

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming  
CA = Conditional  
NC = Nonconforming  
NA = Not Applicable

Decision Date: May 24, 2017

Findings Date: May 24, 2017

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: P-11325-17

Facility: New River Dialysis

FID #: 130178

County: Onslow

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 20 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 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 (TRC-NC) d/b/a New River Dialysis (New River) proposes to add two dialysis stations for a total of 20 certified dialysis stations upon project completion.

#### **Need Determination**

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Onslow County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis

center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for New River in the January 2017 SDR is 3.5 patients per station per week, or 87.5 percent ( $3.5 / 4 \text{ patients per station} = 0.875$ ). This utilization rate was calculated based on 63 in-center dialysis patients and 18 certified dialysis stations ( $63 \text{ patients} / 18 \text{ stations} = 3.5 \text{ patients per station per week}$ ).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

<b>APRIL 1 REVIEW – JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		87.5%
Certified Stations		18
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>18</b>
In-Center Patients as of 6/30/16 (January 2017 SDR) (SDR2)		63
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR1)		46
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	17
(i)	Multiply the difference by 2 for the projected net in-center change	34
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.7391
(ii)	Divide the result of Step (i) by 12	0.0616
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.3696
(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	86.2826
(v)	Divide the result of Step (iv) by 3.2 patients per station and subtract the number of certified and pending stations to determine the number of stations needed	26.9633
		<b>9</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is nine stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

### Policies

**Policy GEN-3: Basic Principles** on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical*

*Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 9-10, Section O, page 53, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, page 10, Section C, page 16, Section L, pages 46-50, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, page 11, Section C, pages 13-19, Section N, page 52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

### Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women,

handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, TRC-NC, proposes to add two stations to the existing New River facility for a total of 20 stations upon project completion.

**Patient Origin**

On page 373, the 2017 SMFP defines the service area for dialysis stations as the “*planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Onslow County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 20, the applicant provides the historical patient origin by county for New River, as shown in the table below.

<b>New River – Historical Patient Origin by County – June 30, 2016</b>			
<b>County</b>	<b># In-Center Patients</b>	<b># HH* Patients</b>	<b># PD** Patients</b>
Onslow	51	3	20
Duplin	6	0	2
Jones	1	0	1
Pender	4	0	1
Other States	1	0	0
<b>Totals</b>	<b>63</b>	<b>3</b>	<b>24</b>

\*HH = Home Hemodialysis

\*\*PD = Peritoneal Dialysis

In Section C.1, page 13, the applicant provides the projected patient origin for New River for in-center, home hemodialysis (HH), and peritoneal dialysis (PD) patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

<b>New River – Projected Patient Origin – CYs 2019 &amp; 2020</b>								
<b>County</b>	<b>OY 1 – CY 2019 # of Patients by Type</b>			<b>OY 2 – CY 2020 # of Patients by Type</b>			<b>County Patients as % of Total</b>	
	<b># IC</b>	<b># HH</b>	<b># PD</b>	<b># IC</b>	<b># HH</b>	<b># PD</b>	<b>OY1</b>	<b>OY2</b>
Onslow	54	7	24	56	8	25	84.2%	84.8%
Duplin	6	0	2	6	0	2	7.9%	7.6%
Jones	1	0	1	1	0	1	2.0%	1.9%
Pender	4	0	1	4	0	1	5.0%	4.8%
Other States	1	0	0	1	0	0	1.0%	1.0%
<b>Total</b>	<b>66</b>	<b>7</b>	<b>28</b>	<b>68</b>	<b>8</b>	<b>29</b>	<b>100.0%</b>	<b>100.0%</b>

In Section C.1, pages 13-15, the applicant provides the assumptions and data utilized to project patient origin.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 16, the applicant states the need for the proposed project is based on the continued growth of the patient population at New River. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section B.2, pages 6-7.

**Projected Utilization – In-Center Patients**

In Section C.1, page 13, the applicant provides the projected patient origin for New River for in-center patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

<b>New River – Projected Patient Origin – CYs 2019 &amp; 2020</b>								
<b>County</b>	<b>OY 1 – CY 2019 # of Patients by Type</b>			<b>OY 2 – CY 2020 # of Patients by Type</b>			<b>County Patients as % of Total</b>	
	<b># IC</b>	<b># HH</b>	<b># PD</b>	<b># IC</b>	<b># HH</b>	<b># PD</b>	<b>OY1</b>	<b>OY2</b>
Onslow	54	7	24	56	8	25	84.2%	84.8%
Duplin	6	0	2	6	0	2	7.9%	7.6%
Jones	1	0	1	1	0	1	2.0%	1.9%
Pender	4	0	1	4	0	1	5.0%	4.8%
Other States	1	0	0	1	0	0	1.0%	1.0%
<b>Total</b>	<b>66</b>	<b>7</b>	<b>28</b>	<b>68</b>	<b>8</b>	<b>29</b>	<b>100.0%</b>	<b>100.0%</b>

