

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 8, 2012

PROJECT ANALYST: Jane Rhoe-Jones  
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: P-8804-12 / Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville / Add four dialysis stations for a total of 42 stations upon project completion / Onslow County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care (TRC) of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville), operates a 38-station dialysis facility at 14 Office Park Drive, Jacksonville, North Carolina. The applicant proposes to add four dialysis stations for a total of 42 stations at SEDC- Jacksonville 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 revised January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Onslow County. 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 Southeastern Dialysis Center-Jacksonville in the January 2012 SDR is 3.57 patients per station. This utilization rate was calculated based on 125 in-center dialysis patients and 35 certified dialysis stations as of June 30, 2011 (125 patients / 35 stations = 3.57 patients per station). As the table below indicates, three stations were subsequently certified since the publication of the January 2012 SDR. The application of the facility need methodology indicates seven additional stations are

needed for this facility, as illustrated in the following table. However, the applicant is applying for four additional stations.

<b>APRIL 1 REVIEW</b>		
<b>Southeastern Dialysis Center-Jacksonville ---P-8804-12</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11__		89.3%
Certified Stations		35
Pending Stations	6/30/11	3
<b>Total Existing and Pending Stations</b>		<b>38</b>
In-Center Patients as of 6/30/11__ (SDR2)		125
In-Center Patients as of 12/31/10 (SDR1)		108
Step	Description	Result
	Difference (SDR2 - SDR1)	17
(i)	Multiply the difference by 2 for the projected net in-center change	34
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.3148
(ii)	Divide the result of step (i) by 12	0.0262
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January[2012] SDR (6/30/11) until the end of calendar year 2011 (6 months)	0.1574
(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	144.6759
(v)	Divide the result of step (iv) by 3.2 patients per station	45.2112
	and subtract the number of certified and pending stations as recorded in SDR2 [38 ] to determine the number of stations needed	<b>7</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven 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 four 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.”*

### Promote Safety and Quality

See Section I, pages 6-8 and Section II, pages 19-20, for the applicant’s discussions on quality dialysis services. The applicant adequately demonstrates that the proposal will promote quality and safety.

### Promote Equitable Access

In Section II.3, pages 17-18, and in Section VI, pages 33-36, the applicant discusses accessibility to services. The applicant adequately demonstrates that the proposal will promote equitable access.

### Maximize Healthcare Value

The applicant demonstrates need as required by the facility need methodology discussed in Criterion (1). The applicant’s costs and charges are reasonable as stated in Section X, pages 48-54 of the application. Further, the applicant demonstrates in Exhibits 17 and 18 that DaVita, Inc., the parent company of Total Renal Care of North Carolina is financially viable. The applicant adequately demonstrates that the proposal will maximize healthcare value.

Consequently, the applicant demonstrates that the projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. See criterion (3) and (13) for additional discussion. The application is consistent with the facility need determination in the January 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.

Total Renal Care (TRC) of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville, proposes to add four dialysis stations, based on the facility need methodology for a total of 42 dialysis stations at SEDC- Jacksonville upon completion of the project.

Population to be Served

In Section III.7, page 23, the applicant projects the number of in-center dialysis patients and home dialysis patients to be served in the first two years of operation following project completion, as illustrated in the following tables:

<b>SEDC-Jacksonville</b>				
<b>County</b>	<b>Operating Year 1 Census 2014</b>	<b>Operating Year 2 Census 2015</b>	<b>County Patients as a Percent of TOTAL</b>	
			<b>Year 1</b>	<b>Year 2</b>
	<b>In Center</b>	<b>In Center</b>		
Onslow	122	124	90.3%	90.5%
Jones	9	9	6.6%	6.5%
Pender	3	3	2.2%	2.1%
Duplin	1	1	0.7%	0.7%
Carteret	0	0	0.0%	0.0%
<b>TOTAL</b>	<b>135</b>	<b>137</b>	<b>100.0%</b>	<b>100.0%</b>

On page 23, the applicant states:

