

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: September 30, 2014
PROJECT ANALYST: Bernetta Thorne-Williams
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: O-10305-14 / Total Renal Care of North Carolina, LLC d/b/a Leland Dialysis / Develop 10 station dialysis facility, by relocating eight dialysis stations from Southeastern Dialysis Center - Shallotte and two dialysis stations from Southport Dialysis Center / Brunswick 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 (TRC) d/b/a Leland Dialysis, whose parent company is DaVita HealthCare Partners Inc. proposes to relocate eight existing certified dialysis stations from Southeastern Dialysis Center - Shallotte (SEDC – Shallotte), in Brunswick County and two existing certified dialysis stations from Southport Dialysis Center, in Brunswick County to develop Leland Dialysis Center in Leland, in Brunswick County for a total of ten certified dialysis stations at Leland Dialysis Center upon project completion. The applicant also proposes to offer home training in peritoneal dialysis at the proposed facility. The applicant does not propose to add new dialysis stations. Therefore, neither the county or facility need methodologies in the 2014 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a facility pursuant to a need determination in the 2014 SMFP. However, Policy ESRD-2: Relocation of Dialysis Stations is to this review applicable to this review.

Policy ESRD-2 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:

- (A) *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*

- (B) *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 relocate ten existing dialysis stations within Brunswick County to establish a new facility, Leland Dialysis. Consequently, there is no change in the dialysis station inventory in Brunswick County, therefore, the application is consistent with Policy ESRD-2.

In summary, the applicant is consistent with Policy ESRD-2 and is therefore conforming to this criterion.

- (2) Repealed effective July 1, 1988.
- (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 d/b/a Leland Dialysis proposes to relocate eight existing certified dialysis stations from Southeastern Dialysis Center - Shallotte, in Shallotte and two existing certified dialysis stations from Southport Dialysis Center, in Southport to develop Leland Dialysis Center in Leland, for a total of ten certified dialysis stations, which includes home training in peritoneal dialysis, at Leland Dialysis Center upon project completion. All facilities are located in Brunswick County. The proposed primary site being considered for Leland Dialysis Center is Parcel ID # 0400046 located at #4 Grandiflora Drive, Magnolia Village in Leland. The applicant does not propose to add new dialysis stations, therefore, the ESRD station inventory of Brunswick County would not change.

Population to be Served

In Section IV.1, page 32, the applicant identifies the population currently being served at SEDC - Shallotte and Southport Dialysis, as of June 30, 2013, as illustrated in the tables below.

SEDC-Shallotte Current Patient Origin		
County	In-Center Patients	Home Trained Patients
Brunswick	42	13
Columbus	0	2
TOTAL	42	15

Southport Dialysis Current Patient Origin		
County	In-Center Patients	Home Trained Patients
Brunswick	34	0
TOTAL	34	0

In Section III.7, page 28, the applicant projects the number of in-center patients to be served in the first two years of operation following project completion, as illustrated in the following table:

COUNTY	LELAND DIALYSIS					
	Operating Year 1 2016		Operating Year 2 2017		County In-Center Patients as % of Total	
	In-Center	Home Dialysis	In-Center	Home Dialysis	Year 1	Year 2
Brunswick	32	8	33	8	90.9%	91.1%
Columbus	4	0	4	0	9.1%	8.9%
Total	36	8	37	8	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Need Analysis

In Section III.3, page 28, the applicant states that improved geographic accessibility of services in Brunswick County is a key factor for the proposed project. In Section III.7, pages 28-29, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize the Leland Dialysis Center, as follows:

“The majority of patients who are projected to utilize Leland Dialysis will be Brunswick County residents. Most of the patients live in Leland. ... [T]hese projections are based on the following assumptions:

- *Thirty-one in-center patients receiving their dialysis services at SEDC-Wilmington (19), Cape Fear Dialysis Center (3), SEDC-Shallotte (2), and Southport Dialysis Center (7) live in Leland in Brunswick County.*
- *Four in-center patients receiving their dialysis services at the Cape Fear Dialysis Center live in Riegelwood in Columbus County.*
- *All of the patients who signed letters of support indicating that they would consider transferring to Leland Dialysis live closer to the proposed site of the new facility from their home than any other dialysis facility, including SEDC-Wilmington, Cape Fear Dialysis Center, Southport Dialysis Center, SEDC-Shallotte, SEDC-Whiteville and the Fresenius facility located in Supply in Brunswick County.*
- *The number of patients is projected to grow at a rate of 4.5% during the first two*

operating years based on the Brunswick County growth experienced over the past five years. This information is contained in Table B of the January 2014 Semiannual Dialysis Report.