In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- The Onslow County patient population will grow at a rate of 2.1 percent (the Five Year Average Annual Change Rate [AACR] for Onslow County, as published in the January 2017 SDR), through the end of the second year of operation.
- The applicant assumes no increase for the patients who utilize the facility and live outside of Onslow County, but assumes that those patients will continue to dialyze at New River and are added to the calculations when appropriate.
- The project is scheduled for completion on January 1, 2019. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

<b>New River</b>	
TRC-NC begins with the Onslow County ESRD patient population of New River as of June 30, 2016.	51
TRC-NC projects the Onslow County population forward six months to December 31, 2016, applying the projected AACR of 2.1 percent to a six month period.	$51 \times 1.0105 = 51.536$
TRC-NC projects this population forward 12 months to December 31, 2017, applying the projected AACR of 2.1 percent.	$51.536 \times 1.021 = 52.618$
TRC-NC projects the Onslow County population forward 12 months to December 31, 2018, applying the projected AACR of 2.1 percent.	$52.618 \times 1.021 = 53.723$
TRC-NC adds the 12 patients from other counties to obtain the starting census for January 1, 2019, the date the stations at New River are projected to be certified.	$53.723 + 12 = 65.723$
TRC-NC projects the Onslow County population forward 12 months to December 31, 2019, applying the projected AACR of 2.1 percent.	$53.723 \times 1.021 = 54.851$
TRC-NC adds the 12 patients from other counties to obtain the ending census for December 31, 2019 (end of OY 1).	$54.851 + 12 = 66.851$
TRC-NC projects the Onslow County population forward 12 months to December 31, 2020, applying the projected five year AACR of 2.1 percent.	$54.851 \times 1.021 = 56.003$
TRC-NC adds the 12 patients from other counties to obtain the ending census for December 31, 2020 (end of OY 2).	$56.003 + 12 = 68.003$

The applicant projects to serve 66 in-center patients on 20 stations, which is 3.3 patients per station per week ( $66 \text{ patients} / 20 \text{ stations} = 3.3$ ), by the end of OY 1 and 68 in-center patients on 20 stations, which is 3.4 patients per station per week ( $68 \text{ patients} / 20 \text{ stations} = 3.4$ ), by the end of OY 2. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis Utilization

The applicant currently provides HH and PD treatment. In Section C.8, page 20, the applicant provides historical utilization for HH and PD. In Section C.1, pages 14-15, the applicant provides the projected utilization for HH and PD and the assumptions and methodology used to project utilization.

Projected utilization for HH, PD, and in-center dialysis are based on reasonable and adequately supported assumptions regarding continued growth.

### Access

In Section L.1(a), pages 46-47, the applicant states that New River, by policy, will make services available to all residents of its service area without qualifications and will “...serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.” On page 47, the applicant projects the payor mix for the second operating year of the project, and it projects that 88.9 percent of projected patients will have some or all of their services paid for by Medicare or Medicaid. The applicant states that the projected payor mix is based on the historical payor mix over the last full operating year. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed dialysis stations, and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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 E.1, page 24, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that this option was not considered because of the continued growth rate of the population at the facility. Additionally, the applicant states that it could create the need for a third shift which is inconvenient to patients or may end up eliminating patient choice. Therefore, this is not an effective alternative.
- Relocate Stations From Another TRC-NC Facility – the applicant states that the other TRC-NC facility in Onslow County is also operating at greater than 80 percent capacity. Relocating stations from that facility would negatively impact the patients receiving services there. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that given the patient population growth at New River and the patient population utilizing the other TRC-NC facility in Onslow County, the proposed project is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that this 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:

- 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 except as modified by the conditions of approval.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall develop and operate no more than two additional dialysis stations at New River Dialysis for a total of no more than 20 certified dialysis stations, which shall include any isolation or home hemodialysis training stations, upon project completion.**
  - 3. 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 two additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
  - 4. 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 Agency 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

The applicant, TRC-NC, proposes to add two stations to the existing New River facility for a total of 20 stations upon project completion.

**Capital and Working Capital Costs**

In Section F.1, page 25, the applicant projects \$32,258 in capital costs, including \$27,500 for dialysis machines and \$4,758 for other equipment and furniture. In Section F.10, page 28, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.



### **Availability of Funds**

In Section F.2, page 26, the applicant states it will finance the capital costs and working capital costs with accumulated reserves. Exhibit F-5 contains a letter dated March 14, 2017, from the Chief Accounting Officer of DaVita, Inc., the parent company of TRC-NC, authorizing and committing \$32,258 in capital costs for the project.

