

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 28, 2014

PROJECT ANALYST: Jane Rhoe-Jones

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: P-10266-14 / Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center - Jacksonville / Add one dialysis station for a total of 25 stations upon project completion and completion of Project ID# P-10123-13 / 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 of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville) is currently certified for 42 in-center dialysis stations. In this application, the applicant proposes to add one dialysis station for a total of 11 stations upon completion of this project and Project ID# P-10123-13 (relocate 18 stations to New River Dialysis – a new facility).

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Onslow County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, SEDC-Jacksonville is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.3 patients per station, or 82%. This utilization rate was calculated based on 138 in-center dialysis patients and 42 certified dialysis stations as of

June 30, 2013 (138 patients / 42 stations = 3.28 patients per station). See the following table, from Section III.1, page 18 of the application:

<b>APRIL 1 REVIEW - JANUARY SDR SEDC-JACKSONVILLE</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		82.1%
Certified Stations		42
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>42</b>
In-Center Patients as of 6/30/13 (SDR2)		138
In-Center Patients as of 12/31/12(SDR1)		138
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.0000
(ii)	Divide the result of step (i) by 12	0.0000
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.0000
(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	138.0000
(v)	Divide the result of step (iv) by 3.2 patients per station	43.1250
	and subtract the number of certified and pending stations as recorded in SDR2 [42 stations] to determine the number of stations needed	<b>1</b>

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.*” As shown in the table above, based on the facility need methodology for dialysis stations, SEDC-Jacksonville has a need for one additional station. The applicant proposes to add one new station and therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2014 SMFP is also 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

In Section II.3, on pages 16-17, the applicant describes the efforts undertaken by DaVita Inc., the parent company of SEDC-Jacksonville, to promote safety and quality. 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. ... 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.*

...

*SEDC-Jacksonville is attended by Southeastern Nephrology Associates, admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. George Thomas serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility 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 SEDC-Jacksonville as a whole, then compares each sister unit to the whole and to industry standards. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”*

The applicant also discusses its safety measures in Section XI.6(g), pages 54-55. In Exhibit 22, the applicant provides a copy of the prevention and safety training outline, and in Exhibit 23, a copy of its in-service training schedule. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Onslow County.

### Promote Equitable Access

In Section VI, page 29, the applicant discusses accessibility with regard to SEDC-Jacksonville. 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.*

*SEDC-Jacksonville 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-Jacksonville provides dialysis six days per week with two patient shifts per day to accommodate patient need.*

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

The applicant adequately demonstrates how its proposal will promote access to dialysis services for medically underserved groups.

### Maximize Healthcare Value

In Section III.9, page 22, the applicant states,

*“SEDC-Jacksonville promotes cost-effective approaches in the facility in the following ways:*

- *... The parent corporation, DaVita, operates over 1,800 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. ...*
- *SEDC-Jacksonville 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-Jacksonville 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-Jacksonville 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-Jacksonville Bio-medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly and semiannual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*
- *SEDC-Jacksonville 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 how its proposal will maximize healthcare value. Furthermore, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of dialysis patients to be served. Thus, the application is consistent with Policy GEN-3.

In summary, the application is consistent with the facility need determination in the 2014 SMFP and is consistent with Policy GEN-3. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

SEDC-Jacksonville currently operates a 42-station dialysis facility located in Jacksonville, in Onslow County. The applicant proposes to add one dialysis station to the existing facility for a total of 25 certified dialysis stations upon completion of this project and Project ID# P-10123-13 (relocate 18 stations to New River Dialysis – a new facility). The applicant provides home hemodialysis training and support at SEDC-Jacksonville. The January 2014 SDR reports SEDC-Jacksonville is currently certified for 42 in-center dialysis stations and was dialyzing 138 in-center patients as of June 30, 2013.

Population to be Served

In Section IV.1, page 23, the applicant identifies its current in-center patient population as illustrated below in the table.

