

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 12, 2013
PROJECT ANALYST: Celia C. Inman
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-10123-13 / Total Renal Care of North Carolina, LLC d/b/a New River Dialysis / Relocate 18 dialysis stations from Southeastern Dialysis Center to New River Dialysis, a new facility / 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 (TRCNC) d/b/a New River Dialysis proposes to establish a new 18-station Kidney Disease Treatment Center which will be certified as an end-stage renal disease (ESRD) facility to provide in-center hemodialysis and home training for peritoneal dialysis and home hemodialysis. The proposed facility will be located at 111 Yopp Road, Lot 18 in Jacksonville, Onslow County. The applicant proposes to relocate 18 existing dialysis stations from TRCNC d/b/a Southeastern Dialysis Center-Jacksonville (SEDC-Jacksonville) to establish New River Dialysis. Both facilities are located in Onslow County.

SEDC-Jacksonville is currently the only ESRD facility in Onslow County. The facility was certified for 42 stations effective December 20, 2012, following completion of Project I.D. #P-8804-12 which approved the addition of 4 stations. Upon the proposed relocation of 18 stations to New River Dialysis, SEDC-Jacksonville will have 24 remaining dialysis stations. It is TRCNC's intent to add stations at SEDC-Jacksonville based on the facility need methodology as stations are needed.

The proposed project will require the up-fit of a building shell, hiring and training of staff and the purchase of equipment needed to operate an ESRD facility. All home training services will be relocated from SEDC-Jacksonville to the New River Dialysis facility. The proposed project does not impact Onslow County's total inventory of dialysis stations.

This application proposes to relocate dialysis stations from SEDC-Jacksonville to a new Onslow County ESRD facility. Therefore, neither the county need nor the facility need methodologies in the 2013 SMFP are applicable to this review. Additionally, Policy GEN-3: BASIC PRINCIPLES is not applicable because neither need methodology is applicable to the review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable because the applicant is not proposing a capital expenditure greater than \$2 million.

However, Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS is applicable to this review. Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:

- (A) Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and*
- (B) Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.”*

In summary, the applicant proposes to relocate 18 certified dialysis stations within Onslow County, creating a new ESRD facility. The applicant states the project will enhance geographical accessibility of dialysis service for Onslow County patients. The project is scheduled for completion in January 2015. In this application, the applicant proposes to relocate dialysis stations between facilities within the county. Consequently, there is no change in dialysis station inventory in Onslow County. The application is consistent with Policy ESRD-2 in the 2013 SMFP. 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

The applicant, TRCNC d/b/a New River Dialysis proposes to relocate 18 dialysis stations from SEDC-Jacksonville to establish a new 18-station ESRD facility to provide in-center dialysis and home training for peritoneal and home hemodialysis in Onslow County. As of December 20, 2012, SEDC-Jacksonville has 42 certified dialysis stations. In Section III.3, page 19, the applicant states,

“Total Renal Care of North Carolina, LLC proposes to relocate eighteen dialysis stations from SEDC-Jacksonville to establish an eighteen-station New River Dialysis facility in Onslow County. We feel this will improve the accessibility of services for patients currently traveling from the southern portion of Jacksonville and the communities of Richlands and Sneads Ferry in Onslow County.”

Population to be Served

In Section 111.7, page 23, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2015		OPERATING YEAR 2 2016		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Onslow	61	31	65	35	95.8%	96.2%
Carteret	0	3	0	3	3.1%	2.9%
Jones	0	1	0	1	1.1%	0.9%
Total	61	35	65	39	100.0%	100.0%

Note: Based on the applicant’s methodology on pages 24-25, the total home-trained patients at the end of Operating Year 2 should be 38, not 39 as shown in the table above and the table on page 23 of the application. It appears the applicant may have rounded up on the patient origin; however the difference is not material.

In Section III, page 23, the applicant provides the following data to support the above projected patient origin:

- SEDC-Jacksonville had 142 in-center patients as of 6/30/2012.
- SEDC-Jacksonville does not have the capacity to add additional dialysis stations to the facility and does not have the property to expand the building.
- Many of the patients dialyzing at the SEDC-Jacksonville facility, which is located in zip code area 28546, live in the Richlands and Sneads Ferry zip code area 28540, which is where the proposed facility will be located.

- The development of a second facility in Jacksonville will provide patients who are admitted to SEDC-Jacksonville, living in the southern Onslow County, Richlands and Sneads Ferry communities easier access to dialysis services.
- Due to space limitations at SEDC-Jacksonville, TRCNC is proposing to move the home training program to New River Dialysis.

In Section III, page 23, the applicant states,

“Fifty-eight patients who currently get dialysis at SEDC-Jacksonville have signed letters of support for the proposed New River dialysis facility. All of the patients have indicated in their letters that they live closer to the proposed New River facility and that the facility will be more convenient for them.

