

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: February 27, 2012  
PROJECT ANALYST: Gregory F. Yakaboski  
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: O-10042-12/ Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center / Add three dialysis stations for a total of 13 certified stations upon completion of this project / Brunswick County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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Total Renal Care of North Carolina, LLC (TRC) d/b/a Southport Dialysis Center ("Southport"), whose parent company is DaVita Inc., (DaVita), proposes to add three dialysis stations for a total of 13 certified dialysis stations upon completion of this project. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations.

According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of (6) six dialysis stations in Brunswick County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Southport in the July 2012 SDR is 3.3 patients per station. This utilization rate was calculated based on 33 in-center dialysis patients dialyzing in the facility on 12/31/2011 and 10 certified dialysis stations. (33 patients / 10 stations = 3.3 patients per station).

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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 12/31/11		82.5%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 12/31/11 (SDR2)		33
In-Center Patients as of 6/30/11 (SDR1)		26
Difference (SDR2 - SDR1)		7
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/11	0.5385
(ii)	Divide the result of Step (i) by 12	0.0449
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the June 2012 SDR (12/31/11) until the end of calendar year 2012 (12 months)	0.5385
(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	50.7692
(v)	Divide the result of Step (iv) by 3.2 patients per station	15.8654
	and subtract the number of certified and pending stations as recorded in SDR2 [15] to determine the number of stations needed	6

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is (6) six 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 40, of the 2012 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.”*

*Policy GEN-3*

*Safety and Quality-* The applicant describes how its proposal will promote safety and quality in Section II.3, pages 16-17, Section I.13(c), page 7 and Exhibit 4. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote equitable access.

*Equitable access-* The applicant describes how its proposal will promote equitable access in Section VI.1, pages 30-31, Section VI.2, pages 31-32 and Exhibit 9 (Business and Admissions Policy). The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote equitable access.

*Maximized Health Care Value-* The applicant describes how its proposal will maximize health care value for resources expended in Section III.9, pages 21-22. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote equitable access.

The applicant adequately demonstrates how its proposal will promote safety and quality, equitable access and maximize health care value for resources expended. Therefore, the application is consistent with Policy GEN-3. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2012 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.

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The July 2012 SDR indicates a total of 10 certified dialysis stations at Southport Dialysis Center. In this application, Southport Dialysis Center is seeking 3 dialysis stations based on facility need for a total of 13 dialysis stations at the facility. Upon completion of this project the Brunswick County total dialysis station count will increase from 38 to 41 dialysis stations including the 10 certified dialysis stations for the new FMC Brunswick County dialysis facility in Supply. The dialysis stations proposed by this project are scheduled to be operational by July 1, 2013.

Population to be Served

In Section IV.1, page 23, the applicant identifies Southport’s historical patient origin as 33 Brunswick County patients dialyzing in-center as of December 31, 2011.

In Section III.7, page 20, and supplemental information dated February 20, 2013, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

County	Operating Year 1 2013/2014		Operating Year 2 2014/2015		County patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
Brunswick	0	42	0	47	100%	100%
Total	0	42	0	47	100%	100%

The applicant adequately identified the population to be served.

Need Analysis

Southport Dialysis Center proposes to add three additional dialysis stations to its facility at 1513 N. Howe Street, Southport for a total of 13 dialysis stations upon project completion. On pages 20-21, and supplemental information dated February 20, 2013, the applicant indicates that the following assumptions and methodology were used to project the future patient population of the facility

Assumptions

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- The proposed project will be completed and certified as of July 31, 2013.
- Operating Year 1 for this project is July 1, 2013 through June 30, 2014.
- Operating Year 2 for this project is July 1, 2014 through June 30, 2015.
- The calculations for growth of the patient population begin from the date of the most recent SDR (July 2012).
- The number of patients projected are rounded down to the nearest whole number.
- The project is not anticipating the transfer of any patients from other facilities.
- All the patients being dialyzed at Southport Dialysis Center reside in Brunswick County.
- The applicant has utilized an annual growth rate of 13.0% to project the number of patients the facility will serve at the end of Operating Year One and Operating Year Two.
- The 13.0% growth rate utilized was based on less than half the actual six-month growth rate between July 1, 2011 and December 31, 2011 which was 26.9% [33 in-center patients as of 12/31/11 less 26 in-center patients as of 6/30/11 = 7 in-center patients or an increase of 26.9%]

