

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 2, 2014

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: O-10324-14/ Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis/ Develop a new 12-station dialysis facility in Wilmington by relocating 10 dialysis stations from Southeastern Dialysis Center-Wilmington and 2 dialysis stations from Cape Fear Dialysis Center/ New Hanover County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis proposes to develop a new 12-station dialysis facility in south Wilmington (New Hanover County) by relocating 10 dialysis stations from Southeastern Dialysis Center (SEDC)-Wilmington and two dialysis stations from Cape Fear Dialysis Center, both of which are located in New Hanover County. The new facility will provide in-center hemodialysis and home peritoneal dialysis training and support. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

The applicant is proposing to relocate dialysis stations within New Hanover County, therefore, the county and facility need methodologies in the 2014 State Medical Facilities Plan (2014 SMFP) are not applicable to this review. Additionally, Policy GEN-3: Basic Principles is not applicable because neither need methodology is applicable to this review.

However, Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities in the 2014 SMFP are applicable to this review.

Policy ESRD-2: Relocation of Dialysis Stations states:

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

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

The applicant proposes to develop a new 12-station dialysis facility, New Hanover Dialysis, in New Hanover County, by relocating 10 existing dialysis stations from SEDC-Wilmington and two from Cape Fear Dialysis Center. Since both facilities are located in New Hanover County, there is no change in dialysis station inventory in New Hanover County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy

efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The applicant proposes to develop New Hanover Dialysis, a new 12-station dialysis facility in New Hanover County, for a total capital cost of \$2,179,999. In Section XI.6, page 73, the applicant states,

"The facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating."

As stated above, Policy GEN-4, specifically the first paragraph of the policy, is applicable to this project. The statement quoted above from the application does not specifically address plans for water conservation and, generally, is not sufficient to be considered *"the project's plan to assure improved energy efficiency and water conservation."* Therefore, the application is not consistent with this policy.

In summary, the application is consistent with Policy ESRD-2 but does not demonstrate consistency with Policy GEN-4. Therefore, the application is conforming to this criterion subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis shall provide the CON Section with a written statement describing the project's plan to assure improved energy efficiency and water conservation.

- (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

Total Renal Care of North Carolina, LLC currently operates two dialysis facilities in New Hanover County. In this application, Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis proposes to establish a new 12-station dialysis facility in south Wilmington, New Hanover County, that will provide both in-center hemodialysis and home peritoneal dialysis training and support by relocating 10 existing dialysis stations from the SEDC-Wilmington facility in New Hanover County, and two existing dialysis stations from the Cape Fear Dialysis facility, also in New Hanover County. In Section

III.3, page 26, the applicant states that 47 current dialysis patients at SEDC-Wilmington and Cape Fear Dialysis have expressed interest in transferring to the new facility. In Section III.7, page 33, the applicant projects that out of those 47 patients, 40 will transfer to New Hanover Dialysis and all 40 will come from New Hanover County. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section IV.1, page 38, the applicant identifies the population of in-center and home patients served, as of December 31, 2013, at SEDC-Wilmington and Cape Fear Dialysis Center, as shown in the tables below.

Southeastern Dialysis Center-Wilmington

County of Residence	In-Center Patients	Home Patients
New Hanover	107	49
Brunswick	18	21
Columbus	4	2
Onslow	1	0
Pender	1	13
Duplin	0	5
Bladen	0	1
Sampson	0	1
South Carolina	0	1
Total	131	93

Cape Fear Dialysis Center

County of Residence	In-Center Patients	Home Patients
New Hanover	84	0
Pender	8	0
Brunswick	6	0
Columbus	3	0
Total	101	0

In Section III.7, page 33, the applicant projects that 40 in-center patients will transfer their treatment to the proposed New Hanover County facility when it becomes operational in January 1, 2016. In Section III.3, pages 28-29, the applicant projects that 28 in-center patients will transfer from SEDC-Wilmington and 12 in-center patients will transfer from Cape Fear Dialysis Center.

In Section III.7, page 32, the applicant provides the projected patient origin of the patients to be served at New Hanover Dialysis for the first two years of operation following completion of the project, illustrated as follows:

County	Operating Year 1 CY 2016		Operating Year 2 CY 2017		County Patients as a Percent of Total	
	In-Center Dialysis Patients	Home Peritoneal Dialysis Patients	In-Center Dialysis Patients	Home Peritoneal Dialysis Patients	Year 1	Year 2
New Hanover	42	8	44	9	100%	100%
Total	42	8	44	9	100%	100%

The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant proposes to relocate 12 certified dialysis stations from two existing Total Renal Care of North Carolina, LLC facilities located in New Hanover County to develop a new facility in south Wilmington, New Hanover County.

In Section III.3, page 26, the applicant states,

“This Certificate of Need application is submitted to provide geographic accessibility of in-center hemodialysis and peritoneal dialysis to a patient population located in south Wilmington. Total Renal Care of North Carolina operates two End Stage Renal Disease facilities in New Hanover County. SEDC -Wilmington, located within three blocks of the New Hanover Regional Medical Center and the Cape Fear Dialysis Center, located on the north side of New Hanover County. In doing an analysis of the patients that are served by the two New Hanover County facilities, it was determined that the existing facilities are serving a total of at least sixty-four patients who live in three zip codes on the south side of the [sic] Wilmington. In order to make the travel to dialysis three times a week for these patients more convenient, it was determined that Total Renal Care of North Carolina needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support. All patients proposed to transfer to New Hanover Dialysis are residents of Wilmington.”

