

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 25, 2015
Findings Date: February 25, 2015

Project Analyst: Gregory F. Yakaboski
Assistant Chief: Martha J. Frisone

Project ID #: O-10346-14
Facility: Southeastern Dialysis Center-Wilmington
FID #: 956055
County: New Hanover
Applicant(s): Total Renal Care of North Carolina, LLC
Project: Add ten dialysis station for a total of 29 stations upon completion of this project and Project ID # O-10324-14 (relocate 10 stations to a new facility)

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 Southeastern Dialysis Center-Wilmington Center (SEDC-Wilmington) proposes to add ten dialysis stations for a total of 29 certified dialysis stations upon completion of this project and Project ID # O-10324-14 (relocate 10 stations to a new facility). Subsequent to the submittal of this application Project ID #O-10324-14 was approved and a certificate of need issued effective November 4, 2014.

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations.

According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of three dialysis stations in New Hanover County. However, the applicant is eligible to apply for additional stations in its existing facility based on application of the facility need methodology because the utilization rate reported for SEDC-Wilmington in the July 2014 SDR is 4.5172 patients per station. This utilization rate was calculated based on 131 in-center dialysis patients and 29 certified dialysis stations (131 patients / 29 stations = 4.5172 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		112.9%
Certified Stations		29
Pending Stations		0
Total Existing and Pending Stations		29
In-Center Patients as of 12/31/13 (July 2014 SDR) (SDR2)		131
In-Center Patients as of 6/30/13 (January 2014 SDR) (SDR1)		90
Step	Description	
(i)	Difference (SDR2 - SDR1)	41
	Multiply the difference by 2 for the projected net in-center change	82
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.9111
(ii)	Divide the result of Step (i) by 12	0.0759
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.9111
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	250.3556
(v)	Divide the result of Step (iv) by 3.2 patients per station	78.2361
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	49

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 49 stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add only ten new stations and, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2014 State Medical Facilities Plan (SMFP) is applicable to this review. Policy GEN-3 states:

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

The applicant addresses Policy GEN-3 beginning on page 25 of the application.

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.3, pages 25-26, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section VI, page 42. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section II, pages 34-35. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.

- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

SEDC-Wilmington proposes to add ten dialysis stations for a total of 29 certified dialysis stations upon completion of this project and Project ID # O-10324-14 (relocate 10 stations to a new facility). Subsequent to the submittal of this application Project ID #O-10324-14 was approved and a certificate of need issued effective November 4, 2014.

Population to be Served

In Section IV.1, page 36, the applicant identifies the population served, as of December 31, 2013, as illustrated in the table below.

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

In Section III.7, pages 29-34 the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

SEDC-Wilmington: Projected Patient Origin

COUNTY	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
New Hanover	96	44	101	46	76.5%	77.3%
Brunswick	1	14	1	14	8.2%	7.9%
Columbus	4	1	4	1	2.8%	2.6%
Onslow	1	0	1	0	0.5%	0.5%
Pender	1	13	1	13	7.7%	7.4%
Bladen	0	1	0	1	0.5%	0.5%
Duplin	0	5	0	5	2.8%	2.8%
Sampson	0	1	0	1	0.5%	0.5%
South Carolina	0	1	0	1	0.5%	0.5%
Total	103	80	108	82	100.0%	100.0%

The applicant adequately identified the population it proposes to serve.

Analysis of Need

In Section III.7, pages 29-334, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- Operating Year One is CY 2016
- Operating Year Two is CY 2017
- The number of patients stated in the calculations below were rounded down to the nearest whole number.
- As of December 31, 2013, SEDC-Wilmington had 131 in-center patients and 29 certified stations. The breakdown of the 131 in-center patients was as follows: 107 New Hanover residents; 18 Brunswick County residents, 4 Columbus County residents and one resident each from Onslow and Pender counties.
- The Average Annual Change Rate for New Hanover County over the past five years is 5.5% as published in Table B in the July 2014 SDR.
- The Average Annual Change Rate for Brunswick County over the past five years is 5.6% as published in Table B in the July 2014 SDR.
- Total Renal Care of North Carolina has two other proposals, both projected to be certified on January 1, 2016, which impact the current application: 1)

Project ID#O-10305-14-develop Leland Dialysis in Brunswick County which includes transfer of 19 in-center Brunswick County residents currently receiving their care at SEDC-Wilmington to the new Leland Dialysis facility. Subsequent to the submittal of this application, Project ID #O-10305-14 was approved and a certificate of need issued effective November 17, 2014; and 2) Project ID #O-10324-14- develop New Hanover Dialysis in New Hanover County which includes the relocation of 10 dialysis stations and 28 in-center patients from SEDC-Wilmington to New Hanover Dialysis. Subsequent to the submittal of this application, Project ID #O-10324-14 was approved and a certificate of need issued effective November 4, 2014.