The project analyst notes that for the year 6-30-11 [26 in-center patients] to 6-30-12 [36 in-center patients] the patient growth rate was 38% (  $36 / 26 = 1.384$  or 38%) at the Southport Dialysis Center which reasonably justifies the annual growth rate of 13.0% utilized by the applicant to project a patient census for the first two operating years.

Methodology

July 1, 2012 – June 30, 2013:  $33 \text{ patients} \times 1.13 = 37.29$

July 1, 2013 – June 30, 2014:  $37.29 \text{ patients} \times 1.13 = 42.1377$

July 1, 2014 – June 30, 2015:  $42.1377 \text{ patients} \times 1.13 = 47.6$

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Operating Year 1: The applicant projects to serve 42 in-center patients or 3.23 patients per station ( $42 / 13 = 3.23$ ) by the end of Year 1 or 80.7% utilization ( $3.23 / 4 = .8075$  or 80.7%).

Operating Year 2: The applicant projects to serve 47 in-center patients or 3.6 patients per station ( $47 / 13 = 3.615$ ) by the end of Year 2 or 90.4% utilization ( $3.615 / 4 = .9037$  or 90.4%) for the proposed 13 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI, page 30, the applicant states,

*“Southport Dialysis Center, 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.”*

In the past year 84.8% patients payment has come from Medicare, 6.1% from Medicaid and 3.0% from the VA. The applicant states in Section VI, pages 30-32, that they will provide services regardless of financial situation or socioeconomic status and that the facility will be handicapped accessible according to all state and local requirements. Home training services for patients living in Brunswick County are provided by SEDC-Wilmington. The applicant is not certified to provide home training services. [See application page 23.] The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional stations at Southport, and demonstrates 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, pages 21-22, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo—Do Nothing. The applicant states that this alternative was dismissed because of the growing in-center population of Brunswick County dialysis patients.
2. Add three dialysis stations for a total of 13 stations at Southport Dialysis Center. The applicant proposes to add three additional stations to the existing treatment space at Southport Dialysis Center to provide adequate access to dialysis services to the growing Brunswick County ESRD patient population.

On page 21, the applicant states:

*“There were only two alternatives of meeting the needs of the proposed project considered. The first was to do nothing. This alternative was dismissed since the facility is rapidly growing. The second was to apply for the three-station expansion. We chose the second alternative in order to help meet the growing demand for dialysis services at Southport Dialysis Center.”*

The applicant adequately demonstrates the need for three additional stations based on the continued growth of the ESRD patient population of Brunswick County and Southport Dialysis Center’s projected utilization. See Criterion (3) for further discussion on need which is incorporated hereby as if fully set forth herein. Maintaining the status quo will do nothing toward meeting the need for additional dialysis service at Southport Dialysis Center.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center shall materially comply with all representations made in the certificate of need application.**
  2. **Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center shall develop no more than three additional stations for a total of no more than 13 stations.**
  3. **Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of 13 stations which shall include any isolation stations.**
  4. **Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 39, the applicant projects a capital cost of \$44,860 for the three station addition, funded through cash reserves. In Section IX, page 40, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

In Section VIII.2, page 40, the applicant states that this project will be funded from cash reserves. Exhibit 13 includes a letter dated September 14, 2012 from the Chief Accounting Officer of DaVita, which states:

*“I am the Chief Accounting Officer of DaVita Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC (“TRC”).*



*We are submitting a Certificate of Need Application to expand our Southport Dialysis Center ESRD facility by three dialysis stations. The project calls for a capital expenditure of \$44,860. This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$44,860 for the project capital expenditure. DaVita, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”*