In addition, the applicant states, in Section III.3(b), page 26, that all of the patients who signed letters of support for the proposed new dialysis facility that is to be located in south Wilmington indicated that *“they live closer to the proposed New Hanover Dialysis and that the facility will be more convenient for them.”*

Projected Utilization

In Section III.7, pages 32-33, the applicant states its assumptions regarding the number of in-center patients at its New Hanover County dialysis facilities who reside in New Hanover County and are willing to consider transferring to New Hanover Dialysis. The assumed number of patients willing to transfer is provided by zip code, as follows:

- 17 in-center dialysis patients from zip code 28412
- 18 in-center dialysis patients from zip code 28403
- 11 in-center dialysis patients from zip code 28409
- 1 in-center dialysis patient from zip code 28402
- Total = 47 in-center dialysis patients willing to consider transfer

However, in Exhibit 23, the applicant actually provides 48 letters from in-center patients at its New Hanover County dialysis facilities who are willing to consider transferring to New Hanover Dialysis. Eighteen in-center dialysis patients from zip code area 28412 indicated a willingness to consider transferring to New Hanover Dialysis rather than 17, thereby bringing the total to 48.

Likewise, on page 33, the applicant provides its assumptions regarding the number of home-trained peritoneal dialysis patients residing in New Hanover County who are receiving follow-up and support services at SEDC-Wilmington, and who are willing to transfer to New Hanover Dialysis, as follows:

- 5 home-trained peritoneal dialysis patients from zip code 28412
- 2 home-trained peritoneal dialysis patients from zip code 28409
- Total = 7 home-trained peritoneal dialysis patients willing to consider transfer

However, the applicant states, in Section III.7, page 34, that *“the facility is projected to have twelve (12) peritoneal dialysis patients transfer their care from SEDC-Wilmington when New Hanover Dialysis is certified...The twelve patients live in Wilmington in New Hanover County. The twelve peritoneal dialysis patients who signed letters of support live in the 28412 and 28409 zip codes.”* In Exhibit 23, the applicant provides seven home peritoneal dialysis patient letters from zip code area 28412, four from zip code area 28409, and one from zip code area 28403 for a total of 12 letters indicating patients’ willingness to transfer to New Hanover Dialysis. Therefore, the Project Analyst concludes that the applicant made an error in stating, on page 33, that only 7 home-trained peritoneal dialysis patients indicated a willingness to transfer. It is reasonable to assume that at least 12 home-trained peritoneal dialysis patients would be willing to consider transferring to New Hanover Dialysis.

In addition, the applicant states, in Section III.7, page 33, that based on patients’ letters, at least 40 in-center patients at its New Hanover County dialysis facilities are expected to transfer, 28 from SEDC-Wilmington and 12 from Cape Fear Dialysis Center. Lastly, as stated on page 33, the applicant uses the average annual growth rate of 5.5% for New

Hanover County, as published in Table B of the July 2014 SDR, to project in-center patients for operating years one and two.

In Section III.7, page 34, the applicant provides its methodology for determining the utilization rates for operating years one and two for the proposed New Hanover Dialysis facility, summarized as follows:

The applicant begins with 40 New Hanover County in-center dialysis patients as of January 1, 2016	40 in-center patients
The applicant projects the in-center population forward for 12 months to December 31, 2016, the end of Operating Year One, using the New Hanover County five year AACR of 5.5%	$(40 \times 0.055) + 40 = 42.2$ in-center patients
The applicant projects the in-center population forward for 12 months to December 31, 2017, the end of Operating Year Two, using the New Hanover County five year AACR of 5.5%	$(42.2 \times 0.055) + 42.2 = 44.5$ in-center patients
The applicant begins with 12 home peritoneal dialysis patients as of January 1, 2016	12 home peritoneal dialysis patients
The applicant projects that the number of home peritoneal dialysis patients will grow by one patient per year, projecting this population forward for 12 months to December 31, 2016, the end of Operating Year One	$12 + 1 = 13$ home peritoneal dialysis patients
The applicant projects that the number of home peritoneal dialysis patients will grow by one patient per year, projecting this population forward for 12 months to December 31, 2017, the end of Operating Year Two	$13 + 1 = 14$ home peritoneal dialysis patients

The applicant provides the following assumptions for projected utilization at New Hanover Dialysis in Section III.7, pages 34-35,

- The applicant rounds down its projected number of in-center patients for Operating Years One and Two to 42 and 44 in-center patients, respectively.
- As stated on page 34, the projections for home peritoneal dialysis patients for Operating Years One and Two “are supported by the growth rate of the peritoneal dialysis home training and support program over the last four years at SEDC-Wilmington.” The applicant provides the number of home peritoneal dialysis (PD) patients receiving services at SEDC-Wilmington, and corresponding annual growth rates, from 2010-2013, as follows:

Year	Home Peritoneal	Growth in	Percentage
------	-----------------	-----------	------------

	Dialysis (PD) Patients	Number of PD patients	Growth in PD patients
2013	78	12	18.2%
2012	66	13	24.5%
2011	53	12	29.3%
2010	41		

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires the applicant to “ ... *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...*” In this application, the applicant adequately demonstrates that New Hanover Dialysis will serve a total of 42 in-center patients on 12 stations at the end of the first operating year, which equates to 3.50 in-center patients per station per week ($42/12 = 3.50$), exceeding the performance standard of 3.2 patients per station per week. Therefore, the applicant demonstrates that the proposed New Hanover County facility would meet the minimum performance standard requirements in the Rule.