*“Based on the patients and stations above, SEDC-Jacksonville is projected to have at least 135 in-center patients by the end of operating year one for a utilization rate of 80% or 3.21 patients per station and at least 137 in-center patients by the end of operating year two for a utilization rate of 81% or 3.26 patients per station. This information is based on calculations below. We have used a growth rate of 1.3% for the 119 in-center patients who live in Onslow County.”*

Also on page 23, the applicant states:

*“Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville) had 132 in-center patients as of December 31, 2011 based on the census report generated by the facility on that day. This is a station utilization rate of 87% based on the 38 certified stations in the facility. Of the 132 in-center patients cited in the SDR, 119 of the patients live in Onslow County, 9 of the patients live in Jones County, 3 of the patients live in Pender County and one patient lives in Duplin County. We are applying for a four-station expansion of the Jacksonville facility that will increase the station capacity of the facility from 38 stations to 42 stations.”*

County	Projected Operating Year 1 Census 2014	Projected Operating Year 2 Census 2015
	<b>Home</b>	<b>Home</b>
Onslow	42	54
Carteret	5	5
Jones	2	2
Pender	0	0
Duplin	0	0
<b>TOTAL</b>	<b>49</b>	<b>61</b>

In Section III, pages 24, the applicant states:

*“SEDC-Jacksonville is certified for home hemodialysis training and home training in peritoneal dialysis. As of December 31, 2011 SEDC-Jacksonville was training and following 26 peritoneal dialysis patients and 7 home hemodialysis patients. We are anticipating that two of the peritoneal patients will eventually transfer to the Wallace Dialysis Center in 2014. Therefore, we have deleted two of the peritoneal dialysis patients from our census projections for SEDC-Jacksonville.”*

The applicant adequately identifies the population to be served.

Demonstration of Need

The following table contains information provided by the applicant in Section III, pages 23-24 which illustrates the applicant’s assumptions and methodology used to project utilization at SEDC-Jacksonville. In Section III.7, page 23, the applicant states the in-center projections of SEDC-Jacksonville using the Onslow County 1.3% Average Annual Change Rate for the past five years. The Carteret County Average Annual Change Rate for the past five years is .071%. The Jones County Average Annual Change Rate for the past five years is .080%. The Pender County Average Annual Change Rate for the past five years is .004%. The Duplin County Average Annual Change Rate for the past five years is .025%. The Average Annual Change Rates for Jones, Carteret, Pender and Duplin Counties are found on pages 18 and 19 of the January 2012 SDR:

SEDC-Jacksonville	
Onslow County	In-Center
January 1, 2012 - December 31, 2012	119 patients x 1.013 = 120.547
January 1, 2013 - June 30, 2013	120.547 x 1.0065 = 121.330
July 1, 2013 - June 30, 2014 (Operating Year 1)	121.330 x 1.013 = 122.907
July 1, 2014 - June 30, 2015 (Operating Year 2)	122.907 x 1.013 = 124.505

The applicant projects to serve 122 Onslow County in-center patients by the end of Year One; plus 9 Jones County, 3 Pender County and 1 Duplin County patient for a total of 135 in-center patient or 3.2 patients per station [135 / 42 = 3.21]. The applicant also projects to serve 124 Onslow County in-center patients by the end of Year Two; plus the same distribution of patients from the counties named above for a total of 137 in-center patients, or 3.3 patients per station [137 / 42 = 3.26]. The projected utilization rate is 80% at the end of

Year One [135 / 168 = 0.803] and 82% in Year Two [137 / 168 = 0.815].

In Section II, page 24 the applicant states:

*“We did not provide a growth rate for the 9 in-center dialysis patients living in Jones County, the 3 in-center dialysis patients living in Pender County or the one in-center patient living in Duplin County. Therefore, SEDC-Jacksonville is projected to have 135 in-center patients at the end of operating year one (122 Onslow County patients, 9 Jones County patients, 3 Pender County patients and one Duplin County patient = 135 in-center dialysis patients). SEDC-Jacksonville is projected to have 137 in-center dialysis patients at the end of operating year two (124 Onslow County patients, 9 Jones County patients, 3 Pender County patients and one Duplin County patient = 137 in-center dialysis patients).”*

Projected in-center utilization at SEDC-Jacksonville is based on reasonable and supported assumptions.