- *TRC assumes that all patients in and around Leland in Brunswick County and Riegelwood in Columbus County want to receive their in-center dialysis and peritoneal dialysis training and support in a facility that will be closer to their homes and more convenient for them to travel to three times a week.*

Thirty-five patients who currently receive their dialysis treatments at the SEDC-Wilmington, Cape Fear Dialysis Center, SEDC-Shallotte and Southport Dialysis Center facilities in [sic] have signed letters of support for the proposed Leland Dialysis. All of the patients have indicated in their letters that they live closer to the proposed Leland Dialysis facility and that the facility will be more convenient for them.

Based on these letters, Leland Dialysis will have at least 35 in-center ESRD patients dialyzing in the facility January 1, 2016, which is projected to be the beginning of the first year of operation. Those 35 patients are projected to transfer from the SEDC-Wilmington, Cape Fear Dialysis Center, SEDC-Shallotte and Southport Dialysis Center. The facility is projected to have 36 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the January 2014 Semiannual Dialysis Report in Table B: ... This meets the requirement that at the end of the first operating year the facility shall have at least 32 patients or 3.2 patients per station, which documents the need for at least 10 stations.

The January 2014 [sic] Semiannual Dialysis Report indicates that the five-year average change rate in Brunswick County is 4.5%. ...

In-Center Utilization Projections using the average annual change rate for the past five years of 4.5% and starting with 31 in-center patients living in Brunswick County that will transfer to Leland Dialysis. On January 2, 2016:

January 2, 2016-December 31, 2016 – 31 in-center patients X 1.045 = 32.395

January 1, 2018-December 31, 2017– 32.395 in-center patients X 1.045 = 33.852775

January 2, 2016-December 31, 2016 is the first operating year.

January 1, 2017-December 31, 2017 is the second operating year.”

In Section III.7, page 29, the applicant projects to serve 36 in-center patients at Leland Dialysis Center in operating year one (2016), of which 32 patients are projected to be from Brunswick County and 4 patients from Columbus County. Thus, the applicant projects to have 3.6 in-center patients per station per week [36 / 10 = 3.6] or 90% utilization [36/(4x10) = 90%] by the end of operating year 1 (2016). According to historical utilization provided by the applicant in Section IV.1, page 32, neither SEDC-Shallotte nor Southport Dialysis have served in-center dialysis patients from Columbus County. The applicant states on page 28 that, “*Thirty-one in-center patients receiving their dialysis services at SEDC-Wilmington (19), Cape Fear Dialysis Center (3), SEDC-Shallotte (2), and Southport Dialysis*

Center (7) live in Leland in Brunswick County.” The applicant actually provides seven letters of support from patients currently dialyzing at Cape Fear Dialysis Center, expressing an interest in transferring their dialysis care to the proposed Leland Dialysis Center. Therefore, the applicant provided 35 letters of support. However, none of the letters of support located in Exhibits 15-18 are from patients who state they currently live in Columbus County. If the applicant only had the 32 patients projected to transfer their care who currently live in Brunswick County and are dialyzing at SEDC-Wilmington, Cape Fear Dialysis Center, SEDC-Shalotte, and Southport Dialysis Center, Leland Dialysis would have 3.2 patients per station or 80% utilization by the end of operating year 1. Either way projected utilization would meet or exceed the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

In Section III.7, page 29, the applicant projects serving 37 in-center patients at Leland Dialysis Center in operating year 2 (2017), of which 33 patients are projected to be from Brunswick County and four from patients from Columbus County. Therefore, the applicant projects to have 3.7 in-center patients per station per week [$37 / 10 = 3.7$] or 92.5% utilization [$37/(4 \times 10) = 92.5\%$] by the end of operating year 2 (2017).

With regard to home trained patients, the applicant states the following on page 29:

“Home training in peritoneal dialysis will be offered at Leland Dialysis. Eight (8) peritoneal dialysis patients who live in Leland have signed letters indicating that they would consider transferring their care to the Leland facility. Growth in the peritoneal training and support program is projected to be flat for the first two years of operation.”

The applicant projects to have eight home-trained patients at the end of operating year 1 and 2, with all eight of those patients being Brunswick County patients. See Exhibit 19 for letters of support from patients currently receiving peritoneal dialysis services and support from a TRC facility in Brunswick County.

Projected utilization is based on reasonable and supported assumptions regarding continued growth in the proposed service area.

Access

In Section VI.1, page 40, the applicant describes how underserved persons will have access to services provided by Leland Dialysis. The applicant states:

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

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area 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.

