

## 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-10348-14  
Facility: Southeastern Dialysis Center-Burgaw  
FID #: 945252  
County: Pender  
Applicant(s): Total Renal Care of North Carolina, LLC  
Project: Add three dialysis stations for a total of 15 stations upon completion of this project and Project ID # O-10125-13 (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-Burgaw (SEDC-Burgaw), located in Pender County, proposes to add three dialysis stations to its existing facility for a total of 15 stations upon completion of this project and Project ID # O-10125-13 (relocate 10 stations to a new facility) by relocating three existing dialysis stations from its Wallace Dialysis Center located in Duplin County to SEDC-Burgaw.

Neither the county or facility need methodologies in the 2014 State Medical Facilities Plan (SMFP) are applicable to this review. Therefore, Policy GEN-3 is also not applicable. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE

FACILITIES is not applicable because the applicant is not proposing a capital expenditure greater than \$2 million.

However, Policy ESRD-2: Relocation of Dialysis Stations, on page 32, is applicable to this review. The policy 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 shall:*

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

Duplin County is contiguous to Pender County. In the July 2014 Semiannual Dialysis Report (SDR), Table B: ESRD Dialysis Station Need Determinations by Planning Area, indicates a 12-station surplus in Duplin County and a 3-station deficit in Pender County. Section D of the June 2014 Data Collection Form for End-Stage Renal Disease Facilities for Wallace Dialysis states that Wallace Dialysis Center was providing in-center dialysis for 8 residents of Pender County as of 6/30/2014.

The applicant proposes to relocate three existing dialysis stations from Duplin County to Pender County. The proposed project will not cause a deficit of dialysis stations in Duplin County nor will it cause a surplus of dialysis stations in Pender County. Wallace Dialysis Center, in Duplin County, is currently serving residents of Pender County which is contiguous to Duplin County. Therefore, the application is consistent with Policy ESRD-2 in the 2014 SMFP and 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.

SEDC-Burgaw, located in Pender County, proposes to add three dialysis stations to its existing facility for a total of 15 stations upon completion of this project and Project ID # O-10125-13 (relocate 10 stations to a new facility) by relocating three existing dialysis stations from its Wallace Dialysis Center located in Duplin County to SEDC-Burgaw.

**Population to be Served**

In Section IV.1, page 30, the applicant identifies the population served, as of December 31, 2013, as illustrated in the table below.

**SEDC-Burgaw: Patient Origin**

County of Residence	# of Patients Dialyzing In-center	# of Home Dialysis Patients
Pender	69	0
New Hanover	1	0
Total	70	0

\*Note: In the application there was a typographical error identifying the two counties of residence as Onslow and Jones. The correct counties were confirmed by a review of the June 2014 Data Collection Form for SEDC-Burgaw.

In Section III.7, pages 26-27, 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-Burgaw: 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
Pender	47	0	50	0	97.9%	98.0%
New Hanover	1	0	1	0	2.1%	2.0%
Total	48	0	51	0	100.0%	100.0%

The applicant adequately identified the population it proposes to serve.

**Analysis of Need**

In Section III.7, pages 26-28, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

Operating Year One is CY 2016 (note: there is a typographical error on page 26 of the application).

Operating Year Two is CY 2017 (note; there is a typographical error on page 26 of the application).

The number of patients stated in the calculations below were rounded down to the nearest whole number.

The Average Annual Change Rate for Pender County over the past five years is 3.2% as published in Table B in the July 2014 SDR.

For the six month period of July 1, 2013 to December 31, 2013, SEDC-Burgaw had an in-center patient growth rate of 6.1% or 12.2% annualized. Based on that historic growth, in projecting utilization for this application, SEDC-Burgaw utilized an annualized growth rate of 6.1%.

The applicant did not grow the in-center patients living outside of Pender County who currently receive treatment at SEDC-Burgaw.

As of December 31, 2013, SEDC-Burgaw had 70 in-center patients (69 patients from Pender County).