Based on these letters, New River Dialysis will have at least 58 in-center ESRD patients dialyzing in the facility January 1, 2015, which we are projecting to be the beginning of the first year of operation. Those 58 patients are projected to transfer from SEDC-Jacksonville. The facility is projected to have 61 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the January 2013 Semiannual Dialysis report on the second page of Table B: ESRD dialysis Station Need Determination by Planning Area.”

Exhibit 14 contains letters from 61 SEDC-Jacksonville patients indicating a willingness to transfer to New River Dialysis for their dialysis treatments.

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

The applicant proposes to relocate 18 dialysis stations from an existing TRCNC Onslow County dialysis facility to develop a new TRCNC dialysis facility in the same county. In Section II, page 14, the applicant states that the relocation of the dialysis stations from SEDC-Jacksonville (the only existing dialysis facility in Onslow County) to New River Dialysis is needed to provide more convenient access to the dialysis patients living in the communities of Richlands and Sneads Ferry in the Onslow County zip code area 28540. On page 13, the applicant projects that the 18 stations to be relocated to New River Dialysis will be utilized at 84% of capacity by the end of the first year of operation following the relocation of the 18 stations (61 patients / (4 x 18) = 84) .

In Section III.3, pages 20-21, the applicant provides the assumptions and methodology it used to project the proposed in-center patient utilization of the existing SEDC-Jacksonville facility, before and after the proposed relocation of the 18 dialysis stations. The January 2013 Semiannual Dialysis Report (SDR) indicates that there were 142 ESRD in-center dialysis patients receiving their treatments at the SEDC-Jacksonville facility. As of June 30, 2012, the facility has 38 certified stations and 4 additional

approved stations pending certification. The facility utilization rate identified in the SDR was 93.42% ($142 / 38 = 3.74 / 4 = .9342$). The facility has since been certified for all 42 stations. See Exhibit 1.

On page 20, the applicant states,

“We are projecting that 58 current in-center patients from the SEDC-Jacksonville [sic] will transfer to New River Dialysis.

With 58 in-center patients and eighteen dialysis stations transferring from the SEDC-Jacksonville to New River Dialysis, this will leave 84 in-center patients and 24 dialysis stations at SEDC-Jacksonville if we do not take into consideration any patient growth between January 1, 2013 and when New River Dialysis is projected to be certified (January 1, 2015).

However, we want to be conservative and project the maximum growth that the population of SEDC-Jacksonville will experience because by doing this we will account for all of the potential growth of that population over the entire period from the data presented in the most recent Semiannual Dialysis Report through the point when the station transfer will occur and New River Dialysis opens. We have projected the growth of the entire current patient population at SEDC-Jacksonville by projecting the growth from the date of the most recent Southeastern Kidney Council data, which is June 30, 2012. ...”

The assumptions are summarized below:

- The January 2013 Semiannual Dialysis Report indicates that the five-year average change rate in Onslow County is 6.2%.
- In-center utilization on June 30, 2012 is 142 patients, as reported in the January 2013 SDR.
- Projected July 1, 2012-December 31, 2012 in-center dialysis patients = 142 in-center patients X 1.031(one-half Onslow County’s average annual growth rate (AAGR) for the six-month period) = 146.402
- Projected January 1, 2013-December 31, 2013 in-center dialysis patients = 146.402 in-center patients X 1.062 = 155.478.
- Projected January 1, 2014 - December 31, 2014 in-center dialysis patients = 155.478 in-center patients X 1.062 = 165.118.
- January 1, 2015 - December 31, 2015 is the first operating year.
- January 1, 2016 - December 31, 2016 is the second operating year.

In Section III.3, pages 20-21, the applicant states:

“Using the projections above, SEDC-Jacksonville would have 165 in-center patients at the point when New River Dialysis is projected to be certified on January 1, 2015. With 58 in-center patients and eighteen dialysis stations transferring from the SEDC-Jacksonville to New River Dialysis, this will leave 107 in-center patients ($165 - 58 = 107$) and 24 dialysis stations at SEDC-Jacksonville. Once the transfer takes place, using the numbers above, the SEDC-Jacksonville utilization rate would be 111%. However, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville will be applying for additional in-center stations as the patient census grows during the development of the New River facility. ... Therefore, based on the plan to apply for additional station [sic] once the SEDC-Jacksonville reaches or exceeds 80% utilization during the development of the Hampstead [sic] facility, the needs of the patients remaining at the SEDC-Jacksonville will be adequately met. Additional Certificate of Need application(s) will be submitted based on facility need at SEDC-Jacksonville until the facility reaches full capacity of stations.”