In Exhibit 14, the applicant provides United States Securities and Exchange Commission Form 10-K for DaVita Inc. for the year ended December 31, 2011. As of December 31, 2011, DaVita had cash and cash equivalents totaling \$393,752,000 with \$8,892,172,000 in total assets and \$2,268,125,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

Based on information provided by the applicant in Section X.1, page 45, the applicant projects the following charge per treatment for each payment source:

**Applicant Projected Allowable  
In-Center Charges**

Payor	In-center
Medicare	\$192
Medicaid	\$192
Medicare/Medicaid	\$240
Commercial	\$800
VA	\$240
Medicare/Commercial	\$240

The applicant projects net revenue in Section X.2, page 45, of the application and operating expenses in Section X.4, page 48, of the application. The applicant projected revenue in excess of expenses in the second operating year following completion of the project is as illustrated in the table below and supported by the accompanying assumptions.

**Southport Dialysis Center  
Projected Net Revenues, Operating Expenses and Net Profit  
7/1/2013 – 6/30/2015**

	Project Year 1	Project Year 2
Net revenue	\$1,553,760	\$1,752,732
Operating expenses	\$1,635,988	\$1,751,200
Profit	(\$82,228)	\$1,532

Assumptions:

1. Patients would be seen three times a week, 52 weeks per year.

2. Patients would miss 5% of treatments in the first year.
3. The actual number of treatments was multiplied by the patient payment percentage by source of revenue to obtain how many treatments would be from each source of revenue.
4. The amount paid by each source of revenue was multiplied by the treatment number by source of revenue to obtain the operating revenue totals.
5. The current year revenue projections include an average of 35 in-center patients being treated during the year. The number of in-center patients is based on 33 in-center patients being treated at the beginning of the year with a growth during the year to 37 in-center patients.
6. The operating year one revenue projections include an average of 39.5 in-center patients being treated during the year. The number of in-center patients is based on 37 in-center patients being treated at the beginning of the year with a growth during the year to 42 in-center patients.
7. The operating year two revenue projections include an average of 44.5 in-center patients being treated during the year. The number of in-center patients is based on 42 in-center patients being treated at the beginning of the year with a growth during the year to 47 in-center patients.

In Section VII.1, page 34, the applicant provides projected staffing and salaries. On page 34, the applicant states Southport will comply with all staffing requirements as stated in 42 C.F.R. Section 405.2100 (now 42 C.F.R. Section 494). Projected staffing by shift is provided on page 36. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates the financial feasibility of the proposal is based on reasonable projections of costs and revenues. 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.

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The applicant proposes to add three dialysis stations to the existing facility for a total of 13 stations upon completion of the proposed project. The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it proposes to serve. Per the July 2012 SDR, as of June 25, 2012, the 10 station Southport facility was operating at 82.5% capacity ( $33/10 = 3.3$ ;  $3.3/4 = 0.825$  or 82.5%). The target utilization rate is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 13 stations serving 42 patients (end of year 1) which is a utilization

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rate of 80.7% ( $42/13 = 3.23$ ;  $3.23/4 = 80.7\%$ ). Therefore the application is conforming with the requirement in 10A NCAC 14C .2203.

The applicant has a second dialysis facility in Brunswick County, SEDC-Shallotte, located in Shallotte. The SEDC-Shallotte facility is approximately 23 miles from the Southport Dialysis Center. As of 12/31/2011 the SEDC-Shallotte facility had 42 in-center patients and 15 certified stations with a utilization of 70.0%. Brunswick County has one other dialysis provider which has 10 certified dialysis stations at a new facility (FMC Brunswick County) in Supply. On page 363, the 2012 SMFP states, “*As a means of making ESRD services more accessible to patients, one of the goals of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the center.*”

The applicant adequately demonstrates 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.