The applicant calculated growth starting on January 1, 2014 with 107 patients from New Hanover County and 18 patients from Brunswick County. The applicant did not grow the 6 in-center patients from outside New Hanover and Brunswick counties who utilized SEDC-Wilmington as of December 31, 2013. The 6 in-center patients from outside New Hanover and Brunswick counties were added back in after growth of the New Hanover and Brunswick County in-center patients was calculated. The projected utilization calculations are set forth below:

New Hanover County patient growth

“January 1, 2014 – December 31, 2014 -107 patients X 1.055 = 112.885

January 1, 2015 – December 31, 2015 – 112.885 patients X 1.055 = 119.093675.

Brunswick County patient growth

“January 1, 2014 – December 31, 2014 -18 patients X 1.056 = 19.008

January 1, 2015 – December 31, 2015 – 19.008 patients X 1.056 = 20.072448.

As of December 31, 2015, SEDC-Wilmington is projected to have 119 patients from New Hanover County, 20 patients from Brunswick County and 6 patients from outside of New Hanover and Brunswick counties (4 from Columbus County, 1 from Onslow County and 1 from Pender County).

As part of the project to develop New Hanover Dialysis, 28 New Hanover County patients receiving in-center treatment at SEDC-Wilmington are projected to transfer from SEDC-Wilmington to New Hanover Dialysis as of January 1, 2016 which would leave 91 New Hanover County patients at SEDC-Wilmington [119-28 = 81].

As part of the project to develop Leland Dialysis, 19 Brunswick County residents receiving in-center treatment at SEDC-Wilmington are projected to transfer from SEDC-Wilmington to Leland Dialysis as of January 1, 2016 which would leave 1 Brunswick County patient at SEDC-Wilmington [20 – 19 = 1].

In addition, the 6 patients from outside of New Hanover and Brunswick counties (4 from Columbus County, 1 from Onslow County and 1 from Pender County) are projected to continue to be receiving in-center dialysis at SEDC-Wilmington as of January 1, 2016.

Next, the applicant calculated growth starting on January 1, 2016, with 91 patients from New Hanover County and 7 in-center patients from outside New Hanover County (4 from Columbus County, 1 from Brunswick County, 1 from Onslow County and 1 from Pender County). The 7 in-center patients from outside New Hanover County were added back in after growth of the New Hanover County in-center patients was calculated. The projected utilization calculations are set forth below:

New Hanover County patient growth for Project Years One and Two

“January 1, 2016 – December 31, 2016 -91 patients X 1.055 = 96.005

January 1, 2017 – December 31, 2017 – 96.005 patients X 1.055 = 101.285275.”

By the end of Year One, the applicant projects to serve 103 in-center patients (96 from New Hanover County and 7 in-center patients living outside of New Hanover County) dialyzing on 29 stations for a utilization rate of 88.8% or 3.55 patients per station [$103 / 29 = 3.55 / 4.0 = 0.8879$ or 88.8%]. The applicant projects 108 in-center patients (101 from New Hanover County and 7 in-center patients living outside of New Hanover County) at the end of Year Two for a utilization rate of 93.1% or 3.72 patients per station [$108 / 29 = 3.72 / 4.0 = 0.9310$ or 93.1%]. This exceeds 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access to Services

In Section VI, page 42, the applicant states:

“Southeastern Dialysis Center, by policy, makes dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve patients without regard to race, sex, age or handicap. We serve patients regardless of ethnic and socioeconomic situation.

...

SEDC-Wilmington does 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.”

On page 42, the applicant projects that 90.0% of its patients will have all or part of their services covered by Medicare and or Medicaid. The applicant adequately demonstrates the

extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

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, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.9, page 34, the applicant discusses the alternatives considered by SEDC-Wilmington, which include:

1. Maintain the Status Quo –the applicant dismissed this alternative based on the fact that with the continued growth at the facility there is a need. Therefore, doing nothing would not be in the best interest of their patients.
2. Add ten stations – the applicant concluded that the proposal to add ten additional dialysis stations was its most effective alternative to meet the fast growing need for dialysis services at the SEDC-Wilmington facility. Thus, the applicant concluded that the project as proposed was its least costly and most effective alternative.