Project O-10125-13, Surf City Dialysis, was approved to relocate 10 stations and 31 patients from SEDC-Burgaw to Surf City Dialysis as of January 1, 2015. This would result in SEDC-Burgaw having 12 stations and 43 patients (42 patients from Pender County) as of January 1, 2015.

SEDC-Burgaw will have 45 in-center patients as of January 1, 2016 (42 patients x 1.061 = 44.562 + 1 patient from outside Pender County = 45.562 in-center patients).

The applicant calculated growth starting on January 1, 2015 with 42 patients from Pender County. The applicant did not grow the 1 in-center patient from outside Pender County who utilized SEDC-Burgaw as of December 31, 2013. The 1 in-center patient from outside Pender County was added back in after growth of the 42 in-center patients from Pender County was calculated. The projected utilization calculations are set forth below:

*“January 1, 2015 – December 31, 2015 -42 patients X 1.061 = 44.562*

*January 1, 2016 – December 31, 2016 – 44.562 patients X 1.61 = 47.280282.*

*January 1, 2017 – December 31, 2017 – 47.280282 patients X 1.61 = 50.1643792.”*

By the end of Year One, the applicant projects to serve 48 in-center patients (47 from Pender County and 1 in-center patient living outside of Pender County) dialyzing on 15 stations for a utilization rate of 80.0% or 3.2 patients per station [48/ 15 = 3.2 / 4.0 = 0.8 or 80.0%]. The applicant projects 51 in-center patients (50 from Pender County and 1 in-center patient living outside of Pender County) at the end of Year Two for a utilization rate of 82.5% or 3.3 patients per station [51 / 15 = 3.4 / 4.0 = 0.85 or 85.0%]. This meets 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 37, the applicant states:

*“SEDC-Burgaw, by policy, has always made 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, handicap or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

...

*SEDC-Burgaw 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. SEDC-Burgaw work's with patients who need transportation, when necessary.”*

On page 37, the applicant projects that 87.10% 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 proposed services.

### **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 proposed services. Therefore, the application is conforming to this criterion.

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

C

SEDC-Burgaw, located in Pender County, proposes to add three dialysis stations to its existing facility for a total of 15 stations upon completion of this project and Project ID # O-10125-13 (relocate 10 stations to a new facility) by relocating three existing dialysis stations from its Wallace Dialysis Center located in Duplin County to SEDC-Burgaw.

Wallace Dialysis Center is currently certified for 17 stations. The proposed project would relocate 3 existing dialysis stations to SEDC-Burgaw leaving Wallace Dialysis Center with 14 certified stations. The proposed project does not involve the transfer of any patients from

Wallace Dialysis Center to SEDC-Burgaw. The July 2014 SDR states that Wallace Dialysis Center was treating 49 in-center patients as of December 31, 2013. According to Table B: ESRD Dialysis Station Need Determinations by Planning Area in the July 2014 SDR, the Average Annual Change Rate for the Past Five Years for Duplin County has been 1.0%.

Operating Year One for the proposed project is CY 2016. Operating Year Two for the proposed project is CY 2017. On pages 23-24 of the application, the applicant projected utilization for Wallace Dialysis Center for Operating Year One and Two as follows:

*January 1, 2014 - December 31, 2014 – 49 patients x 1.01 = 49.9*

*January 1, 2015 – December 31, 2015- 49.9 patients x 1.01 = 49.9849*

*January 1, 2016 – December 31, 2016 – 49.9849 x 1.01 = 50.4847 [Operating Year One]*

*January 1, 2017 – December 31, 2017 – 50.4847 x 1.01 = 50.989 [Operating Year Two]*

At the end of both Operating Year One and Operating Year Two, Wallace Dialysis Center would have a utilization rate of 89.3% (50 patients/ 14 stations = 3.57/4 = 0.8928 or 89.3%).

The patients at Wallace Dialysis Center would have an adequate number of stations available upon completion of this project. Furthermore, the applicant states *“If the Wallace Dialysis Center experiences a more aggressive growth, Total Renal Care of North Carolina will submit a certificate of need application to increase the number of stations utilizing the facility need methodology.”* (See page 24 of the application).

