

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 24, 2012
PROJECT ANALYST: Gregory F. Yakaboski
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: Project I.D. #O-8742-11 / Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte / Add 3 dialysis stations to the existing facility for a total of 18 stations upon completion of this project and Project ID # O-8645-11 (add 2 stations)/ 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 d/b/a Southeastern Dialysis Center-Shallotte ("SEDC-Shallotte") proposes to add three dialysis stations to the existing facility for a total of 18 stations upon completion of this project and Project ID # O-8645-11 (add 2 stations).

The 2011 State Medical Facilities Plan (2011 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2011 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for SEDC-Shallotte in the July 2011 SDR is 3.77 patients per station. This utilization rate was calculated based on 49 in-center dialysis patients and 13 certified dialysis stations as of December 31, 2010 (49 patients / 13 stations = 3.77 patients per station). Therefore, 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 12/31/10		94.0%
Certified Stations		13
Pending Stations		2
Total Existing and Pending Stations		15
In-Center Patients as of 12/31/10 (SDR2)		49
In-Center Patients as of 6/30/10 (SDR1)		45
Difference (SDR2 - SDR1)		4
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/10	0.1778
(ii)	Divide the result of Step (i) by 12	0.0148
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2011 SDR (12/31/10) until the end of calendar year 2011 (12 months)	0.1778
(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	57.7111
(v)	Divide the result of Step (iv) by 3.2 patients per station	18.0347
	and subtract the number of certified and pending stations as recorded in SDR2 [20] to determine the number of stations needed	3

Step C of the facility need methodology states *"The facility may apply to expand to meet the need established in (2)(B)(v) [Step (v) in the table above], up to a maximum of ten stations."* Based on the facility need methodology for dialysis stations, the number of stations needed is three and the applicant proposes to add no more than three new stations. Therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2011 SMFP is also applicable to this review. Policy GEN-3 states:

“A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

Promote Equitable Access

In Section VI.1(a), page 29, the applicant states:

“SEDC- Shallotte, 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- Shallotte 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. SEDC- Shallotte provides dialysis six days per week with two patient shifts per day to accommodate patient need. The facility also provides nocturnal dialysis three nights a week.

SEDC- Shallotte 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- Shallotte works with patients who need transportation, when necessary.”

In Section VI.2, pages 30-31, the applicant states

“SEDC- Shallotte satisfies all state requirements and local building codes to allow equal access for handicapped patients. Many of our patients are severely physically handicapped. The facility ensures access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA compliant doors at the facility. Additionally, our teammates are trained to assist handicapped persons into and out of their dialysis treatment stations.”

In Section VI.7, page 32, the applicant states

“The SEDC-Shallotte has an open policy and accepts all patients including those with hepatitis and/or AIDS. See Exhibit 11 for a copy of the Interpretive Guidelines, Tag Number V266 and the DaVita Hemodialysis Policies, Procedures and Guidelines referencing Hepatitis Surveillance, Vaccination and Infection Control Measures. Total Renal Care of North Carolina, LLC complies with all federal and state requirements pertaining to isolation of patients with communicable diseases.”

The applicant adequately demonstrates how the proposal will promote equitable access to the proposed services.

Promote Safety and Quality

In Section II.3, pages 15-16, the applicant states:

“DaVita Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.

Our Quality Management Program includes the following Quality Programs:

- *Quality Improvement Methodology- utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System- integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program- ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program- systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team- experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team- experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).*

DaVita's Quality Management team works closely with each facility's Quality Improvement team to:

- *Improve patient outcomes*
- *Provide patient and staff training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards*

Our goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita.

SEDC-Shallotte is attended by Southeastern Nephrology Associates, admitting Nephrologists who directly oversees the quality of care of the dialysis facility. In addition, Dr. Jonathon Woods serves as the Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the DaVita Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. This Quality Assurance Program addresses the SEDC- Shallotte as a whole, then compares each sister unit to the whole and to industry standards. The Committee then makes recommendations to improve quality. Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes."

The applicant adequately demonstrates how the proposal will promote safety and quality.