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In Section VII.1, page 34, the applicant provides the current and projected number of full-time equivalent (FTE) positions following completion of the proposed project, as illustrated in the table below:

<b>Position</b>	<b>Current # of FTEs</b>	<b>Total Positions to be Filled</b>	<b>Total FTE Positions Upon Completion</b>
RN	1.5	0.0	1.5

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PCT	4.5	1.5	6.0
Bio-Med Tech	0.5	0.0	0.5
Medical Director	Contract position; not an FTE of the facility		
Administrator	1.0	0.0	1.0
Dietitian	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Unit Secretary	1.0	0.0	1.0
Other- Reuse	0.5	0.0	0.5

Analysis of the salary budgeted on page 49 confirms the use of 11.5 FTE in the calculations.

In Section VII.10, page 37, the applicant provides the direct care staff for each shift offered in the facility after project completion as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:00am to 10:30pm	4	4	4	4	4	4
Afternoon	11:00pm to 4:00pm	4	4	4	4	4	4

The applicant states in Section V.4 (c), page 27, that Dr. Brian Donner will be the Medical Director for the facility. In supplemental information submitted by the applicant during the review, the applicant provides a letter from Dr. Donner in support of the proposed project and states his willingness to continue to serve as the Medical Director for the facility. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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.

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In Section V.1, page 25 of the application, the applicant lists the providers of the necessary ancillary and support services. The supplemental information dated February 20<sup>th</sup> and 22<sup>nd</sup> contains copies of the agreements for: home training agreement, hospital patient transfer, laboratory work, transplantation, medical director and professional training programs. Section V.4(b), page 27, contains a listing of physicians who have expressed support for the addition of 3 dialysis stations at Southport Dialysis Center and who have expressed a willingness to provide medical coverage for ESRD patients. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the

proposed services will be coordinated with the existing health 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

NA

- (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;

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In Section VI.1(a), page 30, the applicant discusses Southport's history of providing dialysis services to the underserved populations. The applicant states:

*“Southport Dialysis Center, 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, or handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

*Southport Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Southport Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need.*

*Southport Dialysis Center 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. Southport Dialysis Center works with patients who need transportation, when necessary.”*

In Section VI.1, page 30, the applicant indicates that historically, 84.8 percent of patients at Southport have some or all of their services paid for by Medicare. An

additional 3.0% are covered by VA. As illustrated in the table below 93.9% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

**Historical Payor Source- Last Year**

Payor Source	In-Center
Medicare	12.1%
Medicaid	6.1%
Medicare/Medicaid	30.3%
Commercial Insurance	6.1%
VA	3.0%
Medicare/Commercial	42.4%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Brunswick County and statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	<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>2009 % Uninsured (Estimate by Cecil G. Sheps Center)</b>
Brunswick	7.0%	2.8%	19.8%
Statewide	17%	6.71%	19.7%

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 Southport Dialysis Center. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

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

The Centers for Medicare & Medicaid Services (CMS) website states:

*“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standing.*

...

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 70. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”<sup>1</sup>*

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010:

*“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy ... .”*

The report validates the statistical constancy reported by the CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states,

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

The report provides 2010 ESRD spending, by payor as follows:

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<sup>1</sup>[www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf](http://www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf)



<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 31, the applicant states:

*“Southort Dialysis Center 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.”*

In Section VI.6(a), page 33 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(c), page 31, the applicant provides projected payor mix of the proposed project as illustrated in the table below.

Payor Source	In-Center
Medicare	12.1%
Medicaid	6.1%
Medicare/Medicaid	30.3%
Commercial Insurance	6.1%
VA	3.0%
Medicare/Commercial	42.4%
<b>Total</b>	<b>100.0%</b>

Compared to the last year's payor mix the applicant does not anticipate any changes in the payor mix as a result of the proposed project. (see application page 30.)

As shown in the table, the applicant projects 84.8% of all in-center patients will have some or all of their services paid for by Medicare with VA covering another 3.0%.