In Section II, pages 12-14, and in Section III.7, pages 23-24, the applicant provides the assumptions and methodology it uses to project the proposed in-center patient utilization of the new facility, as summarized below:

- The January 2013 Semiannual Dialysis Report indicates that the five-year average change rate in Onslow County is 6.2%.
- In-center utilization on January 1, 2015 begins with 58 transferred in-center patients.
- Projected December 31, 2015 in-center dialysis patients = 58 in-center patients X 1.062 = 61.596
- Projected December 31, 2016 in-center dialysis patients = 61.596 in-center patients X 1.062 = 65.415.
- January 1, 2015 - December 31, 2015 is the first operating year.
- January 1, 2016 - December 31, 2016 is the second operating year.

Applying the methodology and assumptions outlined by the applicant above results in the following table which projects in-center patients from July 1, 2012 through December 31, 2016 for the existing facility and the proposed facility:

	SEDC- Jacksonville (Existing)	New River Dialysis (Proposed)
TRCNC begins with the SEDC-Jacksonville 142 in-center hemo-dialysis patients as of June 30, 2012 and projects forward to the end of 2012 at .031(one half the AAGR).	$(142 \times .031) + 142 = 146.402$	
TRCNC projects the SEDC-Jacksonville in-center patients forward for 12 months to December 31, 2013, using the county AAGR of .062.	$(146.402 \times .062) + 146 = 155.479$	
TRCNC projects the SEDC-Jacksonville in-center patients forward for 12 months to December 31, 2014, using the county AAGR of .062.	$(155.479 \times .062) + 155 = 165$	
January 1, 2015 TRCNC relocates 18 stations and transfers 58 patients to New River Dialysis and projects forward for 12 months to December 31, 2015, using the county AAGR of .062	$(107 \times .062) + 107 = 113.634$	$(58 \times .062) + 58 = 61.596$
TRCNC projects the SEDC-Jacksonville in-center patients and New River Dialysis in-center patients forward for 12 months to December 31, 2016, using the county AAGR of .062.	$(113.634 \times .062) + 113 = 120.006$	$(61.596 \times .062) + 61 = 65.414$

The applicant applies the same methodology to project the home training and support program which will be relocated in its entirety to New River Dialysis. On page 24, the applicant states,

“Based on the home training patients [sic] census of 30 as of December 31, 2012, New River Dialysis will have at least 33 home-trained patients as of January 1, 2015, which we are projecting to be the beginning of the first year of operation. Those 33 patients are projected to transfer from SEDC-Jacksonville. The facility is projected to have 35 home-trained patients by the end of operating year one and 38 home-trained patients at the end of operating year two...”

The applicant projects home training patients as shown in the following table:

Home training patients census as of December 31, 2012	30
TRCNC projects the SEDC-Jacksonville home training patients forward for 12 months to December 31, 2013, using the county AAGR of .062.	$(30 \times .062) + 30 = 31.86$
TRCNC projects the SEDC-Jacksonville home training patients forward for 12 months to December 31, 2014, using the county AAGR of .062.	$(31.86 \times .032) + 31.86 = 33.83$
January 1, 2015 TRCNC relocates the home training program to New River Dialysis and projects forward for 12 months to December 31, 2015, using the county AAGR of .062	$(33.83 \times .062) + 33.83 = 35.93$
TRCNC projects the New River Dialysis home training patients forward for 12 months to December 31, 2016, using the county AAGR of .062	$(35.93 \times .062) + 35.93 = 38$

As previously stated, the applicant is not proposing to add stations based on county or facility need, but rather to create a new facility through the in-county relocation of existing stations from an existing facility.

The applicant adequately demonstrates the need the population proposed to be served has for the relocation of the eighteen dialysis stations from SEDC-Jacksonville to New River Dialysis.

Access to Services

In Section VI, page 34, the applicant states,

“New River Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic and socioeconomic situation.

...

New River Dialysis will 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.”

The applicant projects that 52.9% of its patients will be covered by Medicare, Medicaid or VA and another 38.6% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area 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.

C

The applicant, TRCNC d/b/a New River Dialysis proposes to relocate 18 dialysis stations from SEDC-Jacksonville to establish a new 18-station ESRD facility to provide in-center dialysis and home training for peritoneal and home hemodialysis in Onslow County. After the relocation of stations, SEDC-Jacksonville will have 24 ($42-18=24$) certified dialysis stations remaining.