The applicant is also certified for home training in peritoneal dialysis and states:

*“As of December 31, 2011 SEDC-Jacksonville was training and following 26 peritoneal dialysis patients and 7 home hemodialysis patients. We are anticipating that two of the peritoneal dialysis patients will eventually transfer to the Wallace Dialysis Center in 2014. Therefore, we have deleted two of the peritoneal dialysis patients from our census projections for SEDC-Jacksonville.*

*Based on the past home-trained patient growth experience at SEDC-Jacksonville, the period of the growth begins with January 1, 2012 forward to June 30, 2015. The following are the peritoneal dialysis patient projections using the 26% Average Annual Change Rate for the Past Five Years.*

*Based on the above assumption, SEDC-Jacksonville is projected to have 35 peritoneal dialysis home-trained patients by the end of Operating Year One who live in Onslow County and 45 peritoneal home-trained patients by the end of Operating Year Two who live in Onslow County.”*

SEDC-Jacksonville	
Onslow County	<b>Peritoneal Dialysis</b>
January 1, 2012 - December 31, 2012	20 patients x 1.26 = 25.2
January 1, 2013 - June 30, 2013	25.2 x 1.13 = 28.48
July 1, 2013 - June 30, 2014 (Operating Year 1)	28.48 x 1.26 = 35.87
July 1, 2014 - June 30, 2015 (Operating Year 2)	35.87 x 1.26 = 45.21

On page 24-25, the applicant also states:

*“We did not provide a growth rate for the 2 peritoneal dialysis patients living in*

*Jones County, the two peritoneal dialysis patients living in Carteret County and we deleted the two peritoneal dialysis patients living [sic] Duplin County. Therefore, SEDC-Jacksonville is projected to have 39 peritoneal patients at the end of operating year one (35 Onslow County patients, 2 Jones County patients, 2 Carteret County patients and zero Duplin County patients = 39 peritoneal dialysis patients). SEDC-Jacksonville is projected to have 49 peritoneal dialysis patients at the end of operating year two (45 Onslow County patients, 2 Jones County patients, 2 Carteret County patients and zero Duplin County patients = 49 peritoneal dialysis patients).*

Projected peritoneal home-trained patient utilization at SEDC-Jacksonville is based on reasonable and supported assumptions.

The applicant is also certified for home hemodialysis training and states:

*“As of December 31, 2011 SEDC-Jacksonville was training and following 7 home hemodialysis patients. Four of the patients lived in Onslow County and three of the patients lived in Carteret County.*

*Based on past home-trained patient growth experience at SEDC-Jacksonville, the period of the growth begins with January 1, 2012 forward to June 30, 2015. The following are the home hemodialysis patient projections using the 26% Average Annual Change Rate for the past Five Years.*

*Based on the above assumption, SEDC-Jacksonville is projected to have 35 home hemodialysis patients by the end of Operating Year One who live in Onslow County and 45 home hemodialysis patients by the end of Operating Year Two who live in Onslow County.”*

SEDC-Jacksonville	
Onslow County	<b>Home Hemodialysis</b>
January 1, 2012 - December 31, 2012	4 patients x 1.26 = 5.04
January 1, 2013 - June 30, 2013	5.04 x 1.13 = 5.69
July1, 2013 - June 30, 2014 (Operating Year 1)	5.69 x 1.26 = 7.17
July1, 2014 - June 30, 2015 (Operating Year 2)	7.17 x 1.26 = 9.04

On page 25, the applicant also states:

*“We did not provide a growth rate for the 3 home hemodialysis patients living in Carteret County. Therefore, SEDC-Jacksonville is projected to have 10 home hemodialysis patients at the end of operating year one (7 Onslow County patients and 3 Carteret County patients = 10 home hemodialysis patients). SEDC-Jacksonville is projected to have 12 home hemodialysis patients at the end of operating year two (9 Onslow County patients and 3 Carteret County patients = 12 home hemodialysis patients).”*

Projected home hemodialysis trained patient utilization at SEDC-Jacksonville is based on

reasonable and supported assumptions.