<b>SEDC-JACKSONVILLE</b>		
<b>COUNTY OF RESIDENCE</b>	<b>IN-CENTER PATIENTS</b>	<b>HOME-TRAINED PATIENTS</b>
Onslow	136	24
Jones	1	0
Pender	1	0
Carteret	0	5
Craven	0	2
<b>Total</b>	<b>138</b>	<b>31</b>

In Section III.7, page 20, the applicant projects patient origin for SEDC-Jacksonville for the first two project years following the addition of the dialysis station, as shown in the following table:

<b>SEDC-JACKSONVILLE</b>				
<b>COUNTY OF RESIDENCE</b>	<b>OPERATING YEAR ONE 2015</b>	<b>OPERATING YEAR TWO 2016</b>	<b>PATIENTS AS % OF TOTAL</b>	
	<b>IN-CTR. PTS.</b>	<b>IN-CTR. PTS.</b>	<b>YEAR 1</b>	<b>YEAR 2</b>
Onslow	93	98	97.8%	98.0%

Pender	1	1	1.0%	1.0%
Jones	1	1	1.0%	1.0%
Carteret	0	0	0.0%	0.0%
Craven	0	0	0.0%	0.0%
<b>Total</b>	<b>95</b>	<b>100</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant proposes to add one dialysis station to the existing facility for a total of 25 dialysis stations upon project completion and completion of Project ID# P-10123-13 (relocate 18 stations to New River Dialysis – a new facility).

In Section III.7, pages 20-21, the applicant describes its methodology:

- *“SEDC-Jacksonville had 138 in-center patients as of June 30, 2013 based on information included in Table A of the January 2014 Semiannual Dialysis Report (SDR). This is a station utilization rate of 82% based on the 42 certified stations in the facility. Of the 138 in-center patients cited in the SDR, 136 of the patients live in Onslow County, one patient in Pender County and one patient in Jones County. We are applying for a one-station expansion of SEDC-Jacksonville.*
- *The January 2014 SDR indicates in Table B that Onslow County has experienced an average annual change rate of 6.6% for the past five years.*
- *We have grown the patient population of SEDC-Jacksonville patients beginning January 1, 2014 through the projected operating year 2. The calculations below begin with 136 in-center patients living in Onslow County:*

*January 1, 2014-December 31, 2014 – 136 patients X 1.066 = 144.976  
 January 1, 2015-December 31, 2015 – 144.976 patients X 1.066 = 154.544416  
 January 1, 2016-December 31, 2016 – 154.544416 patients X 1.066 =  
 164.7443474*

*January 1, 2015-December 31, 2015 (operating year 1)  
 January 1, 2016-December 31, 2016 (operating year 2)*

*At the end of operating year one SEDC-Jacksonville is projected to have an in-center patient census of 156 patients (154 Onslow County patients, one Pender County and one Jones County patient = 156 total patients) for [sic] utilization rate of 90% or 3.6 patients per station. At the end of operating year two SEDC-Jacksonville is projected to have an in-center patient census of 166 patients (164 Onslow County patients, one Pender County and one Jones County patient = 166 total patients) for [sic] utilization rate of 96% or 3.8 patients per station. We did not calculate the growth of the patients residing outside of Onslow County.*

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

However, in clarifying information received on July 10, 2014, the applicant states the following which factors in the 18 stations and 58 in-center patients relocating to New River Dialysis Center (Project ID# P-10123-13):

*“The methodology utilized in applying for the one-station expansion was the ESRD Facility Based Methodology as indicated in the table on page 18 of the application. The calculations indicate that the facility was eligible for a one-station expansion, which is indicated in Section I on page 3.*

*The assumptions:*

- *SEDC-Jacksonville had 138 in-center patients as of June 30, 2013 for a utilization rate of 82% based on the 42 certified stations ( $138/168 = 82\%$ )*
- *A certificate of need has been secured to develop the New River Dialysis (Project ID #P-10123-13) via transfer of 18 stations and 58 in-center patients from SEDC-Jacksonville, which will leave 24 dialysis stations at SEDC-Jacksonville when the New River project is complete and the 18 stations are relocated*
- *SEDC-Jacksonville is applying for a one-station expansion, which will result in the facility having 25 certified dialysis stations when the New River Dialysis project is complete*
- *Since the New River Dialysis is still under development, all 42 existing stations continue to be located at SEDC-Jacksonville*
- *Since all of the stations are located at Jacksonville, the calculations in Section II and III of the SEDC-Jacksonville CON application to add one station to the existing facility were based the 42 stations*