C

The applicant proposes to relocate eight existing certified dialysis stations from SEDC - Shallotte and two existing certified dialysis stations from Southport Dialysis Center to Leland Dialysis in Brunswick County for a total of ten certified dialysis stations at Leland Dialysis Center upon completion of the project. In Section III.3(c), pages 23-25, the applicant discusses how the needs of dialysis patients at SEDC - Shallotte and Southport Dialysis Center will continue to be met after the transfer of those stations to the proposed Leland Dialysis Center.

Southeastern Dialysis Center - Shallotte

The January 2014 SDR reports that Southeastern Dialysis Center - Shallotte had 42 in-center patients dialyzing on 18 certified stations with a utilization rate of 58.33% as of June 30, 2013 when the data was compiled. The applicant reports on page 23, that the Data Collection Form for ESRD Facilities submitted to the Division of Health Service Regulation to be used in the July 2014 SDR indicates that the facility had 38 in-center dialysis patients as of December 31, 2013. In Section III.3(c), pages 23-24, the applicant states:

“Taking into consideration that the SEDC - Shallotte had 35 in-center patients as of December 31, 2013 and that Brunswick County had an Average Annual Change Rate for the Past Five Years of 4.5%, the calculations below show the growth in the patient population from December 31, 2013 to the date Leland Dialysis is projected to be certified.

January 1, 2014-December 31, 2014 – 38 in-center patients X 1.045 = 39.71

January 1, 2015-December 31, 2015 – 39.71 in-center patients X 1.045 = 41.49695

Using the projections above, the SEDC - Shallotte would have 41 in-center patients at the point when Leland Dialysis is projected to be certified on January 1, 2016. With 2 patients and 8 dialysis stations transferring from the SEDC - Shallotte to Leland Dialysis Center, this will leave 39 patients (41– 2 =39) and 10 dialysis stations at the SEDC - Shallotte. Once the transfer takes place, using the numbers above, the SEDC - Shallotte utilization rate would be 97.5%. ...”

Southport Dialysis Center

The January 2014 SDR reports that Southport Dialysis Center had 34 in-center patients dialyzing on 10 certified stations with a utilization rate of 85.00% as of June 30, 2013 when the data was compiled. The applicant reports on page 24, that the Data Collection Form for ESRD Facilities submitted to the Division of Health Service Regulation to be used in the July 2014 SDR indicates that the facility had 35 in-center dialysis patients as of December 31, 2013. In Section III.3(c), pages 24-25, the applicant states:

“Taking into consideration that the Southport Dialysis Center had 38 [sic] in-center patients as of December 31, 2013 and that Brunswick County had an Average Annual Change Rate for the Past Five Years of 4.5%, the calculations below show the growth in the patient population from December

31, 2013 to the date Leland Dialysis is projected to be certified.

January 1, 2014-December 31, 2014 – 35 in-center patients X 1.045 = 36.575

January 1, 2015-December 31, 2015 – 36.575 in-center patients X 1.045 = 38.220875

Using the projections above, the Southport Dialysis Center would have 38 in-center patients at the point when Leland Dialysis is projected to be certified on January 1, 2016. With 7 patients and 2 dialysis stations transferring from Southport Dialysis Center to Leland Dialysis, this will leave 31 in-center patients (38 – 7 = 31) and 11 dialysis stations at the Southport Dialysis Center. Once the transfer takes place, using the numbers above, the Southport Dialysis Center utilization rate would be 70%.”

Thus, the applicant projects to serve 39 in-center patients at SEDC - Shallotte and 31 in-center patients at Southport Dialysis Center by January 1, 2016. This is a utilization rate of 3.9 patients per station [39/10= 3.9] at SEDC - Shallotte and 2.8 [31/11=2.818] at Southport Dialysis Center. The proposed project does not reduce the total number of stations in Brunswick County; it merely relocates them to another facility owned and operated by DVA Healthcare Renal Care, Inc.

The applicant states the medically underserved population will continue to have access to services provided by DVA Healthcare Renal Care, Inc. as stated in Section VI.1, pages 40-42. Therefore, the applicant demonstrates that the needs of the population presently served at SEDC - Shallotte and Southport Dialysis Center will be adequately met following the relocation of eight stations from SEDC - Shallotte and two stations from Southport Dialysis Center to Leland Dialysis. See Criterion (13) for additional discussion relating to promoting equitable access which is hereby incorporated by reference.

- (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.

C

In Section III.9, pages 30-31, the applicant discusses the two alternatives considered by TRC, which include:

- 1) Do nothing – the applicant concluded that with over 30 in-center ESRD patients living in Leland, to do nothing would not be in the best interest of those patients.
- 2) Develop a ten-station facility – the applicant concluded that the proposal of a new ten-station dialysis facility, as proposed in the application, was its best alternative. Thus, the applicant concluded that the project as proposed was its least costly and most effective alternative.

