialysis	DaVita	127	Wilmington	32	0	99.22%
Southeastern Dialysis Center- Wilmington	DaVita	146	Wilmington	29	3	125.86%
New Hanover Dialysis	DaVita	0	Wilmington	0	12	0.00%

As illustrated above, both of the existing facilities owned and operated by the applicant have a utilization rate of 99% or above. A proposed new facility owned by the applicant has been approved but is not yet operational.

In Section N-1, page 50, 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 Cape Fear Dialysis will have no effect on competition in New Hanover County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care, of North Carolina, LLC.*”

*The expansion of Cape Fear Dialysis 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 B, C, D, F, G, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Cape Fear Dialysis will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Cape Fear Dialysis 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 B-4(a), pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-3, the applicant provides a listing below of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application:

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015*	Yes	9/30/2015

\*Back in compliance prior to survey on 10/7/2015 per the applicant in Project I.D.# P-11248-16

Based on a review of the information in the 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 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- 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 B.2, page 7 and Section C-1, pages 13-15, the applicant documents the need for the project and demonstrates that it will serve a total of 130 in-center patients on 40 stations at the end of the first operating year, which is 3.25 patients per station per week, or a utilization rate of 81.3%. 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 13-15, 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.