*The 3.6 patients per station and 156 total patients for OY1 is based on 43 certified stations. ... subtracted 18 stations and 61 in-center patients ( $58 \times 1.066 = 61.828$ ) which includes the one-year growth associated with the 18 stations that would transfer from SEDC-Jacksonville to New River Dialysis. Based on this information and the calculations in the SEDC-Jacksonville CON application to add one station, SEDC-Jacksonville would have 25 stations at the end of operating year one and 95 in-center patients at the end of operating year one for a utilization rate of 95% or 3.8 patients per station*

*The 3.6 patients per station and 166 total patients for OY2 is based on 43 certified stations. ... subtracted 18 stations and 66 in-center patients ( $61.828 \times 1.066 = 65.908648$  rounded up to 66) which includes the two-year growth of the 58 in-center patients associated with the 18 stations that would transfer from SEDC-Jacksonville to New River Dialysis. Based on this information and the calculations in the SEDC-Jacksonville CON application to add one station, SEDC-Jacksonville would have 25*

*stations at the end of operating year one and 100 in-center patients at the end of operating year two for a utilization rate of 100% or 4.0 patients per station. ...”*

The applicant’s projected in-center patient utilization at the end of Operating Year One exceeds the 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

#### Home Training

In clarifying information submitted by the applicant on August 11, 2014, the applicant states that the home training program at SEDC-Jacksonville will be transferred to the New River Dialysis Center.

Projected utilization is based on reasonable, credible and supported assumptions regarding continued growth of Onslow patients at SEDC-Jacksonville. The applicant adequately demonstrates the need to add one dialysis station.

#### Access to Services

In Section VI.1, page 29, 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 projects 86% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need for one additional dialysis station at SEDC-Jacksonville, and adequately demonstrates the extent to which all residents in the service area, in particular underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, pages 21-22, the applicant discusses two alternatives considered prior to the submission of this application, which are as follows:

1. Maintain the status quo. The applicant states that this alternative is not the most effective alternative because of the continued growth in the patient population.
2. Add one dialysis station. The applicant states that adding one additional station at SEDC-Jacksonville is the most effective alternative to meet the increasing demand for dialysis services at the facility.

The applicant adequately demonstrates the need for one additional station based on the continued growth of the ESRD patient population of Onslow County and the facility's projected utilization. See Criterion (3) for discussion of need which is incorporated hereby as if set forth fully herein. Furthermore, the application is conforming to all other statutory and regulatory review criteria. An application that is not approvable cannot be an effective alternative.

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall materially comply with all representations made in the certificate of need application and clarifying information. In those instances where representations conflict, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville, Inc. shall materially comply with the last-made representation.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall develop no more than one additional dialysis station at SEDC-Jacksonville for a total of no more than 25 dialysis stations upon project completion and completion of Project ID# P-10123-13; including any home hemodialysis 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 no more than one additional dialysis station for a total of no more than 25 stations upon projection completion.**
- 4. Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall submit documentation referenced as Exhibits 9, 10, and 11 which were not provided.**
- 5. 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.

C

In Section VIII.1, pages 37-38, the applicant projects the capital cost will be \$18,963, including the cost of the dialysis machine, dialysis chair, television, computer terminal and other equipment/furniture.

In Section IX, page 42, the applicant indicates that there will be no start-up or initial operating expenses associated with this project.

In Section VIII.3, page 39, the applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita Inc., the applicant's parent company.

Exhibit 17 includes a letter dated March 3, 2014 from the Chief Accounting Officer of DaVita HealthCare Partners, Inc., which states,

*"I am the Chief Accounting Officer of DaVita HealthCare Partners Inc., the parent and 100% owner of Total Renal Care, Inc. ...*

*We are submitting a Certificate of Need application to expand our Southeastern Dialysis Center-Jacksonville by one ESRD dialysis station. The project calls for a capital expenditure of \$18,963. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$18,963. for the project capital expenditure. DaVita HealthCare Partners 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."*

In Exhibit 18, the applicant provides the audited financial statements for DaVita HealthCare Partners Inc. The report shows that, as of December 31, 2013, DaVita HealthCare Partners Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 44, the applicant projects the following charges per treatment for each payment source as follows:

SEDC-JACKSONVILLE	
PAYMENT SOURCE	IN-CENTER CHARGE

Medicare	\$240
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial Insurance	\$1,175
VA	\$193
Medicare/Commercial	\$240

The applicant projects net revenue in Section X.2, page 45, and operating expenses in Section X.4, page 48, of the application. The applicant projects revenues will exceed expenses in each of the first two operating years (OY) following completion of the project, as illustrated below in the table. The applicant provided the following revenue and operating expenses in clarifying information submitted on August 11, 2014.