The applicant adequately demonstrates the need to relocate eight stations from SEDC – Shallotte and two stations from Southport Dialysis to develop a new ten-station ESRD facility in Leland. See Criterion (3) for discussion on need which is incorporated herein by reference.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, 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 Leland 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 Leland Dialysis shall develop and operate no more than ten dialysis stations at Leland Dialysis, including any home hemodialysis training and isolation stations.**
 3. **Total Renal Care of North Carolina, LLC d/b/a Leland Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any home hemodialysis and isolation stations.**
 4. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify eight stations at Southeastern Dialysis Center – Shallotte and two stations at Southport Dialysis Center for a total of no more than ten certified dialysis stations remaining at Southeastern Dialysis Center – Shallotte and 11 certified stations remaining at Southport Dialysis Center upon project completion.**
 5. **Total Renal Care of North Carolina, LLC d/b/a Leland Dialysis 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 VIII.1, page 50, the applicant states that the total capital cost of the project will be \$1,625,123 which includes \$1,053,000 in construction contract cost, \$131,700 for dialysis machines, \$95,000 for water treatment equipment, \$181,873 in equipment/furniture, \$98,000 in architect/engineering fees, \$14,945 for dialysis chairs, \$7,905 for scale cost, \$22,500 for television system cost, and \$20,200 for a patient computer system.

In Section IX.3, page 53, the applicant projects that the total working capital (start-up and initial operating expenses) associated with the proposed project will be \$1,104,997, as illustrated below.

• Start-up Expenses	\$156,067
• Initial Operating Expenses	<u>\$948,930</u>
Total Working Capital	\$1,104,997

In Section VIII.2, page 50, the applicant states that the project will be funded by cash reserves of DaVita Healthcare Partners Inc., the parent company of DVA Healthcare Renal Care, Inc. Exhibit 25 contains a letter dated June 11, 2014 from the Chief Accounting Officer of DaVita Healthcare Partners, which states in part:

“We are submitting a Certificate of Need application to develop a ten-station End Stage Renal Disease hemodialysis facility in Leland in Brunswick County. I am writing this letter ... to confirm DaVita’s commitment of \$1,625,123 for the capital expenditures associated with this project; a commitment of \$156,067, for its start-up expenses; and a further \$948,930 in working capital. ...

DaVita has committed cash reserves in the total sum of \$2,730,120, for the capital costs, start-up costs and working capital for this project.”

Exhibit 26 of the application contains the audited financial statements for DaVita Healthcare Partners Inc. 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 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 55, the applicant provides the allowable charges per treatment for each payment source for Leland Dialysis Center, as illustrated in the table below:

Payor Source	Charge per Treatment
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

In Section X.2-X.4, pages 56-59, the applicant reports projected revenues and expenses for Leland Dialysis, as illustrated in the table below:

Leland Dialysis		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,193,280	\$2,274,079
Total Operating Costs	\$1,897,859	\$1,953,515
Net Profit	\$295,421	\$320,564

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and adequately supported. See Section X, pages 55-61, for the applicant’s assumptions.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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

Total Renal Care of North Carolina, LLC d/b/a Leland Dialysis proposes to relocate eight existing certified dialysis stations from SEDC - Shallotte and two existing certified dialysis stations from Southport Dialysis Center to Leland Dialysis to establish a ten station ESRD facility at # 4 Grandiflora Drive, Magnolia Village, in Leland, upon completion of the proposed project. The January 2014 SDR reports that the following three ESRD facilities are currently located in Brunswick County.

Name of Facility	Own/Operated By	# of Certified Stations As of 12/16/13	% of Utilization As of 6/20/13	Address	Distance to Proposed Facility¹
FMC Brunswick County	Fresenius Medical Care	10	10.00%	98 Stone Chimney Rd - Supply	21.8 miles
SEDC - Shallotte	DaVita Healthcare Partners, Inc.	18	58.33%	4770 Shallotte Ave - Shallotte	29.3 miles
Southport Dialysis Center	DaVita Healthcare Partners, Inc.	13	85.00%	1513 N. Howe St. - Southport	23.8 miles

Source: January 2014 SDR

As illustrated in the table above, there are currently three ESRD facilities in Brunswick County. According to Google Maps¹ all of those facilities are located more than 20 miles from the proposed Leland Dialysis Center with the FMC Brunswick County Dialysis being the closest at 21.8 miles away. FMC Brunswick County received its certification effective August 8, 2012 and has the lowest utilization with 10.0% whereas Southport Dialysis Center has the highest utilization with 85.0%, as reported in the January 2014 SDR. The relocation of the existing stations from SEDC - Shallotte and Southport Dialysis Center would not change the inventory of certified ESRD stations within Brunswick County.