The applicant adequately demonstrates the need for ten additional stations based on the facility's projected utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The application is conforming or conditionally 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 to meet the need. 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 Southeastern Dialysis Center-Wilmington shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall develop no more than ten additional stations for a total of no more than 29 stations upon completion of this project and Project ID # O-10324-14 (relocate ten dialysis stations to a new facility), which shall include any home hemodialysis training or isolation stations.**
 - 3. Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall submit documentation of an invitation to a professional training program in New Hanover County to use the facility for training students.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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, page 51 the applicant projects that there will be no capital costs associated with the proposed project. In Section IX, page 56, the applicant projects no initial start-up costs or initial operating expenses because SEDC-Wilmington is an existing facility.

In Section X.1, page 58, the applicant provides the allowable charges per treatment for each payment source for SEDC-Wilmington, as illustrated in the table below:

Payor	
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

On page 58, the applicant states that the reimbursement rates are the same for both in-center and home-trained patients and includes further details about charges and reimbursement rates.

In Sections X.2-X.4, pages 59-64, the applicant projects revenues and operating expenses for SEDC-Wilmington, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$9,092,281	\$9,425,144
Total Operating Costs	\$7,285,928	\$7,543,429
Net Profit	\$1,806,353	\$1,881,715

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 and adequately supported. See Section X, pages 58-64, for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrated the financial feasibility of the proposal is based upon reasonable projections of the costs of and charges for providing the proposed health services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add ten dialysis stations to its existing facility for a total of 29 certified dialysis stations upon completion of the proposed project. According to the January 2014 SDR, the county need methodology shows there is a deficit of three dialysis stations in New Hanover County. Although the January 2014 SDR shows there is a deficit of three dialysis stations in New Hanover County, in this application, the applicant is applying for additional stations based on the facility need methodology.

According to the January 2014 SDR, SEDC-Wilmington is one of two existing dialysis facilities in New Hanover County owned by the same parent company. In addition, the same parent company applied for and was issued a certificate of need, effective November 4, 2014, to develop a third dialysis facility in New Hanover County [Project ID #O-10324-14], which will have twelve dialysis stations.

The applicant adequately demonstrates the need for ten additional stations based on the number of in-center patients it currently serves and proposes to serve. The growth projections are based on New Hanover County's projected five-year average annual growth rate in the number of dialysis patients. As of December 31, 2013, SEDC-Wilmington had 29 certified stations and was operating at 112.93% of capacity ($131 / 29 = 4.5172 / 4 = 1.1293$ or

112.93 %). The target utilization rate is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. As of December 31, 2016, SEDC-Wilmington projects to serve 103 in-center patients dialyzing on 29 stations for a utilization rate of 88.8% or 3.55 patients per station [$103 / 29 = 3.55 / 4.0 = 0.8879$ or 88.8%]. This exceeds 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The other existing facility in New Hanover County, Cape Fear Dialysis, is certified for 28 stations and is currently serving 101 in-center patients, which is a utilization rate of 90.18% ($101/28= 3.6071$; $3.6071/4 = 0.901775$ or 90.18%).

The approved, but not yet complete, New Hanover Dialysis facility will have 12 dialysis stations and is projected to serve 42 in-center patients as of the end of the first operating year which is 3.50 patients per station per week or a utilization rate of 87.5%.

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 47, the applicant states that SEDC-Wilmington currently employs 37 full-time equivalent (FTE) positions. The applicant does not propose to hire additional staff as a result of the proposed project. The applicant further states on page 48, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100 [sic].*”

In Section VII.10, page 50, the applicant provides the following table that illustrates the current and projected number of direct care staff per shift offered:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11 am	8	8	8	8	8	8
Afternoon	11am to 4pm	8	8	8	8	8	8

In Section V.4, page 40, and Exhibit 13, the applicant states that Dr. Derrick Robinson, M.D., currently serves as the Medical Director of SECD-Wilmington and he has expressed his willingness to continue serving in that role.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 38, the applicant lists the providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by New Hanover Regional Medical Center. See Exhibit 9 for a copy of the Hospital Transfer Agreement with New Hanover Regional Medical Center and Exhibit 10 for a copy of the Transplant Agreement with Carolinas Medical Center. The applicant adequately demonstrates the 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.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1(b), page 42, the applicant reports that 90% of its in-center patients had some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

**SEDC-Wilmington
In-Center Patients Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	16.4%
Medicaid	6.4%
Medicare/Medicaid	32.9%
Commercial Insurance	5.7%
VA	4.3%
Medicare/Commercial	34.3%
TOTAL	100.0%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for New Hanover, Brunswick and Pender counties 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	13.0%	6.0%	20.4%
Brunswick County	7.0%	3.0%	19.8%
Pender County	17.0%	7.0%	21.0%
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 services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. 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, handicapped, minorities or women utilizing health services.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (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).