<b>SEDC - JACKSONVILLE</b>		
	<b>OY1 (CY 2015)</b>	<b>OY2 (CY 2016)</b>
Total Projected Net Revenue	\$4,738,451	\$4,988,182
Total Projected Operating Costs	\$3,712,222	\$3,883,205
Projected Net Profit	\$1,026,229	\$1,104,977

In clarifying information, the applicant provides the following assumptions and methodology to project revenue for OY1 and OY2:

The Assumptions:

1. With regard to the first operating year, the number of stations is 25 and the number of in-center patients is 95, or 3.8 patients per station.
2. With regard to the second operating year, the number of stations is 25 and the number of in-center patients is 100, or 4.0 patients per station.
3. For both operating years, the total number of treatments averages 13 treatments per month, per patient for 12 months.
4. For both operating years, the total number of treatments is reduced five percent to allow for missed treatments; and
5. For both operating years, the average reimbursement per treatment is based on the applicant's historical experience and expected future reimbursement.

The Methodology:

- *“SEDC-Jacksonville had 138 in-center patients as of June 30, 2013 for a utilization rate of 82% based on the 42 certified stations (138/168 = 82%)*
- *A certificate of need has been secured to develop the New River Dialysis (Project ID #P-10123-13) via transfer of 18 stations and 58 in-center patients from SEDC-Jacksonville, which will leave 24 dialysis stations at SEDC-Jacksonville when the New River project is complete and the 18 stations are relocated*

- *SEDC-Jacksonville is applying for a one-station expansion which will result in the facility having 25 certified dialysis stations when the New River Dialysis project is complete*
- *Since the New River Dialysis is still under development, all 42 existing stations continue to be located at SEDC-Jacksonville*
- *Since all of the stations are located at Jacksonville, the calculations in Section II and III of the SEDC-Jacksonville CON application to add one station to the existing facility were based on the 42 stations.*

*The 3.6 patients per station and 156 total patients for OY1 is based on 43 certified stations. ... subtracted 18 stations and 61 in-center patients ( $58 \times 1.066 = 61.828$ ) which includes the one-year growth associated with the 18 stations that would transfer from SEDC-Jacksonville to New River Dialysis. Based on this information and the calculations in the SEDC-Jacksonville CON application to add one station, SEDC-Jacksonville would have 25 stations at the end of operating year one and 95 in-center patients at the end of operating year one for a utilization rate of 95% or 3.8 patients per station*

*The 3.6 patients per station and 166 total patients for OY2 is based on 43 certified stations. ... subtracted 18 stations and 66 in-center patients ( $61.828 \times 1.066 = 65.908648$  rounded up to 66) which includes the two-year growth of the 58 in-center patients associated with the 18 stations that would transfer from SEDC-Jacksonville to New River Dialysis. Based on this information and the calculations in the SEDC-Jacksonville CON application to add one station, SEDC-Jacksonville would have 25 stations at the end of operating year one and 100 in-center patients at the end of operating year two for a utilization rate of 100% or 4.0 patients per station.”*

In clarifying information received from the applicant on August 11, 2014, the applicant provides projected staffing and salaries. In Section VII, page 33, the applicant states the facility is in compliance with the requirements of 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on pages 35-36. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected. In clarifying information submitted by the applicant on July 20, 2014, the applicant states there is no nocturnal shift proposed at SEDC-Jacksonville.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

## C

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville) proposes to add one dialysis station to the existing facility for a total of 25 certified dialysis stations upon project completion and completion of Project ID# P-

10123-13 (relocate 18 stations to New River Dialysis – a new facility). The applicant does not propose to establish a new facility with this project.

According to Table A in the January 2014 SDR, as of June 30, 2013, SEDC-Jacksonville was operating at 82% of capacity, with 138 in-center patients on 42 stations ( $138 / 42 = 3.28$ ;  $3.28 / 4 = 0.82$ ). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations, consistent with the facility need methodology in the 2014 SMFP. In clarifying information, the applicant states that at the end of Operating Year One, the facility will have 25 stations serving 95 patients, which is a utilization rate of 95% ( $95 / 25 = 3.8$ ;  $3.8 / 4 = .95$ ). Dialysis facilities that operate four shifts per week (two per day on alternate days) have a capacity of four patients per station.