Access to Services

In Section VI.1, page 46, the applicant state,

“New Hanover Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”

The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population projected to be served has for the proposed New Hanover Dialysis facility, and demonstrates that all residents of the service area, and, in particular, 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.

The applicant proposes to relocate 10 existing certified dialysis stations from its SEDC-Wilmington facility and two existing dialysis stations from its Cape Fear Dialysis Center facility, both in New Hanover County, to develop a new, 12-station dialysis facility, New Hanover Dialysis. In Section III.3 through Section III.7, pages 27-32, the applicant discusses how the needs of dialysis patients at SEDC-Wilmington and Cape Fear Dialysis Center will continue to be met after the transfer of stations to the proposed New Hanover Dialysis facility.

Southeastern Dialysis Center (SEDC)-Wilmington

The July 2014 Semiannual Dialysis Report (SDR) indicates that as of December 31, 2013 SEDC-Wilmington had 131 in-center dialysis patients and 29 certified dialysis stations. In Section III.6, page 31, the applicant applies the New Hanover County Average Annual Change Rate (AACR) for the past five years of 5.5% to the patient population at SEDC-Wilmington to project growth from January 1, 2014 to December 31, 2015, summarized as follows:

“January 1, 2014 – December 31, 2014 – 131 in-center patients X 1.055 = 138.205

January 1, 2015 – Decembe [sic] 31, 2015 – 138.205 in-center patients X 1.055 = 145.806275”

The applicant states, in Section III.6, page 30, that 19 in-center patients will transfer their care from SEDC-Wilmington to Leland Dialysis, a dialysis facility in Brunswick County, and that all of the transferred patients reside in Brunswick County. This transfer of patients is discussed in a CON application conditionally-approved by the CON Section on September 30, 2014 (CON Project I.D. #O-10305-14). An additional 28 in-center patients will transfer their care from SEDC-Wilmington to New Hanover Dialysis when it becomes certified on January 1, 2016, as stated on page 31. Ten dialysis stations will be transferred from SEDC-Wilmington to New Hanover Dialysis once Leland Dialysis becomes certified, the same day New Hanover Dialysis will become certified, January 1, 2016, as stated on page 31. Lastly, the applicant states, on page 31, “TRC [Total Renal Care of North Carolina, LLC] is planning to apply for up to ten additional dialysis stations on September 15, 2014.” Total Renal Care of North Carolina, LLC has applied to the CON Section for 10 additional dialysis stations for New Hanover Dialysis for the CON application review cycle that began October 1, 2014 (CON Project I.D. #O-10346-14).

Based on the information provided in Section III.6, pages 30-31, described above, the projected utilization for SEDC-Wilmington is calculated by the applicant as follows:

145 in-center patients and 29 dialysis stations as of January 1, 2016

19 in-center patients transfer to Leland Dialysis for a total of 126 in-center patients (145-19 = 126)

28 in-center patients transfer to New Hanover Dialysis for a total of 98 in-center patients (126-28 = 98)

10 dialysis stations are relocated to New Hanover Dialysis for a total of 19 dialysis stations (29-10 = 19)

Therefore, with 98 in-center patients and 19 dialysis stations, SEDC-Wilmington will have a utilization rate of 5.16 patients per station, or 129% ($98/19 = 5.16$; $5.16/4 = 129\%$).

However, the applicant states, on page 31, that it intends to apply for an additional 10 dialysis stations to be added to SEDC-Wilmington and has, in fact, submitted an application to add 10 stations for the CON review period that began October 1, 2014 (CON Project I.D. #O-10346-14).

Cape Fear Dialysis Center

The applicant projects utilization for Cape Fear Dialysis Center in Section III.6, pages 31-32. The July 2014 SDR indicates that as of December 31, 2013 Cape Fear Dialysis Center had 101 in-center dialysis patients and 28 certified dialysis stations. In Section II.1, page 12, the applicant states that Cape Fear Dialysis Center had 32 certified dialysis stations as of June 18, 2014 and refers to a copy of the July 2014 SDR provided in Exhibit 7. In Exhibit 1, the applicant provides a copy of a letter from the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation (DHSR) certifying 32 dialysis stations at Cape Fear Dialysis Center as of January 15, 2014. In Section III.6, page 32, the applicant uses the New Hanover County Average Annual Change Rate (AACR) for the past five years of 5.5% to the patient population at Cape Fear Dialysis Center to project growth each year from January 1, 2014 to December 31, 2015, calculated as follows:

“January 1, 2014 – December 31, 2014 – 101 in-center patients X 1.055 = 106.555

January 1, 2015 – Decembe [sic] 31, 2015 – 106.555 in-center patients X 1.055 = 112.415525”

In Section III.6, page 31, the applicant states that Cape Fear Dialysis Center will transfer three in-center patients to Leland Dialysis as of January 1, 2016, the same date that New Hanover Dialysis will be certified. This transfer of patients is discussed in a CON application conditionally-approved by the CON Section on September 30, 2014 (CON Project I.D. #O-10305-14). The applicant states, on page 31, that 12 in-center patients at Cape Fear Dialysis Center will transfer their care to New Hanover

Dialysis. In addition, as stated on page 32, two dialysis stations will be transferred from Cape Fear Dialysis Center to New Hanover Dialysis. This transfer of in-center patients and dialysis stations is expected to occur once Leland Dialysis becomes certified, the same day New Hanover Dialysis is expected to be certified, January 1, 2016.