Maximize Healthcare Value

In Section III.9, page 21, the applicant states:

"The SEDC-Shallotte promotes cost-effective approaches in the facility in the following ways:

- *This application calls for the purchase of patient TVs (see section VIII of the application). The parent corporation, DaVita, operates over 1,600 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.*

- *SEDC- Shallotte purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- *SEDC- Shallotte utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *SEDC- Shallotte has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- *SEDC- Shallotte Bio-medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*
- *SEDC- Shallotte also has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly."*

The applicant adequately demonstrates the proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

Policy Gen-4: Energy Efficiency and Sustainability for Health Service Facilities of the 2011 SMFP states "Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation." The capital cost of the proposed project is \$44,962. Therefore, Policy Gen-4 is not applicable.

The application is consistent with Policy GEN-3 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.

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SEDC-Shallotte proposes to add three additional dialysis stations for a total of 18 stations following completion of this project and Project ID # O-8645-11 (add 2 stations). The July 2011 SDR indicates a total of 13 certified stations at SEDC-Shallotte, as of December 30, 2010.

Population to be Served

The following table illustrates the current patient origin at SEDC-Shallotte, as reported by the applicant in Section IV.1, page 22.

**SEDC- Shallotte
Patient Origin as of 6/30/11**

County of Residence	# of patients dialyzing in-center
Brunswick	55
Total	55

In Section III.7, page 19, the applicant provides the projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

SEDC- Shallotte -Projected Patient Origin

COUNTY	YEAR ONE: 2012/2013		YEAR TWO: 2013/2014		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Brunswick	58	12	59	13	88.6%	88.9%
Columbus	0	7	0	7	8.9%	8.7%
New Hanover	0	2	0	2	2.5%	2.4%
TOTAL	58	21	59	22	100.0%	100.0%

The applicant adequately identified the population proposed to be served.

Need for the Proposed Stations

The applicant proposes to add three stations to the SEDC-Shallotte facility. The SEDC-Shallotte facility is currently certified for 13 stations and is approved to add 2 dialysis stations pursuant to Project ID # O-8645-11.

In Section III.7, pages 19-20, the applicant states

“SEDC-Shallotte had 55 in-center patients as of June 30, 2011 based on the monthly census report of the facility. This is a station utilization rate of 92% based on the 13 certified stations and 2 stations pending certification in the facility. All of the patients live in Brunswick County. We are applying for a three-station expansion of the Shallotte facility.”

The July 2011 SDR states that the Average Annual Change Rate for the last 5 years for Brunswick County is 2.9%. The applicant utilized the growth rate of 2.9% for in-center patients to project utilization through Year 2. The growth rate was only applied to in-center patients.

In Section III.7, pages 19-20, the applicant states

“The period of growth begins with July 1, 2012 forward to June 30, 2014. The following are the in-center utilization projections using the 2.9% Average Annual Change Rate for the Past Five Years as indicated in Table B of the July 2011 Semiannual Dialysis Report for the 55 in-center patients residing in Brunswick County.

July 1, 2011 – June 30, 2012 – 55 patients X 1.029 = 56.595

July 1, 2012 – June 30, 2013 – 56.595 patients X 1.029 = 58.236255

July 1, 2013 – June 30, 2014 – 58.236255 patients X 1.029 = 59.92510639

Operating Year One is projected to begin July 1, 2012 and end on June 30, 2013.

Operating Year One [sic-Two] is projected to begin July 1, 2013 and end on June 30, 2014.

The number of patients stated in the chart above was rounded down to the nearest whole number.”

In Section III.7, page 19, the applicant states

“Based on the patients and stations above, SEDC-Shallotte is projected to have at least 58 in-center patients by the end of operating year 1 for a utilization rate of 80% or 3.22 patients per station and at least 59 in-center patients by the end of the operating year 2 for a utilization rate of 81% or 3.28 patients per station. This information is based on the calculations below. We have used a growth rate of 2.9% for the 55 in-center patients who live in Brunswick County.”

The following shows the average number of in-center patients per station per week and the utilization rate for each of the first two operating years following completion of the project.