SEDC-Jacksonville is the only existing dialysis facility located in Onslow County. There is one approved new facility, New River Dialysis (Project ID# P-10123-13) which is projected to open by 2015. The applicant or a related entity owns the existing facility and the one approved facility. In Section V.7, on page 28, the applicant states:

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

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

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

C

In clarifying information submitted by the applicant on August 11, 2014, the applicant provides the current and projected number of full-time equivalent (FTE) positions as shown in the following table:

SEDC-JACKSONVILLE		
POSITION	CURRENT FTEs	PROJECTED FTEs
Registered Nurse	4.0	3.0
Home-training RN	2.0	0
Patient Care Technician	15.0	11.0
Bio-Medical Technician	1.0	1.0
Administrative	1.0	1.0
Dietician	1.5	1.0
Social Worker	1.0	1.0

Reuse	2.0	1.0
Unit Secretary	2.0	1.0
<b>TOTAL</b>	<b>29.5</b>	<b>20.0</b>

As shown in the table above, the applicant proposes to employ a total of 20 FTE positions to staff SEDC-Jacksonville upon completion of the proposed project.

In Section V.4, page 27, the applicant states that Dr. George Thomas will continue to serve as medical director of the facility. Exhibit 12 contains a letter of support from Dr. Thomas.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

CA

In Sections V.1 and V.2, on pages 25-26, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at SEDC-Jacksonville. Onslow Memorial Hospital provides the following services: emergency, acute hemodialysis, diagnostic evaluation, X-ray, blood bank, and vascular surgery. The other services are provided by the individual providers listed in the table provided on page 25. The applicant discusses coordination with the existing health care system in Section V.2-V.6, pages 26-28. The applicant states having provided supporting documentation of coordination with the existing health care system in Exhibits 9, 10, and 11. However, there is no information contained those exhibits. Please see Criterion (4), Condition # 4.

The application is conforming to this criterion subject to Condition #4 in Criterion (4).

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the

HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

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

C

In Section VI.1, page 29, 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's dialysis policies, procedures and guidelines with regard to accepting patients for dialysis care are located in Exhibit 13.

In Section VI.1, page 29, the applicant reports that 86% of the patients who received treatments at SEDC-Jacksonville had some or all of the services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payor mix for the facility, as reported by the applicant.

<b>SEDC-JACKSONVILLE HISTORICAL PAYOR MIX</b>	
<b>PAYOR SOURCE</b>	<b>PERCENTAGE</b>
Medicare	15.2%
Medicaid	4.3%
Medicare/Medicaid	25.0%
Medicare/Commercial	41.5%
Commercial Insurance	7.3%
VA	6.7%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Onslow County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Onslow County	11%	4.2%	23.4%
Statewide	17%	6.71%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by SEDC-Jacksonville. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender 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.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”<sup>1</sup> (p. 216)*

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which shows that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)*

The report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$49.2 billion, including Medicare Part D (p.118). The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

<b>ESRD SPENDING BY PAYOR*</b>		
<b>PAYOR</b>	<b>SPENDING IN BILLIONS</b>	<b>% OF TOTAL SPENDING</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>TOTAL</b>	<b>\$49.2</b>	<b>100.0%</b>

\*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 327.

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%

<sup>1</sup> www.usrds.org/adr.aspx

55-64	4,013	26.9%
65+	5,995	40.2%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6. Table includes North Carolina statistics only.<sup>2</sup>

The applicant demonstrates that medically underserved populations currently have adequate access to services available at SEDC-Jacksonville. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(f), page 30, the applicant states, “*SEDC-Jacksonville has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...*” 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

C

In Section VI.1(c), page 30, 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. The applicant projects 86% of all in-center patients will have some or all of their services paid for by Medicare and Medicaid.

<b>SEDC-JACKSONVILLE HISTORICAL PAYOR MIX</b>	
<b>PAYOR SOURCE</b>	<b>PERCENTAGE</b>
Medicare	15.2%
Medicaid	4.3%

<sup>2</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

Medicare/Medicaid	25.0%
Medicare/Commercial	41.5%
Commercial Insurance	7.3%
VA	6.7%
<b>Total</b>	<b>100.0%</b>

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, pages 31-32, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity 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.3, page 27, the applicant states that SEDC-Jacksonville has an existing clinical training agreement with Coastal Carolina Community College. The applicant states, “*See Exhibit 11 for a copy of the agreement.*” Exhibit 11 is empty and does not contain the agreement with Coastal Carolina Community College that the applicant states on page 27 is included in Exhibit 11.