Once the relocation of stations and transfer of patients takes place, the applicant projects that the SEDC Jacksonville utilization rate will be 111% ($165 \text{ patients} - 58 \text{ transferred to New River Dialysis} = 107 \text{ patients} / 24 \text{ stations} = 4.45 / 4 = 1.11$). In Section II.3(c), pages 20-21, the applicant states plans to increase the number of stations at SEDC-Jacksonville as the utilization increases. The applicant states:

“Once the transfer takes place, using the numbers above, the SEDC-Jacksonville utilization rate would be 111%. However, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville will be applying for additional in-center stations as the patient census grows during the development of the New River facility. ... Therefore, based on the plan to apply for additional station [sic] once the SEDC-Jacksonville reaches or exceeds 80% utilization during the development of the Hampstead [sic] facility, the needs of the patients remaining at the [sic] SEDC-Jacksonville will be adequately met. Additional Certificate of Need application(s) will be submitted based on facility need at SEDC-Jacksonville until the facility reaches full capacity of stations. ”

In Section III.7, page 24, the applicant states it is proposing to relocate the home training program currently located at the SEDC-Jacksonville facility to the proposed New River Dialysis. The applicant says the home training program at SEDC-Jacksonville lacks the necessary space for the continued operation of the training and support services and that moving the home training program to the new state-of-the-art facility will improve access to home training services for all its patients.

The city of Jacksonville is fairly central to Onslow County. The SEDC-Jacksonville facility is in the eastern part of Jacksonville in zip code area 28546. The proposed New River Dialysis facility is planned for the western part of Jacksonville in zip code area 28540. There are patients currently dialyzing at SEDC-Jacksonville who live in the western part of Onslow County, i.e. Richlands, Sneads Ferry and zip code area 28540, who will find the proposed New River facility some closer and more convenient as documented in the patient support letters found in Exhibit 14 of the application. However, both facilities are located in central Onslow County. Because of the facilities' locations, the home training services at the proposed New River facility will continue to be accessible to SEDC-Jacksonville patients and other Onslow County dialysis patients.

The applicant demonstrates that the needs of the population presently served at the SEDC-Jacksonville facility will continue to be adequately met following the proposed relocation of dialysis stations to New River Dialysis. See discussion in Criterion (13) with regard to access by medically underserved groups which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

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

CA

In Section III.9, pages 25-26, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – the applicant concludes that continuing to operate the SEDC-Jacksonville facility with all 42 Onslow County dialysis stations will not provide adequate access to dialysis services to the dialysis patients throughout Onslow County. On page 13, the applicant states the SEDC-Jacksonville physical facility cannot accommodate additional growth in capacity and the existing property will not accommodate expansion of the building.
- 2) Develop a new dialysis center in some other area of Onslow County – the applicant states that it analyzed where the SEDC-Jacksonville patients live by mapping their addresses on Google Maps and determined the communities of Richlands and Sneads Ferry in the Onslow County zip code of 28540 have more need for a dialysis center than any other area of the county at this time.
- 3) Chosen alternative – Develop a new dialysis facility in the Jacksonville zip code of 28540, where many of SEDC-Jacksonville patients live in

the Richlands and Sneads Ferry communities. On page 25, the applicant states,

“Total Renal Care of North Carolina, LLC studied appropriate alternatives to this application and concluded that developing a new facility in south Jacksonville is the best option. Total Renal Care of North Carolina, LLC serves a large number of patients who live in the Jacksonville 28540 zip code, the Richlands and Sneads Ferry communities. Dialysis can be a very time-consuming and physically demanding process and sometimes a difference of just a few minutes of travel time can make a significant difference to an individual patient. Fifty-eight patients at SEDC-Jacksonville have indicated an interest in considering transfer to our proposed facility because it will reduce their travel time and be more convenient. This could have a positive effect on their quality of life, and also on their ability and willingness to be more compliant with their treatment schedule.”

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- The SEDC-Jacksonville facility cannot accommodate future growth in capacity.
- Many SEDC-Jacksonville patients live closer to the proposed New River Dialysis location. Onslow County 2010 zip code population data supports the relocation of stations to zip code area 28540 from zip code area 28546.¹

Onslow Zip Code	2010 Population
28540	19,803
28546	16,963
28544	2,273
28547	1,437
28543	1,430

- Minimal capital will be required to upfit a shell building built by the developer. A centralized purchasing department will secure the dialysis chairs and TVs, negotiating the best product available at the best price.
- The facility will be a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in the identified service area.

¹ <http://www.city-data.com/zipmaps/Jacksonville-North-Carolina.html>

- A New River Dialysis Bio-medical Technician will conduct preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.
- Patients will not have to travel an unreasonable distance to dialyze.

Furthermore, the application is conforming or conditionally conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

Comments submitted regarding the proposed project included suggestions that the certification page of the application was improperly signed and that the applicant should have arranged for transplantation services with East Carolina University Medical Center instead of Carolinas Medical Center. The analyst determined that the certification page was properly signed pursuant to 10A NCAC 14C .0203(c) and that the applicant adequately demonstrated that transplantation services will be available pursuant to 10A NCAC 14C .2204(11).

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions and the condition in Criterion (14).