The applicant demonstrates that the needs of the population presently served at the Wallace Dialysis Center will be adequately met following relocation of three stations to SEDC-Burgaw. Therefore, the application is conforming to this criterion.

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

#### CA

In Section III.9, page 28, the applicant discusses the alternatives considered by SEDC-Burgaw, 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 three stations – the applicant concluded that the proposal to add three additional dialysis stations was its most effective alternative to meet the fast growing need for dialysis services at the SEDC-Burgaw facility and to eliminate the station deficit in Pender

County. Thus, the applicant concluded that the project as proposed was its least costly and most effective alternative.

The applicant adequately demonstrates the need for three 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. 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-Burgaw 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-Burgaw shall relocate no more than three additional stations from Wallace Dialysis Center for a total of no more than 15 stations upon completion of this project and Project ID # O-10125-13 (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-Burgaw shall submit documentation of an invitation to a professional training program in Pender or New Hanover counties to use the facility for training students.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

In Section VIII, page 46 the applicant projects that there will be no capital costs associated with the proposed project. In Section IX, page 50, the applicant projects no initial start-up costs or initial operating expenses because SEDC-Burgaw is an existing facility.

In Section X.1, page 52, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:



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

On page 52, the applicant states that the reimbursement for Medicare patients only is 80% of the allowable charge of \$239.02 or \$191.21 and includes further details about the charges and reimbursement rates.

In Sections X.2-X.4, pages 53-56, the applicant projects revenues and operating expenses for SEDC-Burgaw, as illustrated in the table below:

	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$2,258,032	\$2,403,021
Total Operating Costs	\$2,061,618	\$2,163,998
<b>Net Profit</b>	<b>\$196,414</b>	<b>\$239,023</b>

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 52-57, 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

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw (SEDC-Burgaw), whose parent company is DaVita HealthCare Partners, Inc., proposes to add three dialysis stations to its existing facility for a total of 15 stations upon completion of this project and Project ID # O-10125-13 (relocate 10 stations to a new facility) by relocating three existing dialysis stations from its Wallace Dialysis Center located in Duplin County to SEDC-Burgaw. DaVita HealthCare Partners, Inc. is the only provider of ESRD services in Pender County. Pender County has one existing facility and one under development (Surf City Dialysis).

The applicant adequately demonstrates the need to relocate three existing stations from a contiguous county, Duplin, to Pender County based on the projected deficit of three stations for Pender County as stated in Table B of the July 2014 SDR. The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it currently serves and proposes to serve. The actual in-patient growth for the period of July 1, 2013 to December 31, 2013 was 6.1% for that six month period which is an annual growth rate of 12.2% for SEDC-Burgaw. In its calculations, the applicant used an annual growth rate of 6.1% rather than the 12.2% growth rate based on recent historical growth. (See page 26 of the application).

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved certified dialysis stations in Pender County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 41, the applicant states that SEDC-Burgaw currently employs 16.5 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.”*

In Section VII.10, page 44, the applicant provides the following table that illustrates the projected number of direct care staff per shift offered:

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

In Section V.4, page 34, and Exhibit 13, the applicant states that Dr. Brian Donner, M.D., currently serves as the Medical Director of SECD-Burgaw 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 32, 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 Agreements with University of North Carolina Hospital and Duke University 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 36, the applicant reports that 87.10% 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-Burgaw  
 In-Center Patients Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	25.7%
Medicaid	1.4%
Medicare/Medicaid	30.0%
Commercial Insurance	10.0%
VA	2.9%
Medicare/Commercial	30.0%
<b>TOTAL</b>	<b>100.0%</b>

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 and Pender counties and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
New Hanover County	13.0%	6.0%	20.4%
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*).<sup>1</sup>

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 ....”*<sup>2</sup> (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).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
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%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

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

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

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:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
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%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
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.<sup>3</sup>

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 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), page 38, the applicant states:

*“SEDC-Burgaw 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*

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

*and its subsequent amendment in 1993. SEDC-Burgaw has no obligation under the Hill Burton Act.”*

In Section VI.6(a), page 40, 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-Burgaw, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

...