The application is conforming to this criterion subject to Condition #4 in Criterion (4).

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

C

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville) proposes to add one dialysis station to the existing facility for a total of 25 certified dialysis stations upon project completion and completion of Project ID# P-10123-13, New River Dialysis (relocate 18 stations from SEDC-Jacksonville). The applicant does not propose to establish a new facility in this project. The applicant adequately demonstrates the need for one additional station based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

According to Table A in the January 2014 SDR, as of June 30, 2013, SEDC-Jacksonville was operating at 82% of capacity, with 138 in-center patients on 42 stations ( $138 / 42 = 3.28$ ;  $3.28 / 4 = 0.82$ ). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations, consistent with the facility need methodology in the 2014 SMFP.

In clarifying information received on July 10, 2014, the applicant states the following which factors in the 18 stations and 58 in-center patients relocating to New River Dialysis Center (Project ID# P-10123-13):

*The 3.6 patients per station and 156 total patients for OY1 is based on 43 certified stations. I left out a step where I should have subtracted 18 stations and 61 in-center patients ( $58 \times 1.066 = 61.828$ ) which includes the one-year growth associated with the 18 stations that would transfer from SEDC-Jacksonville to New River Dialysis. Based on this information and the calculations in the SEDC-Jacksonville CON application to add one station, SEDC-Jacksonville would have 25 stations at the end of operating year one and 95 in-center patients at the end of operating year one for a utilization rate of 95% or 3.8 patients per station*

*The 3.6 patients per station and 166 total patients for OY2 is based on 43 certified stations. I left out a step where I should have subtracted 18 stations and 66 in-center patients ( $61.828 \times 1.066 = 65.908648$  rounded up to 66) which includes the two-year growth of the 58 in-center patients associated with the 18 stations that would transfer from SEDC-Jacksonville to New River Dialysis. Based on this information and the calculations in the SEDC-Jacksonville CON application to add one station, SEDC-Jacksonville would have 25 stations at the end of operating year one and 100 in-center patients at the end of operating year two for a utilization rate of 100% or 4.0 patients per station. ...”*

SEDC-Jacksonville is the only existing dialysis facility located in Onslow County. There is one approved new facility, New River Dialysis (Project ID# P-10123-13) which is projected to open by 2015. The applicant or a related entity owns the existing facility and the one approved facility.

In Section V.7, page 28, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

*“The proposed expansion of the facility is an effort to provide dialysis services to this community and not intended to be a competitive venture. ... patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. SEDC-Jacksonville provides access to all qualified Nephrologists to admit his or her patients.”*

See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application referenced above and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that that the proposed project is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services;
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

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

## C

The applicant currently provides dialysis services at SEDC-Jacksonville. According to 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 during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and

may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

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

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

- (1) Utilization rates;*  
-C- In Sections II.1 and III.7, pages 12 and 20, the applicant states the utilization rate was 82% or 3.3 patients per station ( $138 / 42 = 3.28$ ) as of June 30, 2013.
- (2) Mortality rates;*  
-C- In Section IV.2, page 23, the applicant states the mortality rates as 8.0%, 16.8%, and 13.5% in 2011, 2012 and 2013 respectively.
- (3) The number of patients that are home trained and the number of patients on home dialysis;*  
-C- In Section IV.3, page 23, the applicant states that SEDC-Jacksonville had 31 home-trained patients as of June 30, 2013.
- (4) The number of transplants performed or referred;*  
-C- In Section IV.4, page 24, the applicant states that SEDC-Jacksonville referred 11 patients for transplant evaluation in 2013. The applicant states that four patients received transplants in 2013.
- (5) The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 24, the applicant states that SEDC-Jacksonville has 25 patients currently on the transplant waiting list.
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

- C- In Section IV.6, page 24, the applicant states that there were 264 hospital admissions in 2013, 20 of which were dialysis related and 244 that were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 24, the applicant states that there were four patients at the facility with infectious diseases, and no patients converted to infectious disease status in 2013.