- 1. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall relocate and operate no more than a total of eighteen (18) certified dialysis stations which shall include any home hemodialysis training stations or isolation stations.**
- 3. After the certification of the eighteen (18) relocated dialysis stations at New River Dialysis, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Jacksonville shall take steps to decertify eighteen (18) dialysis stations for a total of no more than twenty-four (24) certified stations at Southeastern Dialysis Center-Jacksonville. Southeastern Dialysis Center-Jacksonville shall no longer provide training and support of peritoneal and home hemodialysis patients.**
- 4. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall install plumbing and electrical wiring through the walls for no more than eighteen (18) dialysis stations which shall include any home training or isolation stations.**

5. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis 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, page 42, the applicant states, “*The cost of establishing the dialysis center is estimated to be \$1,725,286.*” In the table in Section VIII, page 43, the applicant shows the capital cost of the project includes \$1,050,000 in construction costs and \$675,286 for architect/engineering fees, dialysis machines, water treatment equipment, dialysis chairs, a television system, patient computer system and other equipment and furniture.

In Section IX.3, page 46, the applicant projects that there will be start-up expenses of \$407,230 and estimated initial operating expenses of \$1,899,368 for a total working capital of \$2,306,598 associated with the proposed project.

Exhibit 19 contains a letter from the Chief Accounting Officer of DaVita Healthcare Partners Inc. (DaVita), who is also Chief Operating Officer for Total Renal Care, Inc., confirming DaVita’s commitment of cash reserves in the sum of \$4,031,884 for the capital and working capital needs of the project. DaVita’s Form 10-K in Exhibit 20 confirms the availability of said cash reserves on the consolidated balance sheet, page F-6.

Based on information provided by the applicant in Section X.1, page 48, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

Based on the calculations presented in Section X.3, page 49, the facility reimbursement is as follows:

SOURCE OF PAYMENT	REIMBURSEMENT PER TREATMENT
Medicare	\$192.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.² In Sections X.2-X.4, pages 48-51, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$ 4,490,032	\$ 4,777,402
Total Operating Costs	\$3,798,736	\$3,997,050
Net Profit	\$691,296	\$780,352

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant’s assumptions on number of treatments (3 days/week, 52 weeks/year with 5% missed treatments). On page 25, the applicant states,

“Note: The numbers of hemodialysis patients for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses. This will include the number of patients in the in-center and home training and support modalities.” [Emphasis in original]

The applicant’s projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. In Section VII.1, page 39 and Section X.5, page 51, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 41. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable

² http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Pro prospective_Payment_System_ICN905143.pdf

projections of revenues and operating costs. 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

TRCNC d/b/a New River Dialysis proposes to relocate 18 in-center dialysis stations from SEDC-Jacksonville to create a new 18 station dialysis facility in the southwestern portion of Jacksonville. Exhibit 1 provides documentation of the certification of the four additional dialysis stations at SEDC-Jacksonville approved in Project I.D.# P-8804-12. The applicant says SEDC-Jacksonville is currently serving 142 patients weekly at 3.38 patients per station, which is 84.5% of capacity ($142/(4*42) = .8452$). Dialysis facilities that operate four shifts per week (2 / day on alternate days) have a capacity of four patients per station. After the relocation of the 18 stations in January of 2015, 24 certified stations will remain at the SEDC-Jacksonville facility. The applicant also proposes to relocate the home-training program to the New River Dialysis facility. The applicant discusses projections for the in-center patient population on pages 12-16 of the application and projections for home-training on pages 24-25. At the end of Operating Year Two, with 18 dialysis stations and 64 dialysis patients, the applicant projects New River Dialysis utilization will be 3.5 in-center patients per station ($64 \text{ patients} / 18 \text{ dialysis stations} = 3.55$). The applicant projects 38 patients in the home training program at New River Dialysis by the end of year two.

With the relocation of the 18 stations, SEDC-Jacksonville's dialysis station inventory will be reduced to 24 stations. With 107 patients and 24 stations at January 1, 2015, SEDC-Jacksonville's utilization will be at 4 patients per station, triggering the need for additional stations based on the facility need methodology. The applicant states its intent to apply for additional stations at SEDC-Jacksonville as facility utilization dictates a need. The growth projections are based on Onslow County's projected five-year average annual growth rate in the number of dialysis patients.

The applicant adequately demonstrates the need to relocate 18 dialysis stations to create New River Dialysis based on the inability to physically expand SEDC-Jacksonville and the projected number of in-center patients to be served at both facilities. The total number of dialysis stations in Onslow County will not change as a result of this project. 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

The following table illustrates the projected staffing for New River Dialysis, as provided by the applicant in Section VII.1, page 39.