On page 25, the applicant states the following summary of patient projections:

*“Based on the patients [sic] projections above, SEDC-Jacksonville is projected to have a total of 135 in-center dialysis patients at the end of operating year one and 137 in-center dialysis patients at the end of operating year two. SEDC-Jacksonville is projected to have a total of 49 peritoneal dialysis and home hemodialysis patients (39 peritoneal dialysis patients and 10 home hemodialysis patients = 49 home trained patients) at the end of operating year one. SEDC-Jacksonville is projected to have a total of 61 peritoneal dialysis and home hemodialysis patients (49 peritoneal dialysis patients and 12 home hemodialysis patients = 61 home-trained patients) at the end of operating year two.”*

In summary, the applicant adequately identifies the population proposed to be served and demonstrates the need to add four dialysis stations at the Southeastern Dialysis Center-Jacksonville. Therefore, the application is conforming to this criterion as conditioned.

- (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, page 26, the applicant discusses alternatives considered as the least costly and most effective means to meeting the needs for the project. The alternatives include doing nothing and applying for four stations. The applicant states that applying for four additional stations is the better alternative as it is the least costly and most effective to meet the growing demand for dialysis services. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a) (20); and the Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200. Therefore, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC. d/b/a Southeastern Dialysis Center-Jacksonville shall materially comply with all representations made in its certificate of need application.**



2. **Total Renal Care of North Carolina, LLC. d/b/a Southeastern Dialysis Center-Jacksonville shall develop and operate no more than four additional dialysis stations for a total of 42 certified stations which shall include any home hemodialysis training or isolation stations.**
  3. **Total Renal Care of North Carolina, LLC. d/b/a Southeastern Dialysis Center-Jacksonville shall install plumbing and electrical wiring through the walls for four additional dialysis stations for a total of 42 dialysis stations which shall include any isolation stations and home hemodialysis training stations.**
  4. **Total Renal Care of North Carolina, LLC. d/b/a Southeastern Dialysis Center-Jacksonville shall provide Exhibit 11 – Community College Documentation, as discussed in Section V.3(a), page 31 of the application prior to issuance of the certificate of need.**
  5. **The approved capital expenditure shall be \$64,162.**
  6. **Total Renal Care of North Carolina, LLC. d/b/a Southeastern Dialysis Center-Jacksonville 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.

CA

In Section VIII, the applicant projects capital costs of \$64,162 associated with this project. The applicant states that the project will be financed through cash reserves. This amount includes four new dialysis machines, dialysis chairs, patient televisions, and computers. The project analyst calculated project capital costs of \$65,760. It appears that the applicant miscalculated the costs for four chair side computers, stating \$1600 vs. \$3200 (4 x \$800 = \$3200). The approved capital expenditure shall be \$64,162 as indicated in Condition 5 of Criterion (4).

In Section IX, page 46, the applicant projects there will be no start-up costs or initial operating expenses as SEDC-Jacksonville is an existing facility. The breakdown of capital costs (per the project analyst) is as follows:

SEDC-Jacksonville	
Dialysis Machines	\$47,420
Equipment/Furniture (not included above)	1,480
TVs	4,780
Dialysis Chairs	3,880

Chair side Computers	3,200
(RO) Water Treatment Equipment	5,000
<b>TOTAL</b>	<b>\$65,760</b>

Exhibit 17 contains a letter from the chief accounting officer of DaVita, Inc. and Total Renal Care of North Carolina, LLC., which provides capital costs and confirms financing for the project and states in part:

*“... The project calls for a capital expenditure of \$64,162 [sic]. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$64,162. [sic] 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 Section X, page 44, the applicant provides the allowable charge per treatment by each payor source for SEDC-Jacksonville, as follows:

SEDC-Jacksonville	
Payor	In-Center
Commercial Insurance	\$1313.00
Medicare	\$240.00
Medicare/ Commercial	\$240.00
Medicaid	\$240.00
Medicare/ Medicaid	\$240.00
VA	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X, page 53, the applicant projects that revenue will exceed operating expenses in each of the first two operating years.