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

- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
  - NA- SEDC-Jacksonville is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
  - (A) timeframe for initial assessment and evaluation of patients for transplantation,
  - (B) composition of the assessment/evaluation team at the transplant center,
  - (C) method for periodic re-evaluation,
  - (D) criteria by which a patient will be evaluated and periodically re- evaluated for transplantation, and
  - (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.
  - NA- SEDC-Jacksonville is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
  - NA- SEDC-Jacksonville is an existing facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
  - C- See Exhibit 8 for a copy of the policies and procedures for back-up electrical service in the event of a power outage for SEDC-Jacksonville.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the*

*applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- SEDC-Jacksonville is an existing facility.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section XI.6(g), page 54, the applicant states, “*SEDC-Jacksonville has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.*”

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

-C- In clarifying information, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

<b>SEDC-JACKSONVILLE</b>				
<b>COUNTY OF RESIDENCE</b>	<b>OPERATING YEAR ONE 2015</b>	<b>OPERATING YEAR TWO 2016</b>	<b>PATIENTS AS % OF TOTAL</b>	
	<b>IN-CTR. PTS.</b>	<b>IN-CTR. PTS.</b>	<b>YEAR 1</b>	<b>YEAR 2</b>
Onslow	93	98	97.8%	98.0%
Pender	1	1	1.0%	1.0%
Jones	1	1	1.0%	1.0%
Carteret	0	0	0.0%	0.0%
Craven	0	0	0.0%	0.0%
<b>Total</b>	<b>95</b>	<b>100</b>	<b>100.0%</b>	<b>100.0%</b>

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

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

-NA- SEDC-Jacksonville is an existing facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1, page 12, the applicant states, “*Total Renal Care of North Carolina d/b/a Southeastern Dialysis Center-Jacksonville will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per 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 does not propose to establish a new End Stage Renal Disease facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for 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- SEDC-Jacksonville projects 3.8 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12-15, and Section III.7, pages 22-23; and more accurately in clarifying information provided by the applicant on July 11, 2014. See also Criteria (3), (6) and (18a) for discussion which is incorporated hereby as if set forth fully herein.

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

-C- SEDC-Jacksonville projects 3.8 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12-15, and Section III.7, pages 22-23; and more accurately in clarifying information provided by the applicant on July 11, 2014. See also Criteria (3), (6) and (18a) for discussion which is incorporated hereby as if set forth fully herein.

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

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

(1) *diagnostic and evaluation services;*

- C- In Section V.1, page 25, the applicant states patients will receive diagnostic evaluation services from Onslow Memorial Hospital.
- (2) *maintenance dialysis;*
- C- In Section V.1, page 25, the applicant states patients will receive maintenance dialysis services at the facility.
- (3) *accessible self-care training;*
- C- In clarifying information submitted by the applicant on August 11, 2014, the applicant states that the home training program will be transferred to New River Dialysis.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In clarifying information submitted by the applicant on August 11, 2014, the applicant states that the home training program will be transferred to New River Dialysis.
- (5) *x-ray services;*
- C- In Section V.1, page 25, the applicant states that Onslow Memorial Hospital will provide x-ray services.
- (6) *laboratory services;*
- C- In Section V.1, page 25, the applicant states that Dialysis Laboratories will provide laboratory services.
- (7) *blood bank services;*
- C- In Section V.1, page 25, the applicant states that Onslow Memorial Hospital will provide blood bank services.
- (8) *emergency care;*
- C- In Section V.1, page 25, the applicant states that Onslow Memorial Hospital will provide emergency care services.
- (9) *acute dialysis in an acute care setting;*
- C- In Section V.1, page 25, the applicant states that Onslow Memorial Hospital will provide acute dialysis services.
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section V.1, page 25, the applicant states that Onslow Memorial Hospital will provide vascular surgery services.
- (11) *transplantation services;*
- C- In Section V.1, page 25, the applicant states that Duke University Medical Center and East Carolina University will provide transplantation services.
- (12) vocational rehabilitation counseling and services; and

-C- In Section V.1, page 25, the applicant states that the North Carolina Division of Vocational Rehabilitation Services will provide vocational rehabilitation counseling.

(13) *transportation.*

-C- In Section V.1, page 25, the applicant states that Onslow Transit Company will provide transportation services.

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

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

-C- In Section VII.1, on page 33, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if set forth fully herein.

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

-C- In Section VII.5, on page 35, the applicant refers the reader to Exhibit 16, where the applicant provides a copy of the applicant's training policy for nurses and technicians at the facility.