Consequently, the applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities or facilities. Therefore, the application is conforming to this criterion.

- (8) 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

¹ <http://www.googlemaps.com>

In Section VII.1, page 46, the applicant provides projected staffing for Leland Dialysis upon project completion, as illustrated in the following table:

Leland Dialysis Full-Time Equivalent (FTE) Positions	
RN	1.50
HTRN	.50
PCT	4.50
Bio-Med Tech	.30
Admin.	1.00
Dietician	.50
Social Worker	.50
Unit Secretary	1.00
Total FTEs	9.80

The applicant projects a total of 9.80 FTE's upon project completion and states on page 47 that it is expected that some teammates from facilities in Brunswick and New Hanover Counties will transfer to the proposed Leland Dialysis Center. On pages 46-47, the applicant discusses DaVita HealthCare Partners' recruitment policy and states that they do not anticipate difficulty in recruiting and retaining qualified staff because of their aggressive recruiting practice and their competitive salary structure. In Section V.4, page 37, the applicant identifies the Medical Director for Leland Dialysis as Dr. John Herion. In Exhibit 13, the applicant provides a letter from Dr. Herion indicating his willingness to serve as Medical Director of the facility. Additionally, in Section VII.10, page 48, the applicant states Leland Dialysis will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m. with three direct care staff per shift.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 V.1, page 35, the applicant lists the providers of the necessary ancillary and support services. Exhibits 8-11 contain documentation of service agreements. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming 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.

- (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, 1988.
- (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 XI, pages 62-64, the applicant discusses the primary and secondary sites being considered for the proposed Leland Dialysis Center. The applicant states that DVA HealthCare Renal Care, Inc. plans to lease space for the proposed new facility. The applicant states there are two sites being considered for the proposed facility. The primary site consists of 1.37 acres and is located at #4 Grandiflora Drive, Magnolia Village and is currently zoned for dialysis facility use. The secondary site consists of 1+ acres and is located at US 17 and Oceangate Boulevard and is also currently zoned for dialysis facility use. See Exhibits 29 and 30 for documentation on the availability of both sites for leasing. Also, see Exhibits 29 and 30 for documentation on the availability of water, sewer, and electric services for the proposed sites. Maps for the proposed sites can be found in Exhibit 31 and Exhibit 32 contains a line drawing of the proposed facility. The applicant further states on pages 63-64, that both sites are located on major highways that are easily accessible by patients and transportation agencies. In Section XI.6, page 65, the applicant states that each dialysis station will be 276 square feet and constructed with energy saving features such as energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating systems. The applicant projects the construction cost will be \$1,053,000 and architect and engineering fees will be \$98,000, which is a total of \$1,151,000. On page 68, the applicant indicates that the proposed square footage is 8,404, thus, the per square foot construction cost is projected to be \$136.96 ($\$1,151,000/8,404 = \136.958). See Section VIII.1, page 50 and Section XI.6(h), page 68. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 68:

Leland Dialysis	
Facility Area	Estimated Total Sq. Ft.

Ancillary Areas:	
Administration/Offices/Receptions/Elevator & Lobby	376
Public Lobby	584
Mechanical Equipment	60
Biomedical	100
General Storage/Medical Records	420
Exam/Treatment/ PD Training & Medical Offices	574
Staff Lounge & Lockers	399
RO	288
Other: Handicap baths, dock and walkways	0
Sub-Total Support	2,801
Treatment Areas:	
Nurses Station	657
Dialysis Stations	2,769
Isolation Room(s)	103
Other: Walkways, Lab, Storage	132
Sub-Total Treatment	3,661
Miscellaneous (Corridors/Walls)	1,942
Total Square Feet	8,404

In Section VI.2, page 43, the applicant states:

“Leland Dialysis will satisfy all state requirements and local building codes to allow equal access for handicapped patients. Many of our patients will be severely physically handicapped. The facility will ensure access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA complaint doors at the facility.”