Based on the information provided in Section III.6, pages 31-32, described above, the projected utilization for Cape Fear Dialysis Center is calculated by the applicant as follows:

112 in-center patients and 32 dialysis stations as of January 1, 2016

3 in-center patients transfer to Leland Dialysis for a total of 109 in-center patients ($112-3 = 109$)

12 in-center patients transfer to New Hanover Dialysis for a total of 97 in-center patients ($109-12 = 97$)

2 dialysis stations are relocated to New Hanover Dialysis for a total of 30 dialysis stations ($32-2 = 30$)

Therefore, with 97 in-center patients and 30 dialysis stations, Cape Fear Dialysis Center will have a utilization rate of 3.23 patients per station, or 80.8% ($97/30 = 3.23$; $3.23/4 = 80.8\%$).

In summary, the applicant projects to serve 98 in-center patients at SEDC-Wilmington on 19 dialysis stations for a utilization rate of 5.16 patients per station, or 129%, and projects to serve 97 in-center patients at Cape Fear Dialysis Center for a utilization rate of 3.23 patients per station, or 80.8%, by January 1, 2016. The proposed project does not reduce the total number of dialysis stations in New Hanover County; it merely moves some of them to a proposed new facility in the same county to be owned and operated by Total Renal Care of North Carolina, LLC.

The applicant adequately demonstrates that the two facilities from which dialysis stations would be transferred to create a new 12-station New Hanover Dialysis facility would have sufficient capacity following the transfer of stations to the proposed New Hanover County facility. Therefore, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. Therefore, the application is conforming to this criterion.

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

In Section III.9, pages 35-36, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicant states that the combined utilization rates of its two existing dialysis facilities in New Hanover County, SEDC-Wilmington and Cape Fear Dialysis are high enough, even without accounting for population growth, to establish a new facility. In addition, neither facility can be expanded due to property size constraints. Therefore, maintaining the status quo is not a viable alternative.
- 2) Selecting a Different Location within New Hanover County to Develop the Facility – the applicant states that this alternative is not effective since the largest number of patients being served at SEDC-Wilmington and Cape Fear Dialysis, analyzed by zip code, live in the south Wilmington area where they propose to locate New Hanover Dialysis. Further, the applicant states, on page 36, *“There is not a patient population in any of [sic] other area of Wilmington or New Hanover County to support a dialysis facility.”*

After considering the above alternatives, the applicant states that the alternative represented in the application, to develop a new facility in the south Wilmington area, is the most effective alternative.

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 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 New Hanover 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 New Hanover Dialysis shall relocate no more than 12 dialysis stations to New Hanover Dialysis, which shall include any isolation or home hemodialysis stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any isolation or home hemodialysis stations.**

4. **Total Renal Care of North Carolina, LLC d/b/a New Hanover Dialysis shall provide the CON Section with a written statement describing the project's plan to assure improved energy efficiency and water conservation.**
 5. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 10 dialysis stations at Southeastern Dialysis Center-Wilmington for a total of no more than 19 dialysis stations at Southeastern Dialysis Center-Wilmington.**
 6. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify two dialysis stations at Cape Fear Dialysis Center for a total of no more than 30 dialysis stations at Cape Fear Dialysis Center.**
 7. **Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section XI.2, page 70, the applicant states, "*We will lease 9,600 square feet in a building with 11,000 square feet.*" In Section VIII.1, page 57, the applicant states that the total capital cost of the project will be \$2,179,999 which includes \$1,525,000 in construction costs, \$75,000 in architect/engineering fees, \$150,000 for dialysis machines, and \$429,999 in miscellaneous costs, including furniture, water treatment equipment, a television system, and a patient computer system.

In Section IX, page 60, the applicant states it will have start-up expenses and initial operating expenses estimated at \$1,324,055, as illustrated below:

• Start-up Expenses	\$ 190,010
• Initial Operating Expenses	<u>\$1,134,045</u>
Total Working Capital	\$1,324,055

In Section VIII.2, pages 57-58, and Section IX, page 61, the applicant indicates that the total capital cost and the total working capital of the project will be financed by cash reserves of DaVita HealthCare Partners Inc., the parent company of Total Renal Care of North Carolina, LLC. Exhibit 28 contains a copy of a letter from the Chief Accounting Officer for DaVita

HealthCare Partners, Inc. and Total Renal Care of North Carolina, LLC, dated August 13, 2014, that states,

“I am writing this letter as Chief Accounting Officer of DaVita, to confirm DaVita’s commitment of \$2,179,999 for the capital expenditures associated with this project; a commitment of \$190,010 for its start-up expenses; and a further commitment of \$1,134,045 in working capital. Note that this working capital commitment is sufficient to cover all of the projected operating expenses for a period of approximately six months of operation of this new facility.