In Section II.1, page 12, the applicant states:

*“Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5(a), page 32, the applicant states:

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral to a Nephrologist with privileges at Southport Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in the Brunswick County. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact Southport Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Southport Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Southport Dialysis Center transfer and transient policies which comprise Exhibit 9.”*

The applicant adequately demonstrates that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V, page 27, the applicant states health related education and training programs can visit the facility, receive instruction and observe the operation of the unit while patients are treated. The applicant further states that it has relationships with the following professional training programs: James Sprunt Community College, East Carolina University and Miller-Motte. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add three dialysis stations to its existing center for a total of 13 certified stations upon completion of the proposed project. The July 2012 SDR shows there is a surplus of six (6) dialysis stations in Brunswick County; however, the applicant qualifies for additional dialysis stations based on the facility need methodology.

In Section V.7, pages 28-29, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access.

There are three operational dialysis facilities in Brunswick County:

- Southport Dialysis Center;
- Southeastern Dialysis Center-Shallotte (also a Total Renal Care of North Carolina, LLC facility); and
- FMC of Brunswick County in Supply.

Southeastern Dialysis Center- Shallotte has a utilization rate of 70.0% with 15 certified stations and 42 in-center patients. FMC of Brunswick County in Supply is a newly opened 10-station facility, however it does not yet have a Medicare Provider Number. The applicant states that the proposed project is not intended to be a competitive venture but rather an effort to provide dialysis services to the community. [See page 28]

*“The addition of stations to the Southport Dialysis Center will have no impact the [sic] patient census of either the Shallotte or Supply facilities. This is because the patients in each facility have established service areas and referral sources. The Fresenius facility has their own Medical Director who is not associated with Southeastern Nephrology Associates.”* [See pages 28-29]

The Project Analyst notes that the dialysis facilities in Southport and Supply are located in different areas of Brunswick County both by geography and transportation corridors.

In Section V.7, page 29, the applicant states that all qualified Nephrologists can admit their patients to the Southport Dialysis Center and that the determining factor with respect to which facility is selected by the patient is which provider *“gives them the highest quality service and best meets their needs.”*

See also Sections II, III, V, VI and VII. The information the applicant provides in those sections is reasonable and credible and adequately demonstrates that adding three dialysis stations to the existing Southport facility will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need, based on “Facility Need”, to add three dialysis stations for a total of 13 certified dialysis stations following completion of this project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Southport patients.
- The applicant adequately documents that it will provide quality care and services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 pages 25-28 and referenced in exhibits is reasonable and credible and demonstrates the provision of quality care services.

On pages 16-17, the applicant describes the systems and methods in place to insure quality care at Southport Dialysis Center.

- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 30, the applicant states:

*“Southport Dialysis Center 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. Southport Dialysis Center works with patients who need transportation, when necessary.”*

The applicant states on page 30 that it has served and will continue to serve all of the people in its service area without qualifications including continuing to serve without regard to race, age, ethnicity, handicap, gender, or socioeconomic groups.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

The applicant has been providing dialysis services at Southport Dialysis Center since 2009. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Southport Dialysis has operated in compliance with all Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen 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.

#### **10A NCAC 14C .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 10, and Exhibit 7 the applicant provides the utilization rate as reported in the July 2012 SDR of 82.5% with 3.3 patients per station. [33/10 = 3.3 patients per station; 3.3/4 = .825 or 82.5%]

- (2) *Mortality rates;*

- C- In Section IV.2, page 23, the applicant provides the mortality rates for Southport as 17.4%, 17.4%, and 17.8% for 2009, 2010, and 2011, respectively.
  - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
  - C- In Section IV.3, page 23, the applicant states that Southport is not certified to provide home training services. SEDC- Wilmington provides the home training services for patients living in Brunswick County.
  - (4) *The number of transplants performed or referred;*
  - C- In Section IV.4, page 23, the applicant states Southport referred 1 patient for transplant evaluation in 2011. No transplants were performed in 2011.
  - (5) *The number of patients currently on the transplant waiting list;*
  - C- In Section IV.5, pages 23-24, the applicant states that Southport has 3 patients on the transplant waiting list.
  - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis versus non-dialysis related;*
  - C- In Section IV.6, page 24, the applicant documents that Southport had 42 hospital admissions in 2011. Seven were dialysis related and 42 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 24, and supplemental information dated February 20<sup>th</sup> the applicant states as of December 31, 2011 there were no patients at Southport with an infectious disease. No patients converted to infectious status within the last year.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage renal Disease (ESRD) Treatment application form:*



(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- Southport 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- Southport is an existing facility.