SEDC-Jacksonville		
	Year 1	Year 2
Revenue	\$8,975,280	\$9,584,850
Operating Costs	\$6,964,795	\$7,374,676
<b>Total Revenue</b>	<b>\$2,010,485</b>	<b>\$2,210,174</b>

In Exhibit 18, the applicant provides audited balance sheets for DaVita, Inc. which shows that as of December 31, 2011, DaVita, Inc. had \$8,892,172,000 in total assets, including \$393,752,000 in cash and cash equivalents. The balance sheet also shows that DaVita, Inc. had \$2,268,125,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the financial solvency of the company.

The assumptions used in preparation of the pro formas, including the number of projected treatments are reasonable. See Section X, pages 51-52, for the applicant’s assumptions. In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. Therefore, the application is conforming to this criterion, subject to Condition 5 in Criterion (4).

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

C

Southeastern Dialysis Center-Jacksonville is the only dialysis facility in Onslow County. TRC proposes to add four dialysis stations at this existing facility, for a total of 42 stations upon project completion. SEDC- Jacksonville is currently serving 125 patients weekly at 3.57 patients per station, or 89% of capacity. Dialysis facilities that operate four shifts per week (2/day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new dialysis facility. The applicant discusses projections for the in-center patient population on pages 23-24 of the application. At the end of Operating Year Two, with 42 dialysis stations and 137 dialysis patients after the three-station addition, the SEDC- Jacksonville projects the utilization will be 3.3 in-center patients per station (137 patients / 42 dialysis stations = 3.26). The growth projections are based on Onslow County projected 1.3% Average Annual Growth Rate in the number of dialysis patients.

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

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

C

In Section VII, page 37, the applicant provides projected staffing for SEDC-Jacksonville upon project completion, as illustrated in the following table:

SEDC-Jacksonville Full-Time Equivalent (FTE) Positions	
RN	4.0
HTRN	4.0
PCT	16.0
Bio-Med Tech	1.0
Admin	1.5
Dietician	1.5
Social Worker	1.0
Unit Secretary	2.0
Reuse Tech	2.0

Total FTEs	33.0
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The applicant projects a total of 33.0 FTE positions upon project completion and states on page 38 that there is no difficulty expected in recruiting staff. In Section V.4, page 31, the SEDC-Jacksonville identifies the current Medical Director. The applicant provides in Exhibit 12, a letter of support from the current Medical Director. The applicant adequately documents the availability of health manpower and management personnel for the provision of the services to be provided. Therefore, the application is conforming to this criterion.

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

C

In Section V, page 29, the applicant lists the providers of the necessary ancillary and support services. On pages 30-31, the applicant discusses relationships with other local healthcare and social service providers. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

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 June 2010 and CY 2008-2009, respectively. The data in the table were obtained on June 6, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	<b>Total # of Medicaid Eligible as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Onslow County	11.0%	4.2%	23.4%
Statewide	17.0%	6.7%	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 SEDC-Jacksonville of Onslow County.

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 June 6, 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as a secondary payer. Also, the 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 standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. 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.”*

In Section VI.1, page 33, the applicant provides the payor mix for services currently provided at the facility. The applicant states:

*“... SEDC-Jacksonville, 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.”*

The applicant states that 93.4% of dialysis services were provided to Medicare and/or Medicaid patients in the year prior to submitting this application. An additional 6.6% of services were provided by VA sponsorship. See the following table, from page 33:

SEDC-Jacksonville	
PAYOR	% OF TOTAL PATIENTS
Medicare/Commercial	41.2%
Medicare/Medicaid	24.0%
Medicare	13.8%
Commercial Insurance	9.0%
VA	6.6%
Medicaid	5.4%
TOTAL	100.0%

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Southeastern Dialysis Center-Jacksonville of Onslow County. 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.6(a), page 36, the applicant states there have been no civil rights access complaints filed against SEDC-Jacksonville within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 34, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. The applicant demonstrates that the elderly and medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 31, the applicant states in part:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at SEDC-Jacksonville. ... Should a patient contact SEDC- Jacksonville directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. ... ”*

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.