DaVita has committed cash reserves in the total sum of \$3,504,054 for the capital costs, start-up costs and working capital for this project. As Chief Accounting Officer of TRC, I can also confirm that TRC will ensure that these funds are made available for the development and operation of this project.”

In Exhibit 29, the applicant provides a copy of DaVita HealthCare Partners Inc.’s corporate financial statements from the United States Securities and Exchange Commission for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita HealthCare Partners Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 62, and Section X.3, page 65, the applicant provides the allowable charge per treatment for each payment source for New Hanover Dialysis, as follows:

Payor Source	Charge per Treatment In-Center Dialysis	Charge per Treatment Peritoneal Dialysis
Medicare	\$239.02	\$239.02
Medicaid	\$143.00	\$143.00
Medicare/Medicaid	\$239.02	\$239.02
Commercial Insurance	\$1,275.00	\$1,275.00
VA	\$193.00	\$193.00
Medicare/Commercial	\$239.02	\$239.02

The applicant states, on page 62, that the Medicare rate “...is the 2014 bundle reimbursement rate as documented in the Federal Register dated December 2, 2013.” In addition, the applicant states, on page 62, “The Center for Medicare and Medicaid Services has recommended that the Medicare Reimbursement rate will not change for the next two years.”

The applicant projects revenues in Section X.2, page 63, and operating expenses in Section X.4, page 67, for the first two years of operation of the proposed project, illustrated as follows:

New Hanover Dialysis	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,723,174	\$2,881,238
Total Operating Expenses	\$2,268,089	\$2,375,580
Net Profit	\$455,085	\$505,658

In Section III.7, page 35, the applicant states that it uses a total of 41 in-center patients for operating year one of the project instead of 42 as calculated in Criterion 3 for its projected utilization, as an average of in-center patients “*over the course of the year to determine the number of treatments and the associated operating revenue and expenses.*” Likewise, the applicant uses an average of 43 in-center patients for operating year two of the project instead of 44, as calculated in Criterion 3 for its projected utilization.

In addition, as stated in Section III.7, page 35, the applicant uses 12.5 home peritoneal dialysis patients for operating year one, instead of 13 as calculated in Criterion 3 for its projected utilization, as an average of home peritoneal patients “*over the course of the year to determine the number of treatments and the associated operating revenue and expenses.*” Likewise, the applicant states it uses an average of 13.5 home peritoneal patients for operating year two instead of 14, as calculated in Criterion 3 for its projected utilization.

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. Operating expenses and revenues are based on reasonable assumptions including projected utilization. See Section X.3, pages 64-69, of the application for the assumptions. See Criterion (3) for discussion regarding projected utilization which is hereby incorporated by reference as if set forth fully herein.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 12-station dialysis facility in south Wilmington, New Hanover Dialysis, by relocating 10 existing dialysis stations from SEDC-Wilmington and two existing dialysis stations from Cape Fear Dialysis Center, both located in New Hanover County. The July 2014 SDR provides the following information for the two dialysis facilities located in New Hanover County:

**New Hanover County Dialysis Facility Data
As of December 31, 2013**

Facility	# of In-Center Patients	# of Certified Stations	% Utilization
Southeastern Dialysis Center (SEDC) – Wilmington	101	28	90.18%
Cape Fear Dialysis Center	131	29	112.93%

As illustrated in the table above, there are currently two dialysis facilities in New Hanover County. SEDC-Wilmington is located approximately 1.5 miles from the proposed New Hanover Dialysis facility and Cape Fear Dialysis Center is located approximately 9.5 miles from the proposed facility. In Exhibit 23, the applicant provides letters from dialysis patients currently receiving care at SEDC-Wilmington or Cape Fear Dialysis Center indicating their willingness to transfer their care to the proposed New Hanover Dialysis facility. Eighteen of the 48 letters provided are from patients who reside in the 28412 zip code area, the same zip code area that the proposed facility will be located in. Eighteen additional letters are from patients who reside in the 28403 zip code area. The 28403 zip code area is south of both SEDC-Wilmington and Cape Fear Dialysis Center and is closer to the 28412 zip code area that the proposed facility will be located in. A map of New Hanover County's zip code areas is included in Exhibit 20.

Total Renal Care of North Carolina, LLC is not adding dialysis stations in New Hanover County but is transferring stations from two existing facilities, SEDC-Wilmington and Cape Fear Dialysis Center. As shown on the table above, both facilities were operating at over 80% of capacity as of December 31, 2013.

In Section III.7, page 32, the applicant demonstrates that New Hanover Dialysis will serve a total of 42 in-center patients on 12 stations at the end of the first operating year, which is 3.50 patients per station per week, or a utilization rate of 87.5% ($42/12 = 3.50$; $3.50/4 = 87.5\%$). Also, the applicant's projected utilization rates are based entirely on patients currently served at Total Renal Care of North Carolina, LLC dialysis facilities in New Hanover County who have expressed their willingness to consider transferring to the proposed south Wilmington facility because it will be more convenient for them.

Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in New Hanover County. Therefore, 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.

In Section VII.1, page 52, the applicant projects the number of FTE positions following completion of the proposed project, as illustrated in the table below:

Position	Projected # of FTEs
RN	1.5
Home Training Nurse	1.0
Patient Care Technician	4.5
Bio-Medical Technician	0.3
Medical Director	Contract Position – Not an FTE of facility
Unit Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Re-use Technician	1.0
Unit Secretary	1.0
Total	11.3

In Section V.4, page 43, the applicant states that Dr. Derrick Robinson has agreed to serve as the Medical Director of the proposed facility. In Exhibit 22, the applicant provides a letter dated July 30, 2014 from Dr. Robinson, a practicing Nephrologist with Southeastern Nephrology Associates, wherein he has agreed to serve as Medical Director for New Hanover Dialysis. In Section VII.4, page 53, the applicant states that some of the positions for the new facility will be filled by current employees from SEDC-Wilmington and Cape Fear Dialysis Center who will transfer. Any remaining vacant positions will be advertised. The applicant further states, on page 54, that “*DaVita HealthCare Partners has an aggressive recruiting presence in North Carolina*” and does not anticipate having any difficulties filling positions at New Hanover Dialysis. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 V.1, page 41, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility, indicating whether the services will be provided on premises or off-site. The applicant discusses coordination with the existing health care system on pages 42-44. Exhibits 8, 9, 16 and 23 contain documents which demonstrate 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 V.1 and Exhibits 8, 9, 16 and 23 is reasonable and credible 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 VIII.1, page 56, the applicant states that it will up fit an existing shell building provided by a lessor. In Section XI.2, page 70, the applicant states that it will lease 9,600 square feet of an 11,000 square foot building for the proposed dialysis facility, New Hanover Dialysis. In Section XI.6, page 73, the applicant states, "*The facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.*"

Costs and charges are described by the applicant in Section X of the application, pages 62-69. 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, 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 VI.1(b), pages 46-47, the applicant provides the historical payor mix for SEDC-Wilmington and Cape Fear Dialysis Center for 2013, illustrated as follows:

Payor Source	SEDC- Wilmington In-Center Dialysis	SEDC- Wilmington Home Peritoneal Dialysis	Cape Fear Dialysis Center In-Center Dialysis
Medicare	15.1%	18.2%	24.8%
Medicaid	6.5%	4.5%	7.4%
Medicare/Medicaid	34.5%	19.7%	21.5%
Medicare/Commercial	33.8%	34.9%	30.6%
Commercial Insurance	5.8%	21.2%	12.4%
VA	4.3%	1.5%	3.3%
Total	100.0%	100.0%	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for New Hanover County and statewide:

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
New Hanover County	13.1%	5.7%	20.4%
Statewide	16.5%	6.7%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by Total Renal Care of North Carolina's New Hanover County facilities that will be contributing stations to the proposed New Hanover Dialysis facility. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2013 – 12/31/2013*, page 99.).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number

of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*"The December 31, 2011 prevalent population included 430,273 patients on dialysis..."*¹ (p.216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native Americans (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p.223). The report further states:

"In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant." (p.216)

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

¹ www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race and Gender 2013*		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.3%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%
Total	15,389	100.0%

*Source: SKC Network 6. Table includes North Carolina statistics only.²

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

*Source: 2013 USRDS Annual Data Report, page 332.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and are therefore 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

² www.esrdnetwork6.org/publications/reports.html

assistance, including the existence of any civil rights access complaints against the applicants;

C

In Section VI.1(f), page 49, the applicant states,

“New Hanover Dialysis will have 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. New Hanover Dialysis will have no obligation under the Hill Burton Act.”

In Section VI.6(a), page 51, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”* Therefore, 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 VI.1(a), page 46, the applicant states,

“New Hanover Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

...

New Hanover Dialysis will not require payment upon admission to its services; 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 VI.1(c), pages 47-48, the applicant provides the projected payor mix for New Hanover Dialysis, as follows:

Payor Source	New Hanover Dialysis In-Center Dialysis	New Hanover Dialysis Home Peritoneal Dialysis
Medicare	19.6%	18.2%
Medicaid	6.9%	4.5%
Medicare/Medicaid	28.5%	19.7%
Medicare/Commercial	32.4%	34.9%
Commercial Insurance	8.8%	21.2%
VA	3.8%	1.5%
Total	100.0%	100.0%

As shown in the table above, the applicant projects that 55.0% of in-center patients will be either Medicare, Medicaid, or Medicare/Medicaid beneficiaries and that 42.4% of home peritoneal dialysis patients will be Medicare, Medicaid, or Medicare/Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would 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 VI.5, page 50, the applicant states,

“Patients with End State Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at New Hanover Dialysis.

...

Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Wilmington and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area.”

In addition, the applicant states, on page 50, that patients, families or friends may obtain dialysis services by contacting a Nephrologist with privileges at the facility.