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

-NA- Southport 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 for a copy of Southport's manual which has policies and procedures for testing the generator that provides 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- Southport 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 regulations.*

-NA- Southport is an existing facility.

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- See Section III.7, pages 20-21, and supplemental information dated February 20<sup>th</sup> for the methodology and assumptions the applicant uses to project patient origin as presented in the following table.

County	Operating Year 1 2013/2014		Operating Year 2 2014/2015		County patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
Brunswick	0	42	0	47	100%	100%
Total	0	42	0	47	100%	100%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

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

-NA- Southport 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 12, the applicant states:

*“Total Renal Care of North Carolina, LLC d/b/a Southport Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

#### **10A NCAC 14C .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 stations 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- Southport does not propose to establish a new End Stage Renal Disease 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 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- Southport projects utilization of 3.22 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 13-14, and Section III.7, pages 20-21, and supplemental information dated February 20<sup>th</sup>. See discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 13-14, and Section III.7, pages 20-21, and supplemental information dated February 20<sup>th</sup>. Additionally, see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

#### **10A NCAC 14C .2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

- C- In Section V.1, page 25, the applicant documents that diagnostic and evaluation services will be provided by New Hanover Regional Medical Center.
- (2) *maintenance dialysis;*
- C- In Section V.1, page 25, the applicant documents that Southport will provide maintenance dialysis at its own facility.
- (3) *accessible self-care training;*
- C- In Section II., page 25, the applicant states self-care training is provided by SEDC-Wilmington.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.2, page 25, the applicant states that a follow-up program for support of patients dialyzing at home is provided by SEDC-Wilmington.
- (5) *x-ray services;*
- C- In Section V.1, page 25, the applicant documents that x-ray services will be provided by New Hanover Regional Medical Center.
- (6) *laboratory services;*
- C- In Section V.2, page 25, the applicant states that Dialysis Laboratories will provide laboratory services for Southport patients.
- (7) *blood bank services;*
- C- In Section V.1, page 25, the applicant states that blood bank services will be provided by New Hanover Regional Medical Center.
- (8) *emergency care;*
- C- In Section V.1, page 25, the applicant states that emergency care services will be provided by New Hanover Regional Medical Center.
- (9) *acute dialysis in an acute care setting;*
- C- In Section V.1, page 25, the applicant documents that blood bank services will be provided by New Hanover Regional Medical Center.

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

-C- In Section V.1, page 25, the applicant documents that vascular surgery services will be provided by New Hanover Regional Medical Center.

(11) *transplantation services;*

-C- In Section V.1, page 25, the applicant states that transplantation services will be provided by “*DUMC and ECU.*”

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

-C- In Section V.1, page 25, the applicant documents that vocational rehabilitation counseling and services will be provided by the N.C. Department of Vocational Rehabilitation.

(13) *transportation.*

-C- In Section V.1, page 25, the applicant documents that transportation services will be provided by “*DSS/Various Providers.*”

#### **10A NCAC 14C .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.*

-C- In Section VII., pages 40-41, the applicant states that Southport will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

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

-C- In Section II., pages 16-17, the applicant states “*DaVita’s Quality Management Program ...includes .... Staff and Patient education program-ensuring continuous updates and training to ensure high quality patient care.*” Exhibit 12 contains a copy of the training program outlines and programs for new patient care provider teammates. Exhibit 18 contains a copy of the *Health and Safety Policy and Procedure Manual*. Exhibit 19 contains a copy of the *Southport Dialysis Center Annual In-Service Calendar*.