Year 1 (July 1, 2012- June 30, 2013)

Average # of Patients/Station/Week: 58 in-center patients dialyzing on 18 stations = 3.22

Utilization Rate: $58 / (4 \times 18) = .805$ or 81% utilization

Year 2 (January 1, 2013 – December 31, 2013)

Average # of Patients/Station/Week: 59 in-center patients dialyzing on 18 stations = 3.27

Utilization Rate: $59 / (4 \times 18) = .819$ or 82% utilization

Projected utilization at the end of Year 1 equals 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b) and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for two additional dialysis stations. 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.

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In Section III.9, pages 20-21, the applicant discusses the alternatives it considered to meet the need for the proposed services. The application is conforming to the facility need methodology for additional stations. See Criterion (1) for discussion. Furthermore, the applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrates that the proposal to add three dialysis

stations 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-Shallotte shall materially comply with all representations made in its certificate of need application.**
 2. **Upon completion of this project and Project ID # O-8645-11 (add 2 stations) Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte shall be certified for no more than 18 dialysis stations, which shall include any home hemodialysis and isolation stations.**
 3. **Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of 18 stations, which shall include any home hemodialysis and isolation stations, upon completion of this project and Project ID # O-8645-11 (add 2 stations).**
 4. **Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte 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.

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In Section VIII.1, page 38, the applicant states the capital cost is projected to be \$44,962. In Section IX, page 42, the applicant states that there will be no start-up costs or initial operating expenses.

In Section VIII.2-3, page 39, SEDC-Shallotte states it will fund the capital costs of the project from the cash reserves of DaVita Inc., the ultimate parent company of Total Renal Care of North Carolina, LLC. Exhibit 14 contains a letter, dated September 12, 2011, from the Chief Accounting Officer of DaVita, Inc. and Total Renal Care, Inc. (the parent of Total Renal Care of North Carolina, LLC.) 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 Southeastern Dialysis Center- Shallotte ESRD dialysis facility by three dialysis stations. The project calls for a capital expenditure of \$44,962. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$44,962 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 15, the applicant provides audited financial statements for DaVita, Inc. which document that DaVita, Inc. had \$539,459 million in cash and cash equivalents as of December 31, 2009. The project analyst notes that in a previous application the applicant submitted more recent audited financial statements which document that DaVita, Inc. had had \$860,117,000 million in cash and cash equivalents as of December 31, 2010. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section X, pages 44-47, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 43, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with 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 SEDC-Shallotte facility for a total of 18 dialysis stations upon completion of this project and Project ID # O-8645-11 (add 2 stations). Based on the facility need methodology for dialysis stations, the number of stations needed is three and the applicant proposes to add no more than three new stations. The application is therefore consistent with the SMFP 2011 facility need determination and Criterion (1). The applicant adequately demonstrates the need to add three stations based on the number of in-center patients it proposes to serve. See Section III.7, pages 19-20, Section III.9, pages 20-21, and Section V.7, pages 27-28. See Criterion (3) for additional discussion. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming with 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 33, the applicant states 3 full-time equivalent (FTE) positions will be required as a result of this project. Exhibit 9 contains a letter from Jonathon Woods, MD stating that he is the current Medical Director of SEDC- Shallotte and supports proposed expansion of 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 24, the applicant lists the providers of the necessary ancillary and support services, and in Sections V.2, page 25, V.4, page 26, and V.5, page 27 illustrates how the project will be coordinated with the existing health care system. The information provided in Section V is reasonable and credible and supports a finding of conformity with 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(b), page 29, the applicant reports that 87.7% of the patients who received treatments at SEDC-Shallotte had some or all of their services paid for by Medicare or Medicaid [12.3% Medicare + 1.8% Medicaid + 22.8%

Medicare/Medicaid + 50.8% Medicare/Commercial = 87.7%]. On page 30 the applicant projects that the payor mix for the proposed service will match the historic experience.

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 as of CY2008-2009. The data in the table was obtained January 13, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
County			
Brunswick	7%	2.8%	19.8%
Columbus	28%	13%	20.4%
New Hanover	13%	5.7%	20.4%
Statewide	17%	6.7%	19.7%

*Source: DMA Website: <http://www.ncdhhs.gov/dma/pub/index.htm>

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services to be offered at SEDC-Shallotte.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of January 13, 2012 no population data was available by

age, race or gender. Even if the data were available, 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 applicants demonstrated that medically underserved populations currently have adequate access to SEDC-Shallotte's 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;

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In Section VI.1(f), page 30, the applicant states:

"SEDC-Shallotte 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 32, 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

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In Section VI.1(a), page 29, the applicant states:

"SEDC-Shallotte, 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-Shallotte, 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-Shallotte, works with patients who need transportation, when necessary."