*SEDC-Burgaw, 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 37, the applicant projects that 87.10% 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-Burgaw  
In-Center Patients Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	25.7%
Medicaid	1.4%
Medicare/Medicaid	30.0%
Commercial Insurance	10.0%
VA	2.9%
Medicare/Commercial	30.0%
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 39-40, 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 34, the applicant states “*SEDC-Burgaw has an agreement with Education Corporation of America. ... SEDC-Burgaw will provide access to any area health professional training programs upon execution of an agreement.*” Exhibit 12 contains a copy of the agreement with the Education Corporation of America. . 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

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw (SEDC-Burgaw), whose parent company is DaVita HealthCare Partners, Inc., located in



Pender County, proposes to add three dialysis stations to its existing facility for a total of 15 stations upon completion of this project and Project ID # O-10125-13 (relocate 10 stations to a new facility) by relocating three existing dialysis stations from its Wallace Dialysis Center located in Duplin County to SEDC-Burgaw.

DaVita HealthCare Partners, Inc. is the only provider of dialysis services in Pender County. Pender County has one existing facility and one under development (Surf City Dialysis).

In Section V.7, page 35, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states

*“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. The bottom line is that 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-Burgaw provides access to all qualified Nephrologists to admit his or her patients.”*

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-Burgaw. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, SEDC-Burgaw 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 12, 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-Burgaw was 3.1818 patients per station. This utilization rate was calculated based on 70 in-center dialysis patients and 22 certified dialysis stations (70 patients / 22 stations = 3.1818 patients per station).

(2) *Mortality rates;*

- C- In Section IV.2, page 30, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 4.4%, 8.8% and 10.1%, respectively.
  - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- NA- The facility does not provide home dialysis services on site. Patients are referred to SEDC-Wilmington for home dialysis services.
  - (4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 30, the applicant states that in 2013 SEDC-Burgaw referred four patients for transplant evaluation and had two patients receive a transplant.
  - (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 31, the applicant states the facility has three 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 31, the applicant states that SEDC-Burgaw had 60 hospital admissions in 2013, 12 (20.0%) of which were dialysis related and 48 (80.0%) 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 31, the applicant states that there were two patients dialyzing at the facility with infectious disease (AIDS) as of December 31, 2013. 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-Burgaw 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-Burgaw is an existing facility.

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

-NA- SEDC-Burgaw 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-Burgaw 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 62, the applicant states, “*SEDC-Burgaw 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 26-28 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-Burgaw: 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	47	0	50	0	97.9%	98.0%
Pender	1	0	1	0	2.1%	2.0%
Total	48	0	51	0	100.0%	100.0%

The discussion regarding population to be served found 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-Burgaw 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 14, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw 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-Burgaw 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 48 in-center patients by the end of year one for a utilization rate of 80.0% or 3.2 patients per station per week [  $148 / 15 = 3.2 / 4.0 = 0.80$  or 80.0%]. 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 32, 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 32, states the applicant will provide in-center maintenance dialysis at SEDC-Burgaw.

(3) *accessible self-care training;*

-C- The table in Section V.1, page 32, 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 33. 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. See Exhibit 11 for a copy of the home training agreement between SEDC-Burgaw and SEDC-Wilmington."*

(5) *x-ray services;*

- C- The table in Section V.1, page 33, 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 33, 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 33, 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 33, 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 33, 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 33, 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 33, states patients will be referred to University of North Carolina Hospital and Duke University Medical Center for transplantation services.

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

- C- The table in Section V.1, page 33, 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 33, states patients will be referred to Pender County Transportation.

#### **.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 41, the applicant provides the current staffing for SEDC-Burgaw. On page 41, 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-Burgaw plans to continue having two dialysis shifts including direct care staffing of four direct care personnel per shift on Monday through Saturday for both shifts. (See application page 44.)
- (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 43, 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-Burgaw’s Annual In-Service Calendar.