¹<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

²www.usrds.org/adr.aspx

The 2013 *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%

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

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	26.2%
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%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicant demonstrates that the elderly and medically underserved have adequate access to its existing services. 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

³<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), pages 44-45, the applicant states:

“SEDC-Wilmington has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. SEDC-Wilmington has no obligation under the Hill Burton Act.”

In Section VI.6(a), page 46, the applicant states: *“There have been no civil rights equal access complaints filed within the last five years.”* The application is conforming to this criterion.

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

C

In Section VI.1(a), page 42, the applicant states:

“Southeastern Dialysis Center-Wilmington, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic and socioeconomic situation. .

...

SEDC-Wilmington, does 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), page 43, the applicant projects that 90% of its in-center patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

**SEDC-Wilmington
In-Center Patients Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	16.4%
Medicaid	6.4%
Medicare/Medicaid	32.9%
Commercial Insurance	5.7%
VA	4.3%
Medicare/Commercial	34.3%
TOTAL	100.0%

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, pages 45-46, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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.

CA

In Section V.3(c), page 40, the applicant states “*SEDC-Wilmington has a health professional program agreement with Education Corporation of America. (See Exhibit 12).*” However, the applicant does not adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, the application is conforming to this criterion subject to Condition #3 in Criterion (4).

- (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

SEDC-Wilmington proposes to add ten dialysis stations for a total of 29 certified dialysis stations upon completion of this project and Project ID # O-10324-14 (relocate 10 stations to a new facility).

DaVita HealthCare Partners, Inc., the parent company of Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center- Wilmington Center, is the only provider of dialysis services in New Hanover County. New Hanover County has two existing facilities: SEDC-Wilmington and Cape Fear Dialysis. In addition, the same parent company applied for and was issued a certificate of need, effective November 4, 2014, to develop a third dialysis facility in New Hanover County [Project ID #O-10324-14]. The new facility, New Hanover Dialysis, will have twelve dialysis stations.

In Section V.7, page 41, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

“The proposed expansion of the facility is an effort to provide dialysis services to the community and is not intended to be a competitive venture. There are no other dialysis facilities in the proposed service area: therefore, there can be no effect on the competition.

The effect upon the competition is unknown. However, 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. SEDC-Wilmington provides access to all qualified Nephrologists to admit his or her patients.

We view this project as having no impact, positive or negative, on the cost effectiveness or quality of our services. Our costs are low and our quality superior. However, we do feel that accessibility to our services by the patients living in the service area identified will be enhanced.”

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

- ◆ The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant currently provides dialysis services at SEDC-Wilmington. According to the Acute and Home Care Licensure and Certification Section, DHSR, SEDC-Wilmington has 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant states the utilization rate is reported in the July 2014 SDR provided in Exhibit 7. As of December 31, 2013, the utilization rate at SEDC-Wilmington was 4.5172 patients per station. This utilization rate was calculated based on 131 in-center dialysis patients and 29 certified dialysis stations (131 patients / 29 stations = 4.5172 patients per station).

(2) *Mortality rates;*

-C- In Section IV.2, page 36, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 18.7%, 12.8% and 11.8%, respectively.

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

-C- In Section IV.3, page 37, the applicant states that as of December 31, 2013, SEDC-Wilmington had “15 home hemodialysis and 78 peritoneal dialysis patients.”

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

-C- In Section IV.4, page 37, the applicant states that in 2013, SEDC-Wilmington referred 105 patients for transplant evaluation and had 3 patients receive a transplant.

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

-C- In Section IV.5, page 37, the applicant states the facility has 28 patients on the transplant waiting list.

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

-C- In Section IV.6, page 37, the applicant states that SEDC-Wilmington had 501 hospital admissions in 2013, 69 (13.8%) of which were dialysis related and 432 (86.2%) of which were non-dialysis related.