In Section VI.1(c), page 30, the applicant projects that that 87.7% of patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

**SEDC-Shallotte
Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	12.3%
Medicaid	1.8%
Medicare/Medicaid	22.8%
Commercial Insurance	8.8%
VA	3.5%
Medicare/Commercial	50.8%
TOTAL	100.0%

The applicant demonstrated that medically underserved populations will 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.

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In Section VI.5, pages 31-32, 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.

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In Section V.3(c), page 26, that applicant states "*SEDC-Shallotte has sent a letter to the President of the local community college offering the facility as a clinical learning site. See Exhibit 8.*" In Section V.3(a), page 26, the applicant states "*SEDC-Shallotte*

anticipates that the facility will eventually establish a working relationship with Brunswick Community College. The facility would serve as a clinical learning site for nursing students.” The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with 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

See Sections II.6, II.7, III.1, III.2, III.3, III.6, III.7, V.7, VI, VII, and XI.7. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the SEDC-Shallotte addition of three dialysis stations for a total of 18 stations upon completion of this project and Project ID # O-8645-11 (add 2 stations) would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The addition of three dialysis stations to SEDC-Shallotte is needed to meet the needs of the increasing dialysis population in the area. The proposal is a cost-effective alternative to meet the need and to improve access to the proposed services. [see Criteria (1), (3), (4) and (5) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

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 currently provides dialysis services as Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy within 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANTS

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

- .2202(a)(1) *Utilization Rates;*
 -C- See Section III.2, page 17, the July 2011 SDR and Section III.7, pages 19-20.
- .2202(a)(2) *Mortality rates;*
 -C- See Section IV.2, page 22.
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
 -C- See Section IV.3, page 22.

- .2202(a)(4) *The number of transplants performed or referred;*
 -C- See Section IV.4, page 22.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
 -C- See Section IV.5, page 22.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
 -C- See Section IV.6, pages 23.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
 -C- See Section IV.7, page 23.

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

- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
 -NA- Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte is an existing facility.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) composition of the assessment/evaluation team at the transplant center,*
 - (C) method for periodic re-evaluation,*
 - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
 -NA- Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte is an existing facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- See Section XI.6(f), page 53, and Exhibit 7.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
-NA- Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
-C- Section VII, pages 33-36, and Section XI.6(g), pages 53-54.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
-C- See Section III.7, pages 19-20. See Criterion (3) for discussion.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
-NA- Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
-C- See Section II.1(b)(9), page 11.

.2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
-NA- Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Shallotte is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section III.7, pages 19-20, the applicant projects to serve 58 in-center patients or 3.2 patients per station [$58 / 18 = 3.22$] by the end of Year 1 for the proposed 18-station facility. See Criterion (3) for discussion.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section III.7, pages 19-20, the applicant provided the assumptions and methodology used to project patient utilization. See Criterion (3) for discussion.

.2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*

-C- See Section V.1, page 24.

.2204(2) *Maintenance dialysis;*

-C- See Section V.1, page 24.

.2204(3) *Accessible self-care training;*

-C- See Section V.1, page 24.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See Section V.1, page 24.

.2204(5)

X-ray services;

-C- See Section V.1, page 24.

.2204(6) *Laboratory services;*

-C- See Section V.1, page 24.

.2204(7) *Blood bank services;*

-C- See Section V.1, page 24.

.2204(8)

Emergency care;

-C- See Section V.1, page 24.

.2204(9)

Acute dialysis in an acute care setting;

-C- See Section V.1, page 24.

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

-C- See Section V.1, page 24.

.2204(11)

Transplantation services;

-C- See Section V.1, page 24.

.2204(12)

Vocational rehabilitation counseling and services;

-C- See Section V.1, page 24.

.2204(13)

Transportation

-C- See Section V.1, page 24.

.2205 STAFFING AND STAFF TRAINING

.2205(a)

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

-C- See Section VII, pages 33-34.

.2205(b)

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

-C- See Section VII.5, page 34, and Exhibit 13.