Position	Total FTE Positions
RN	4
HTRN	4
PCT	9
Bio-Med Tech	0.5
MD	
Admin	1
Dietician	1
Social Worker	1
Unit Secretary	2
Other-Reuse	1
Total	23.5

As shown in the above table, the applicant proposes to employ a total of 23.5 full-time equivalent (FTE) positions to staff the New River Dialysis facility upon completion of the proposed project. In Section VII.1, page 40, the applicant states,

“The Regional Operations Director is responsible for the overall operation of the facility and serves as liaison to the governing body. He is also responsible for ensuring compliance with 42 C.F.R. and budgetary compliance.

...

The UA [unit administrator] is responsible for the quality dialysis care for all patients in the facility on a daily basis through planning and staff scheduling. ... The UA also ensures that direct patient care is provided. The UA also supervises orientation and training of new teammates and ensures that teammates adhere to facility policies and procedures”

The following table shows the projected number of direct care staff for each shift offered in the New River Dialysis facility after the relocation of the 18 stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	5	5	5	5	5	5
Afternoon	11am to 4pm	5	5	5	5	5	5
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 31, the applicant states that Dr. George Thomas, of Southeastern Nephrology Associates, will serve as Medical Director of the proposed facility. Exhibit 13 contains a letter signed by Dr. Thomas, expressing support for the relocation of 18 dialysis stations and the home training program to New River Dialysis, and agreeing to be the Medical Director for the new facility. In Section VII.2, page 40, the applicant states Dr. George Thomas is board-certified in Nephrology with several years of experience in the care of ESRD patients.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 29, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by Onslow Memorial Hospital. Exhibit 8 contains a letter from the CEO of Onslow Memorial Hospital agreeing to enter into a transfer agreement to provide New River Dialysis patients with the above services. Carolinas Medical Center provides a letter in Exhibit 9 agreeing to enter into a Transplant Agreement with New River Dialysis. Exhibit 14 contains letters of support from area healthcare providers and the local community. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

The applicant proposes to construct a 9,448 square foot dialysis facility, with 158 square feet per dialysis station. In section VIII.1, page 43, the applicant provides a cost breakdown showing construction costs of \$1,050,000 and \$60,000 in architect and engineering fees. In Section XI.6 (d), page 56, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

- (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(a), page 34, the applicant states TRCNC d/b/a New River Dialysis will utilize a policy of making dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 34, the applicant reports that 83.7% of the patients who received treatments at TRCNC d/b/a SEDC-Jacksonville had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

SEDC-JACKSONVILLE PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	11.8%
Medicaid	9.1%
Medicare/Medicaid	24.2%
Commercial Insurance	8.5%
VA	7.8%
Medicare/Commercial	38.6%
Total	100.0%

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.

	2011 Total # of Medicaid Eligibles as % of Total Population *	2011 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
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 services offered by dialysis facilities. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.³

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 are 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 do 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 the 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.”⁴

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

³ Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

⁴ <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”⁵

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

ESRD Spending by Payor⁶		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below:

⁵ United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:
http://www.usrds.org/2012/pdf/v2_ch1_12.pdf.

⁶ United States Renal Data System 2012 USRDS Report, Chapter 11, page 340:
http://www.usrds.org/2012/pdf/v2_ch11_12.pdf

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

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.⁷

TRCNC demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(f), page 36, the applicant states,

“New River Dialysis will have no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. New River Dialysis will have no obligation under the Hill Burton Act.”

⁷Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

In Section VI.6 (a), page 38, the applicant states, “*There have been no civil rights 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 35, the applicant provides the projected payor mix for the proposed services at the new facility as follows:

NEW RIVER DIALYSIS PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	11.8%
Medicaid	9.1%
Medicare/Medicaid	24.2%
Commercial Insurance	8.5%
VA	7.8%
Medicare/Commercial	38.6%
Total	100.0%

The applicant projects no change in the projected New River Dialysis payor mix from the current payor mix for SEDC-Jacksonville dialysis visits as stated in Criterion (13a) above.

In Section VI.1(a), page 34, the applicant states,

“New River Dialysis will 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.”

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

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

C

In Section VI.5, page 37, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at New River Dialysis. New Rover Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Onslow, Pender, Duplin and New Hanover Counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise **Exhibit 15**. [Emphasis in original.] The patient, again, will be referred to a qualified Nephrologist for final evaluation and then admission based on a doctor’s orders.”*

The applicant adequately demonstrates that it provides a range of means by which a person can access the proposed 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.3, page 31, the applicant states,

“New River Dialysis will be offered as a clinical learning site for nursing students at the local community college. ... New River Dialysis will be open to developing relationships with any program that offers clinical training programs.”

The applicant further states that Exhibit 12 contains a letter from the facility administrator at SEDC-Jacksonville indicating New River Dialysis’ interest in establishing a relationship with the Coastal Carolina Community College. The letter is not included in Exhibit 12. However, the information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion, subject to the following condition.