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

-C- In Section IV.7, page 37, the applicant states that there was one patient dialyzing at the facility with infectious disease (Hepatitis B) as of June 30, 2014. The applicant also states that the number of patients treated with infectious disease who have converted to infectious status within the last year is zero.

(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:*

(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.*

-NA- SEDC-Wilmington is an existing facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

(A) *timeframe for initial assessment and evaluation of patients for transplantation,*

(B) *composition of the assessment/evaluation team at the transplant center,*

(C) *method for periodic re-evaluation,*

(D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*

(E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- SEDC-Wilmington is an existing facility.

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

-NA- SEDC-Wilmington is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

- C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- SEDC-Wilmington is an existing facility.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section XI.6(g), page 69, the applicant states, “*SEDC-Wilmington will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*”
- (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 III.7, pages 29-34 the applicant provides the projected patient origin, including all assumptions and the methodology by which the patient origin is projected, as illustrated in the table below.

SEDC-Wilmington: Projected Dialysis Patient Origin

COUNTY	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
New Hanover	96	44	101	46	76.5%	77.3%
Brunswick	1	14	1	14	8.2%	7.9%
Columbus	4	1	4	1	2.8%	2.6%
Onslow	1	0	1	0	0.5%	0.5%
Pender	1	13	1	13	7.7%	7.4%
Bladen	0	1	0	1	0.5%	0.5%
Duplin	0	5	0	5	2.8%	2.8%
Sampson	0	1	0	1	0.5%	0.5%
South Carolina	0	1	0	1	0.5%	0.5%
Total	103	80	108	82	100.0%	100.0%

The discussion regarding population to be served in Criterion (3) is incorporated herein by reference.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- SEDC-Wilmington is an existing facility.

- (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 rate for such services.*

-C- In Section II. 1, page 13, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington admits and provides 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 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the*

exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- SEDC-Wilmington is an existing facility.

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

-C- The applicant projects to have 103 in-center patients by the end of year one for a utilization rate of 88.8% or 3.55 patients per station per week [$103 / 29 = 3.55 / 4.0 = 0.8879$ or 88.8.0%]. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- The table in Section V.1, page 38, states patients will be referred to New Hanover Regional Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 38, states the applicant will provide in-center maintenance dialysis at SEDC-Wilmington.

(3) *accessible self-care training;*

-C- The table in Section V.1(d), page 38, states that in-center hemodialysis, CAPD and CCPD will be provided by SEDC-Wilmington.

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

-C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 39. The applicant states:

“SEDC-Wilmington provides protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board

Certified Nephrologist for examination. The Home Training Nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well-being of home patients. Patient's blood chemistries are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team."

(5) *x-ray services;*

-C- The table in Section V.1, page 38, states patients will be referred to New Hanover Regional Medical Center for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 38, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) *blood bank services;*

-C- The table in Section V.1, page 38, states patients will be referred to New Hanover Regional Medical Center for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 38, states patients will be referred to New Hanover Regional Medical Center for emergency care.

(9) *acute dialysis in an acute care setting;*

-C- The table in Section V.1, page 38, states patients will be referred to New Hanover Regional Medical Center for acute dialysis in an acute care setting.

(10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1, page 38, states dialysis patients will be referred to New Hanover Regional Medical Center for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 38, states patients will be referred to DUMC and ECU for transplantation services.

(12) *vocational rehabilitation counseling and services; and*

- C- The table in Section V.1, page 38, states patients will be referred to the North Carolina Division of Vocational Rehabilitation for vocational rehabilitation counseling and services.

(13) transportation.

- C- The table in Section V.1, page 38, states patients will be referred to Cape Fear Public Transportation Authority.

.2205 STAFFING AND STAFF TRAINING

(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 [sic].

- C- In Section VII.1, page 47, the applicant provides the current staffing for SEDC-Wilmington. On page 48, the applicant states, *“The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 [sic] as evidenced below.”* SECD-Wilmington plans to continue having two dialysis shifts including direct care staffing of eight direct care personnel per shift on Monday through Saturday for both shifts. (See application page 50.)

(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.5, page 49, the applicant refers to Exhibit 17 for a copy of the training program description/outline. Exhibit 17 contains a copy of DaVita’s Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains a copy of the applicant’s Safety Training Outline and Exhibit 24 contains SEDC-Wilmington’s Annual In-Service Calendar.