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed dialysis 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(a), page 40, the applicant states Leland Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 40, the applicant reports that 87.7% of the patients who received treatments at SEDC - Shallotte and 85.0% of patients who received treatments at Southport Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payment source for these two existing facilities:

SOUTHEASTERN DIALYSIS CENTER - SHALLOTTE PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	17.5%
Medicaid	5.3%
Medicare/Medicaid	15.8%
Commercial Insurance	10.5%
VA	1.8%
Medicare/Commercial	49.1%
Total	100.0%

SOUTHPORT DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	17.5%
Medicaid	7.5%
Medicare/Medicaid	25.0%
Commercial Insurance	12.5%
VA	2.5%
Medicare/Commercial	35.0%
Total	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 Brunswick 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) *
Brunswick County	7%	2.8%	19.8%
Statewide	17%	6.7%	19.7%

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

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 to be offered by Leland Dialysis Center. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (ESRD

Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012, page 84).

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 does 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 430,283 patients on dialysis ...”² (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, 4.8% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-84 year old population grew by 31% since 2000 and by 48% for those aged 85 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 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 86, summarized as follows:

² www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	83	0.5%
20-34	851	5.0%
35-44	1,442	9.8%
45-54	2,644	18.8%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.8%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.³

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	\$30.8	62.4%
Medicare Patient Obligation	\$4.8	9.6%
Medicare HMO	\$3.6	8.3%
Non-Medicare	\$10.2	20.8%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

SEDC - Shallotte and Southport Dialysis Center demonstrate that each 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

³ www.esrdnetwork6.org/publications/reports.html

In Section VI.1(f), page 43, the applicant states:

“Leland Dialysis Center 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 1983 and its subsequent amendment in 1993. Leland Dialysis will have no obligation under the Hill Burton Act.”

In Section VI.6(a), page 44, 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(c), page 41, the applicant provides the projected payor mix for the proposed services at Leland Dialysis, as shown in the table below.

Source of Payment	As a % of Total
Medicare	19.2%
Medicaid	4.2%
Medicare/Medicaid	20.8%
Commercial Insurance	11.7%
VA	5.0%
Medicare/Commercial	39.1%
Total	100.0%

As shown in the table above, the applicant projects 83.3% of all patients will have their care paid for by Medicare or Medicaid. The applicant indicates on page 41, that the payment source for Leland Dialysis Center is based, in part, on the historical in-center patient payor mix for SEDC-Shallotte and Southport Dialysis Center.

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services at Leland Dialysis. 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(a), pages 43-44, the applicant states:

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at Leland Dialysis. Leland Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Brunswick, Columbus and New Hanover Counties or transfer referral from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise **Exhibit 21.**”* [Emphasis in original]

The applicant adequately demonstrates that Leland Dialysis will offer a range of means by which a person can access 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 37, the applicant states that Leland Dialysis will be offered as a training site for nursing students. Exhibit 12 includes a letter dated May 6, 2014 from DaVita HealthCare Partners Inc. to the President of Brunswick Community College offering the use of Leland Dialysis Center as a clinical training site.

The information provided in Section V.3 is reasonable and credible for a new facility and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1988.
(16) Repealed effective July 1, 1988.
(18) Repealed effective July 1, 1988.
(18) Repealed effective July 1, 1988.
- (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 relocate eight existing certified dialysis stations from SEDC - Shallotte and two existing certified dialysis stations from Southport Dialysis Center in Brunswick County to Leland Dialysis also in Brunswick County for a total of ten certified dialysis stations at Leland Dialysis upon completion of the project. According to the January 2014 SDR there are currently three ESRD facilities located in Brunswick County. Of those existing ESRD facilities, two operated below 80% utilization (SEDC - Shallotte at 58.33% and FMC Brunswick County with 10%) and one facility operated above 80% utilization. The applicant projects that 83.3% of all patients who receive services at Leland Dialysis will

have their care paid for by Medicare and Medicaid.

In Section V.7, page 39, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost effectiveness, quality and access. The applicant states in part:

“There are currently three dialysis facilities in Brunswick County. ... Southport Dialysis Center ... serves the Southport area that includes Oak Island, Bald Head Island and surrounding communities. The SEDC - Shallotte serves the Southeastern part of the county.

Fresenius Medical Care developed a facility near the center of the county Leland is located about 20 miles to the northeast of Supply. ...

The development of Leland Dialysis will have no effect on the Fresenius facility located in Supply. All of the patients who will be transferring to Leland Dialysis live in Leland, Navassa or Riegelwood. ...

Total Renal Care of North Carolina has no intent to heighten or increase competition. ...

Leland 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 involved in the dialysis process to receive services.”