The applicant adequately demonstrates that it will provide a range of means by which a person will have access to its 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 V.3, page 43, the applicant states that New Hanover Dialysis will be open to clinical training programs as a learning site. In addition, the applicant includes a copy of a letter in Exhibit 21, dated August 1, 2014, from the Director of Healthcare Planning of Total Renal Care of North Carolina, LLC to Cape Fear Community College offering New Hanover Dialysis as a training site for nursing students once it is fully operational. The information provided in Section V.3 and Exhibit 21 is reasonable and credible 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 develop a new 12-station dialysis facility in south Wilmington, New Hanover County, by transferring existing stations from two Total Renal Care of North Carolina, LLC facilities in New Hanover County. There are currently two dialysis facilities in New Hanover County, both operated by Total Renal Care of North Carolina, LLC.

In Section V.7, page 45, the applicant states,

“The proposed New Hanover Dialysis will not have an adverse effect on competition since the patients already being served by Total Renal Care of North Carolina will be transferring their care from one TRC facility to another TRC facility, which will be more convenient for the patients who have indicated this in

the letters they signed. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.”

The applicant further states, on page 45, that the next closest dialysis facility is “30.4 miles by road” from New Hanover Dialysis, and is located in Supply, Brunswick County. The Supply dialysis facility is owned by Fresenius.

The applicant further states, on page 45,

“...New Hanover 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 other [sic] involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in New Hanover County. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need to relocate 12 dialysis stations within New Hanover County, and that it is a cost-effective alternative to meet that need;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

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.

The applicant proposes to relocate stations from two New Hanover County dialysis facilities, SEDC-Wilmington and Cape Fear Dialysis Center, to a new facility in New Hanover County, New Hanover Dialysis. According to the Acute and Home Care Licensure and Certification Section, DHSR, both of these New Hanover County facilities have operated in compliance with all Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The 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, which are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- See Section II.1, page 12, and Exhibit 7 (copy of the July 2014 SDR, Tables A and B), the applicant provides the utilization rates for SEDC-Wilmington and Cape Fear Dialysis Center.

.2202(a)(2) Mortality rates;

- C- In Section IV.2, page 39, the applicant reports the 2011, 2012 and 2013 facility mortality rates for Southeastern Dialysis Center-Wilmington and reports the 2012 and 2013 facility mortality rates for Cape Fear Dialysis Center, the only years it has been in operation.

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

- C- In Section IV.3, page 39, the applicant states that SEDC-Wilmington had 93 home trained patients as of December 31, 2013. Cape Fear Dialysis Center refers patients for home dialysis to SEDC-Wilmington.

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

- C- In Section IV.4, page 39, the applicant states that SEDC-Wilmington referred 105 patients for transplant evaluation in 2013 and that three patients received a transplant in 2013. Cape Fear Dialysis Center referred 23 patients for transplant evaluation in 2013, and two patients received transplants in 2013.

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

- C- In Section IV.5, page 40, the applicant states that SEDC-Wilmington has 28 patients on the transplant waiting list, and that Cape Fear Dialysis Center has 18 patients on the transplant waiting list.

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

- C- In Section IV.6, page 40, the applicant reports that SEDC-Wilmington had a total of 501 hospital admissions in 2013; 86.2% were non-dialysis related and 13.8% were dialysis-related. For Cape Fear Dialysis Center, the applicant reports a total of 240 hospital admissions in 2013; 84.6% were non-dialysis related and 15.4% were dialysis-related.

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

- C- In Section IV.7, page 40, the applicant states that there was one patient with infectious disease as of June 30, 2014 and two with AIDS dialyzing at SEDC-Wilmington. No patients converted to infectious status at SEDC-Wilmington within the last year. For Cape Fear Dialysis Center, the applicant states that there were no patients with infectious disease as of June 30, 2014, however there were two patients with AIDS. There were no patients who converted to infectious status at Cape Fear Dialysis Center within the last year.

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

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

- C- Exhibit 8 contains a copy of a letter from the Executive Vice President/COO of New Hanover Regional Medical Center confirming the hospital's willingness to enter into a patient transfer agreement with Total Renal Care of North Carolina, LLC for the proposed New Hanover Dialysis facility once a certificate of need is issued. The letter specifies a range of services that the hospital will provide to patients dialyzing at New Hanover Dialysis.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
 - (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- C- Exhibit 9 contains a letter signed by the Director of Quality, Compliance and Finance of Duke University Medical Center's Transplant Center indicating the hospital's intention to enter into a transplant agreement with New Hanover Dialysis once a certificate of need for the facility is received. Exhibit 9 also contains a letter signed by the Professor and Chief of Surgical Immunology and Transplantation of Vidant Health indicating the hospital's intention to enter into a transplant agreement with New Hanover Dialysis. Both letters state that their respective transplant agreements will include each item required by this rule.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
 - C- Exhibit 12 contains a letter from The Cape Fear Public Utility Authority stating that water and sewer service is available to the proposed site. Exhibit 12 also contains a letter from Duke Energy stating that electrical service is available at the site.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
 - C- Exhibit 10 contains copies of three procedures used by the parent company, DaVita Inc., to provide for back up electrical service in the event of a power outage.