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall provide the CON Section with a copy of the letter sent to Coastal Carolina Community College indicating an interest in establishing a training program relationship at New River Dialysis.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 18-station dialysis facility in Jacksonville, Onslow County by relocating 18 existing dialysis stations from SEDC-Jacksonville to New River Dialysis. SEDC-Jacksonville, with 42 certified dialysis stations as of December 20, 2012, is currently the only dialysis facility in Onslow County. See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 32-33, in which the applicant discusses the impact of the project on competition as it relates to promoting cost-effectiveness, quality and access. On page 33, the applicant states,

“The development of this facility will have no impact on the other outpatient dialysis facility, SEDC-Jacksonville. Total Renal Care of North Carolina, LLC operates SEDC-Jacksonville. There are four counties contiguous to Onslow County. In two of the counties, Total Renal Care of North Carolina, LLC operates facilities. They are Pender County (SEDC-Burgaw) and Duplin County [sic]SEDC-Kenansville and Wallace Dialysis Center).

Fresenius Medical Care operates facilities in Carteret County (BMA Crystal Coast), Jones County (FMC of Jones County) and Duplin County (Warsaw Dialysis). None of these facilities are in close proximity of the proposed New River Dialysis.”

The applicant further states that relocating the stations and transferring existing patients will provide dialysis services closer to where many of the SEDC-Jacksonville patients live, and closer to an area of Jacksonville where a large concentration of dialysis patients live. The applicant states,

“The growth projections for SEDC-Jacksonville are based on that existing patient population. Therefore, our projections for the proposed New River Dialysis facility do not depend on any change in existing referral patterns.”

...

For these reasons, we do not believe that this new facility will have an impact on any Fresenius facility located in contiguous counties. New River Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”

The information provided by the applicant in the sections above is reasonable and credible and adequately demonstrates that relocating existing dialysis stations from SEDC-Jacksonville to New River Dialysis will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services because:

- The applicant adequately demonstrates the need to relocate 18 dialysis stations from SEDC-Jacksonville to New River Dialysis to provide better access to services for Onslow County dialysis patients;
- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide better access to patients in Onslow County;
- The applicant adequately demonstrates it will provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V and VII, pages 29-32 and 39-41 respectively, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care; and
- The applicant demonstrates it will provide adequate access to medically underserved populations (more than 80% are Medicare or Medicaid patients).

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

TRCNC currently provides dialysis services at SEDC-Jacksonville. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the SEDC-Jacksonville facility operated in compliance with the 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.

G.S. 131E-183(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.2202 INFORMATION REQUIRED OF APPLICANT

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

- (1) *Utilization rates;*

- C- In Section II.1, page 10, the applicant states the utilization rate is reported in the January 2013 SDR provided in Exhibit 7. The January 2013 SDR utilization rate of 93.42% was calculated based on 142 in-center dialysis patients and 38 certified dialysis stations as of June 30, 2012 (142 patients / 38 stations = 3.74 patients per station; 3.74 patients per station / 4.00 patients per station = 93.42%). SEDC-Jacksonville had four approved dialysis stations pending certification as of June 30, 2012. These dialysis stations have since been certified

for a SECD-Jacksonville total of 42 certified stations and a utilization rate of 85% ($142/42 = 3.38/4 = 84.5\%$). See Exhibit 1.

(2) *Mortality rates;*

-C- In Section IV.2, page 27, the applicant reports the 2010, 2011 and 2012 facility mortality rates as 17.3%, 12.7% and 15.7%, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 27, the applicant states, “*Southeastern Dialysis Center-Jacksonville had 22 peritoneal dialysis and 8 home hemodialysis patients as of December 31, 2012.*”

(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 27, the applicant states, “*SEDC-Jacksonville had seven patients receive transplants in 2012. Thirty-four patients were referred for transplant evaluation in 2012.*”

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 28, the applicant states, “*SEDC-Jacksonville has eighteen patients on the transplant waiting list.*”

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section IV.6, page 28, the applicant states that there were 233 hospital admissions in 2012 for SEDC-Jacksonville, 45 (19.3%) of which were dialysis related and 188 (80.7%) 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 28, the applicant states that there were three patients dialyzing at SEDC-Jacksonville with AIDS and one patient with Hepatitis B, as of December 31, 2012. The number of patients treated with infectious disease who have converted to infectious status within the last year is zero. The patient with Hepatitis B utilizes the isolation station for dialysis treatments.