See also Sections II, III, V, VI and VII where the applicant discusses cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on the 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 to relocate eight existing dialysis stations from SEDC - Shallotte and two existing dialysis stations from Southport Dialysis to develop Leland Dialysis Center, a new ten station ESRD facility that will offer home training in peritoneal dialysis. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Brunswick County dialysis patients;
- The applicant will provide quality services; and
- The applicant will provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1988.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, SEDC - Shallotte and Southport Dialysis operated in compliance with the 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, 1988.
- (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, as 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 IV, page 32, and Exhibit 7 (copy of the January 2014 SDR, Tables A and B). As of June 30, 2013, the utilization rate for Southeastern Dialysis Center - Shallotte was 58.33% and the utilization rate at Southport Dialysis Center was 85.00%.

.2202(a)(2) Mortality rates;

- C- In Section IV.2, pages 32-33, the applicant states mortality rates for Southeastern Dialysis Center - Shallotte were 11.6% in 2011, 24.1% in 2012, and 19.1% in 2013. The mortality rates for Southport Dialysis Center for the same timeframe were 17.2%, 26.5% and 29.4%, respectively.

.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 33, the applicant states, “*SEDC - Shallotte has 15 home dialysis patients.*” The applicant further states on page 33, regarding Southport Dialysis Center, “*Southport Dialysis Center has an agreement with the SEDC – Shallotte for the provision of home training and support.*”

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

-C- In Section IV.4, page 33, the applicant states Southeastern Dialysis Center - Shallotte referred 16 patients for transplant evaluation and one transplant was performed in 2013. Southport Dialysis Center referred 9 patients for transplant evaluation and none of the patients received a transplant in 2013.

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

-C- In Section IV.5, page 33, the applicant states there are currently seven patients on the transplant waiting list at SEDC - Shallotte and two patients on the transplant waiting list at Southport Dialysis Center.

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

-C- In Section IV.6, pages 33-34, the applicant provides the hospital admissions rates, by admission diagnosis, as illustrated in the tables below.

SEDC - Shallotte Hospital Admissions

01/13-12/13 Hospital Admissions	Total
<i>Number dialysis related</i>	27
<i>Percent Dialysis related</i>	26.7%
<i>Number non-dialysis related</i>	74
<i>Percent non-dialysis related</i>	73.3%
Total number Admissions	101

Southport Dialysis Center Hospital Admissions

01/13-12/13 Hospital Admissions	Total
<i>Number dialysis related</i>	18
<i>Percent Dialysis related</i>	23.4%
<i>Number non-dialysis related</i>	59
<i>Percent non-dialysis related</i>	76.6%
Total number Admissions	77

.2202(a)(8) *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.8, page 34, the applicant reported as of December 31, 2013 there were no patients dialyzing at SED Center - Shallotte or Southport Dialysis Center with an infectious disease (Hepatitis B or AIDS). Additionally, the applicant reports that none of the patients dialyzing at either facility converted to infectious disease status.

(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.*

-C- See Exhibit 8 for an acute care hospital agreement with New Hanover Regional Medical Center to provide the following services: acute dialysis and emergency room care, diagnostic evaluation, x-ray, special, immunological and routine laboratory services, blood bank and surgical services including vascular surgery.

.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- In Section V.1(f), page 35, the applicant indicates that transplantation services will be provided by Duke University Medical Center and Vidant Health. The applicant references Exhibit 9 which contains a transplantation agreement with Duke Transplant Center and with Vidant Health.

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

-C- In Section XI.6(e), page 66, the applicant states that the facility will be located in an area that is supplied by portable city water and sewer. In Section XI.6(f), page 66, the applicant further states that the facility will be served by standing power service. See Exhibit 10 for a copy of a letter dated June 4, 2014 from the Manager Engineering of Brunswick Electric stating the Parcel I.D.# 0470004104 (secondary site) will have electrical power. Exhibit 10 also contains a letter to the Regional Operations Director for DaVita requesting that Southeastern Dialysis Center – Wilmington and Cape Fear Dialysis Center serve as the primary back-up for Leland Dialysis and that Southeastern Dialysis Center – Shallotte serve as a secondary back-up facility. Additionally, Exhibit 10 contains copies of the applicant's policies, procedures and guidelines which include policies on,