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section XI.2, page 70, the applicant states that the primary site will be located at 3147 South 17th Street in Wilmington. Exhibit 11 contains a copy of a letter from Cameron Management stating that the building located on this site is available for lease. The applicant states, on page 71, that secondary sites for the facility are located at 4431-4435 Junction Park Drive in Wilmington. Exhibit 11 contains a copy of a letter from Seamist Properties, LLC stating that both lots are currently available for purchase.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section XI.6, page 74, and Exhibits 12-14.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section II.1, pages 14-16, the applicant provides the projected patient origin for New Hanover Dialysis, including all assumptions and methodology.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- In Section III.8, page 35, the applicant states that all of the patients who expressed a willingness to transfer their care to New Hanover Dialysis live less than 30 miles from the facility. The applicant provides the zip codes where the patients live in New Hanover County, in Section III.3, page 29, Section III.7, page 34, Section III.9, page 36, and in Exhibit 23. A zip code map of New Hanover County, where the proposed facility will be located, is provided in Exhibit 20.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II.1, page 16, the applicant states, “DVA Healthcare Renal Care, Inc. d/b/a New Hanover Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

- .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.*
- C- In Section II.1, pages 17-21, the applicant demonstrates it will serve a total of 42 in-center patients on 12 stations at the end of the first operating year, which is 3.50 patients per station per week, or a utilization rate of 87.5%. Therefore, the applicant demonstrates that the proposed New Hanover County facility will meet the minimum performance standard requirements in this rule.
- .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.*
- N/A- The applicant is not 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.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 17-21, the applicant provides the assumptions and methodology used to project utilization of the facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

- .2204(1) *Diagnostic and evaluation services;*
- C- The applicant states, in Section II.1, page 21, that New Hanover Regional Medical Center will provide diagnostic and evaluation services.
- .2204(2) *Maintenance dialysis;*
- C- In Section II.1, page 21, the applicant states that New Hanover Dialysis will provide maintenance dialysis services.
- .2204(3) *Accessible self-care training;*
- C- In Section II.1, page 21, the applicant states that New Hanover Dialysis will provide self-care training in peritoneal dialysis.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.1, page 21, the applicant states that New Hanover Dialysis will provide an accessible program for follow-up and support of home peritoneal dialysis patients

and that SEDC-Wilmington will also provide follow-up and support of home peritoneal dialysis patients through an agreement with New Hanover Dialysis. A signed agreement between the facilities for these services is provided in Exhibit 16.

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

- C- In Section II.1, page 21, the applicant states that x-ray services will be provided by New Hanover Regional Medical Center. A letter from New Hanover Regional Medical Center agreeing to provide these services under a transfer agreement is provided in Exhibit 8.

.2204(6) *Laboratory services;*

- C- See Exhibit 17 for a letter of agreement between DaVita Inc., the parent company, and two laboratory services providers, DVA Laboratory Services, Inc. and DaVita Laboratory Services, Inc. to provide these services.

.2204(7) *Blood bank services;*

- C- In Section II.1, page 21, the applicant states that blood bank services will be provided by New Hanover Regional Medical Center. A letter from New Hanover Regional Medical Center agreeing to provide these services under a transfer agreement is provided in Exhibit 8.

.2204(8) *Emergency care;*

- C- In Section II.1, page 22, the applicant states that emergency care services will be provided by New Hanover Regional Medical Center. A letter from New Hanover Regional Medical Center agreeing to provide these services under a transfer agreement is provided in Exhibit 8. In addition, the applicant states, on page 22, "*New Hanover Dialysis will have an emergency cart available to the clinical teammates in emergency situations.*"

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

- C- In Section II.1, page 22, the applicant states that acute dialysis in an acute care setting will be provided by New Hanover Regional Medical Center. A letter from New Hanover Regional Medical Center agreeing to provide these services under a transfer agreement is provided in Exhibit 8.

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

- C- In Section II.1, page 22, the applicant states that vascular surgery for dialysis patients will be provided by New Hanover Regional Medical Center. A letter from New Hanover Regional Medical Center agreeing to provide these services under a transfer agreement is provided in Exhibit 8.

.2204(11) *Transplantation services;*

- C- In Section II.1, page 22, the applicant states that transplantation services will be provided by Vidant Health and Duke Medical Center. Letters of intent to provide these services through an agreement with DaVita HealthCare Partners, Inc., from

both Vidant Health and Duke Medical Center, are provided in Exhibit 9.

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

- C- In Section II.1, page 22, and Section V.1, page 41, the applicant states that vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) *Transportation*

- C- In Section II.1, page 22, the applicant states that transportation services will be provided by New Hanover County Senior Resource Center. See Exhibit 18 for a copy of a letter provided by New Hanover County Senior Resource Center.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

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

- C- In Section II.1, page 22, the applicant states that the proposed facility will comply with all staffing requirements set forth in the Federal code. In Section VII, page 52, the applicant provides the proposed staffing for New Hanover Dialysis. New Hanover Dialysis will operate two dialysis shifts Monday through Saturday staffed with three direct care staff per shift, as indicated in Section VII, page 55. Additional information on staffing qualifications and responsibilities is provided in Section II.1, pages 22-23. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for additional discussion which is hereby incorporated by reference as if set forth fully herein.

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

- C- In Section II.1, page 23, the applicant states that all staff who provide patient care must attend training in hemodialysis, receive on the job training, and pass a certification test. National certification must be achieved by all patient care technicians within eighteen months of employment. The applicant provides a copy of DaVita's training program outline for new patient care provider teammates in Exhibit 19.