(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.*
- C- Exhibit 8 contains a signed letter of intent from Onslow Memorial Hospital agreeing to enter into a Patient Transfer Agreement with New River Dialysis and to provide the following services to patients receiving their dialysis treatments at New River Dialysis:
- Acute Dialysis
 - Emergency Room Care
 - Diagnostic Evaluation Services
 - X-ray Services
 - Special, Immunological and Routine Laboratory Services
 - Blood Banking Services
 - Surgical Services including Vascular Surgery
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- Exhibit 9 contains a letter from Carolina Medical Center agreeing to enter into a Transplant Agreement for New River Dialysis including the components identified above.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibit 22 provides site specific documentation of the availability of power and water from the City of Jacksonville, Progress Energy and Piedmont Natural Gas.

- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 10, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- The applicant provides written documentation of availability and commitment to pursue acquiring the proposed primary and/or secondary site in Exhibit 22.
- (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 56, the applicant states, “*New River Dialysis will operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*”
- The applicant states that New River Dialysis will acquire and maintain Medicare Certification. See Exhibit 25 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 26 for the In-Service Calendar with mandatory training classes.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- The applicant provides the following projected patient origin on page 23 of the application, as shown below.

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2015		OPERATING YEAR 2 2016		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Onslow	61	31	65	35	95.8%	96.2%
Carteret	0	3	0	3	3.1%	2.9%
Jones	0	1	0	1	1.1%	0.9%
Total	61	35	65	39	100.0%	100.0%

Note: Based on the applicant’s methodology on pages 24-25, the total home-trained patients at the end of Operating Year 2 should be 38, not 39 as shown in the table above and the table on

page 23 of the application. It appears the applicant may have rounded up on the patient origin; however the difference is not material.

See Section III.7, pages 23–25 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin 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.*

-C- In Section III.8, page 25, the applicant states, “100% of the patients that [sic] will travel less than 30 miles one way for dialysis treatments.”

Mapquest confirms the applicant’s statement. The proposed facility, which will be located in zip code area 28540, where a large number of SEDC-Jacksonville dialysis patients live, is only six miles and a ten minute drive from SEDC-Jacksonville. Based on population data for Onslow County, zip code area 28540 has the highest population of any zip code area in Onslow County.⁸

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

-C- In Section II. 1, page 12, the applicant states,

“Total Renal Care of North Carolina, LLC d/b/a New River Dialysis 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.”

.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.*

-C- The applicant proposes to establish New River Dialysis, a new ESRD facility, with the relocation of 18 stations. In Section II, page 13, the applicant states that it anticipates 61 in-center patients and 3.3 patients per station per week at the end of

⁸ <http://www.city-data.com/zipmaps/Jacksonville-North-Carolina.html>

operating year one, based on the methodology and assumptions found on pages 12-13 of the application.

(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.*

-NA- New River Dialysis is proposing to develop a new ESRD facility through the relocation of existing Onslow County dialysis stations.

.2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- The table in Section V.1, page 29, states patients will be referred to Onslow Memorial Hospital for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 29, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

-C- The table in Section V.1, page 29, states the applicant will provide in-center hemodialysis self-care training, intermittent peritoneal dialysis, CAPD and CCPD.

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

-C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 30, stating,

“New River Dialysis will provide protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient’s blood chemistries are sent to a Medicare certified

laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”

The home training program currently located at SEDC-Jacksonville will be relocated to New River Dialysis.

(5) *x-ray services;*

-C- The table in Section V.1, page 29, states patients will be referred to Onslow Memorial Hospital for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 29, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) *blood bank services;*

-C- The table in Section V.1, page 29, states patients will be referred to Onslow Memorial Hospital for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 29, states patients will be referred to Onslow Memorial Hospital for emergency care.

(9) *acute dialysis in an acute care setting;*

-C- The table in Section V.1, page 29, states patients will be referred to Onslow Memorial Hospital for acute dialysis in an acute care setting. See Exhibit 8 for a copy of the hospital's letter of intent to enter into a patient transfer agreement with New River Dialysis.

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

-C- The table in Section V.1, page 29, states dialysis patients will be referred to Onslow Memorial Hospital for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 2, states patients will be referred to Carolinas Medical Center for transplantation services. See Exhibit 9 for documentation from Carolinas Medical Center.

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

-C- The table in Section V.1, page 29, states patients will be referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 29, states patients will be referred to Onslow United Transit System for transportation.

.2205 STAFFING AND STAFF TRAINING

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

-C- In Section VII.1, page 39, the applicant provides the proposed staffing for New River Dialysis. The applicant states, *“The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.”* New River Dialysis plans for two dialysis shifts; direct care staffing of 5.0 FTE per shift on Monday through Saturday as noted in response to VII.10.

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

-C- In Section VII.5, page 41, the applicant refers to Exhibit 18 for a copy of the training program description/outline. Exhibit 18 contains a copy of DaVita’s Training Programs for New Patient Care Provider. Exhibit 26 contains the New River Dialysis Annual In-Service Calendar.