Termination of Dialysis in an Emergency, Using Hand Crank During Power Failure and Back Up Generator Operational Checks. See also Exhibit 11 for copies of the applicant's policies, procedures and guidelines which include policies on, *Water Culture Policy and General Water Quality Policy.* Exhibit 29 and 30 contain additional documentation of the availability of power and water at the proposed site.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 10 for copies of the applicant's policies, procedures and guidelines; which includes a section on power failure.
- .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- See Exhibit 28 for documentation from Hill/ Gray Stevens, LLC stating that the primary site Magnolia Village Parcel ID # - 04700046 and Oceangate Parcel ID # 0470004104, both in Brunswick, are available for purchase. Either parcel of land has the option of being purchased and a building constructed of a total of approximately 8,400 square feet. Hill/Gray Stevens, LLC will then lease the building to Total Renal Care of North Carolina, LLC for a term of 15 years with two five-year option periods.
- .2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section VII.2, pages 46-47, Section XI.6, pages 65-68, and Exhibits 13 and 14. In Section XI.6(g), page 66, the applicant states, "*Leland Dialysis will operate within the applicable laws and regulations pertaining to staffing, and fire safety equipment, physical environment and other relevant health safety requirements.*"
- .2202(b)(8) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 28-29, for all assumptions, including the methodology by which patient origin is projected. The applicant provides projected patient origin which is based, in part, on 31 in-center patients dialyzing at SEDC-Wilmington (19), Cape Fear Dialysis Center (3), SEDC-Shallotte (2), and Southport Dialysis Center (7) and those patient's letters of support for the proposed project, as shown in the below table.

LELAND DIALYSIS						
COUNTY	Operating Year 1 2016		Operating Year 2 2017		County In-Center Patients as % of Total	
	In-Center	Home Dialysis	In-Center	Home Dialysis	Year 1	Year 2
Brunswick	32	8	33	8	90.9%	91.1%
Columbus	4	0	4	0	9.1%	8.9%
Total	36	8	37	8	100.0%	100.0%

.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 30, the applicant states that 100% of its patients will reside within 30 miles of the proposed Leland Dialysis Center.

.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, page 13, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Leland 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.*”

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.*

-C- In Section II, pages 13-14, the applicant states Leland Dialysis Center is projected to have 32 patients by the end of operating year 1. Therefore, the applicant projects to have 3.2 patients $[32/10 = 3.2]$ per station per week as of the end of the first operating year of Leland Dialysis. See Criterion (3) for discussion regarding projected utilization which is incorporated herein by reference.

.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.

- NA- Leland Dialysis is a new ESRD facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, pages 13-14 and Section III.7, pages 28-29, the applicant provides the assumptions and methodology used to project utilization of the proposed 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- In Section V.1(e), page 35, the applicant states that diagnostic and evaluation services will be provided by New Hanover Regional Medical Center.
- .2204(2) *Maintenance dialysis;*
- C- In Section V.1(c), page 35, the applicant states that maintenance dialysis will be provided by the applicant.
- .2204(3) *Accessible self-care training;*
- C- In Section V.1(d), page 35, the applicant states that accessible self-care training will be provided by the applicant.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- In Section V.1, page 35, the applicant states that an accessible follow-up program for support of patients dialyzing at home will be provided by SEDC-Wilmington. See Exhibit 35 for a copy of a service agreement between SEDC-Wilmington and Leland Dialysis for SEDC-Wilmington to provide home training in home hemodialysis.
- .2204(5) *X-ray services;*
- C- In Section V.1(g), page 35, the applicant states that X-ray services will be provided by New Hanover Regional Medical Center.
- .2204(6) *Laboratory services;*

- C- In Section V.1(h), page 35, the applicant states that routine and special laboratory services will be provided by Dialysis Laboratories.
- .2204(8) *Blood bank services;*
- C- In Section V.1(i), page 35, the applicant states that blood bank services will be provided by New Hanover Regional Medical Center.
- .2204(8) *Emergency care;*
- C- In Section V.1(b), page 35, the applicant states emergency care will be provided by New Hanover Regional Medical Center.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- In Section V.1(a), page 35, the applicant states that acute dialysis in an acute care setting will be provided by New Hanover Regional Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V.1(p), page 35, the applicant states vascular surgery for dialysis treatment patients will be provided by New Hanover Regional Medical Center.
- .2204(11) *Transplantation services;*
- C- In Section V.1(F), page 35, the applicant indicates that transplantation services will be provided by Duke University Medical Center and Vidant Health. The applicant provides a copy of a transplantation agreement with Duke University Medical Center and Vidant Health in Exhibit 9.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- In Section V.1(o), page 35, the applicant states that referrals will be made to NC Department of Vocational Rehabilitation for vocational rehabilitation counseling and services.
- .2204(13) *Transportation*
- C- In Section V.1(q), page 35, the applicant states that transportation will be provided by Brunswick County DSS.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

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

- C- In Section VII, page 46, the applicant provides the proposed staffing for Leland Dialysis. The applicant projects to have 9.8 full time equivalent staff (FTEs), 4.5 of which are projected to be patient care technicians (PCT). The applicant states on page 46 that the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (8) for discussion which is incorporated herein by reference.

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

- C- In Section VII, page 47, the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 24 contains the training outline.