CA

In Section V, page 31, the applicant states:

*“SEDC-Jacksonville has an established relationship with Coastal Carolina Community College. See Exhibit 11 [sic] for a copy of the agreement.”*

Exhibit 11 is labeled in the applicant’s table of contents as ‘Community College Documentation’; however, the Exhibit is blank. There is no document in the referenced exhibit that demonstrates the clinical needs of health professional training programs are accommodated. Therefore, this criterion is conforming as conditioned in Criterion (4), Condition 6.

- (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, III, V, VI, and VII in the Southeastern Dialysis Center-Jacksonville application. In particular, see Section V.7, page 32 in which the SEDC- Jacksonville discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Onslow County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add three dialysis stations and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations. The proposed project improves geographic access to patients who wish to transfer their care to a closer facility.

In Section VI.1, page 33, the applicant provides a data table that demonstrates that more than 84% of the facility's population are recipients of Medicare or Medicaid and will have access to its services.

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Southeastern Dialysis Center-Jacksonville operated in compliance with all Medicare conditions of participation within the 18 months immediately preceding the date of this decision. Therefore the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is [conforming] [not conforming] with all applicable Criteria and Standards for &. The specific criteria are discussed below.

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 promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

- .2202(a)(1) Utilization rates;*
  - C- See Section IV, pages 27-28, and Exhibit 7 (copy of the January 2012 SDR, Tables A and B).
- .2202(a)(2) Mortality rates;*
  - C- See Section IV, page 27.
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*
  - C- See Section IV, page 27.
- .2202(a)(4) The number of transplants performed or referred;*
  - C- See Section IV, page 28.
- .2202(a)(5) The number of patients currently on the transplant waiting list;*
  - C- See Section IV, page 28.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
  - C- See Section IV, page 28.
- .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, page 28.

*(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-  
.2202(b)(2) SEDC-Jacksonville is an existing facility.  
*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-  
.2202(b)(3) SEDC-Jacksonville is an existing facility.  
*For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA-  
.2202(b)(4) SEDC-Jacksonville is an existing facility.  
*Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C-  
.2202(b)(5) See Exhibit 8.  
*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-  
.2202(b)(6) SEDC-Jacksonville is an existing facility.  
*Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C-  
.2202(b)(7) See Section XI.6(g), pages 59-60; and Exhibits 14, 22 and 23.  
*The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C-  
.2202(b)(8) See Section III.7, pages 23-25.  
*For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA-  
.2202(b)(9) SEDC-Jacksonville is an existing facility.  
*A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C-  
In Section VI(d), page 34, the applicant states: “SEDC-Jacksonville maintains an open-door policy of accepting all patients, regardless of ability to pay, who

*develop end stage renal disease while residing in the service area of SEDC-Jacksonville.”*

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

*-NA- SEDC-Jacksonville 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, page 24, the applicant projects to serve 122 Onslow County in-center patients by the end of Year One; plus 9 Jones County, 3 Pender County and 1 Duplin County patient for a total of 135 in-center patient or 3.2 patients per station [135 / 42 = 3.21]. 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 II, pages 12-17, and Section III, pages 21, 23-25, the applicant provides the assumptions and methodology used to utilization of the proposed facility.*

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

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

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

- C- See Section V, page 29.
- .2204(2) *Maintenance dialysis;*
- C- See Section V, page 29.
- .2204(3) *Accessible self-care training;*
- C- See Section V, page 29.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V, pages 29 and 30.
- .2204(5) *X-ray services;*
- C- See Section V, page 29.
- .2204(6) *Laboratory services;*
- C- See Section V, page 29.
- .2204(7) *Blood bank services;*
- C- See Section V, page 29.
- .2204(8) *Emergency care;*
- C- See Section V, page 29.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- See Section V, page 29.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V, page 29.
- .2204(11) *Transplantation services;*
- C- See Section V, page 29.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- See Section V, page 29.
- .2204(13) *Transportation*
- C- See Section V, page 29.

**10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- See Section VII, pages 37-40. Also, in Section VII, page 37, the applicant provides the proposed staffing. The applicant states on page 37 that the facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .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 Exhibit 16.