Exhibit F-7 contains the Consolidated Financial Statements for DaVita Healthcare Partners, Inc. for the year ending December 31, 2016. These statements indicate that as of December 31, 2016, it had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>New River</b>	<b>Operating Year 1 CY 2019</b>	<b>Operating Year 2 CY 2020</b>
Total Treatments	14,740	15,258
Total Gross Revenues (Charges)	\$4,200,944	\$4,385,894
Total Net Revenue	\$4,045,891	\$4,226,925
Total Operating Expenses (Costs)	\$3,357,643	\$3,475,896
<b>Net Income</b>	<b>\$688,248</b>	<b>\$751,029</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

### **Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the project 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

The applicant, TRC-NC, proposes to add two stations to the existing New River facility for a total of 20 stations upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis stations as the “*planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Onslow County. Facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis facilities in Onslow County. The Onslow County dialysis facilities are shown below:

<b>Onslow County Dialysis Facilities as of June 30, 2016</b>				
<b>Dialysis Facility</b>	<b>Certified Stations</b>	<b>CON Issued Not Certified</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
SEDC – Jacksonville	25	5	96.0%	3.84
New River Dialysis	18	0	87.5%	3.50

Source: Table A, January 2017 SDR.

As shown in the table above, both operational facilities in Onslow County were operating at a capacity of greater than 80 percent (3.2 patients per station) as of June 30, 2016.

In Section C, pages 13-15, the applicant demonstrates that New River will serve a total of 66 patients at the end of OY 1 for a utilization rate of 82.5 percent or 3.3 patients per station (66 patients / 20 stations = 3.3;  $3.3 / 4 = .825$  or 82.5%). The projected utilization of 3.3 patients per station per week for Operating Year One meets the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add two additional stations at New River based on the number of patients it projects to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis services in Onslow County. Consequently, the application is conforming to this criterion.

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

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In Section H.1, page 32, the applicant provides current and projected staffing for New River, which includes 18 full-time equivalent (FTE) employee positions, summarized as follows:

<b>New River Current and Projected Staffing</b>			
<b>Position</b>	<b>Current # FTEs</b>	<b># FTEs Positions added/deleted</b>	<b>Projected # FTEs</b>
Registered Nurse	3.0	0.0	3.0
Technician (PCT)	7.0	1.0	8.0
Administrator	1.0	0.0	1.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Home Training RN	2.0	0.0	2.0
Admin. Assistant	1.0	0.0	1.0
Biomed Tech	1.0	0.0	1.0
<b>Total</b>	<b>17.0</b>	<b>1.0</b>	<b>18.0</b>

**Note:** The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, pages 33-34, along with Exhibit H-3, the applicant describes its experience and process for recruiting and retaining staff. Section H.7, page 35, contains the applicant's projected direct care staffing hours for the second operating year following project completion.

In Section H.2, the applicant identifies Dr. George Thomas as the Medical Director of New River. Exhibit I-3 contains a copy of a letter dated February 15, 2017 from Dr. George Thomas supporting the proposed expansion of New River and agreeing to continue to serve as the Medical Director.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, 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.

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In Section I.1, page 36, the applicant includes a list of providers of the necessary ancillary and support services and indicates how they are or will be made available. Exhibit I-3 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 37-38. Exhibit I-1 contains copies of agreements for laboratory services and a letter from the facility administrator describing the additional provisions for ancillary and support services. The information in Section I.1 and Exhibit I-3 is reasonable and adequately supports a finding of conformity with this criterion.

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

NA

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

NA

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

NA

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

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In Section L.1, pages 46-47, the applicant lists the ways TRC-NC helps provide access to dialysis services for the underserved populations of North Carolina and states its policy to

provide services to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and any other underserved group. In addition, the applicant describes its admission and financial policies in Section L.3, pages 47-49, and provides a copy of its admission policy in Exhibit L-3.

In Section L.7, page 47, the applicant provides the historical payor mix for New River, as shown below:

<b>New River Historical Payor Mix – CY 2016</b>				
<b>Payor Type</b>	<b>% of Total Patients</b>	<b>% of IC Patients</b>	<b>% of HH Patients</b>	<b>% of PD Patients</b>
Medicare	24.4%	28.4%	0.0%	15.0%
Medicaid	1.1%	1.5%	0.0%	0.0%
Commercial Insurance	4.4%	3.0%	33.3%	5.0%
Medicare/Commercial	37.8%	35.7%	0.0%	50.0%
Medicare/Medicaid	25.6%	23.9%	66.7%	25.0%
VA	6.7%	7.5%	0.0%	5.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

As illustrated in the tables above, 88.9 percent of New River patients had some or all of their services paid for by Medicare and/or Medicaid.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Onslow	8%	45%	33%	14%	11%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, [2014 Estimate as of December 22, 2015](http://www.census.gov/quickfacts/table).

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28<sup>1</sup>. The ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions’ Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015

<sup>1</sup>[http://esrd.ipro.org/wp-content/uploads/2016/11/2015\\_NW-6\\_Annual-Report\\_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf](http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf)

Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>2</sup> percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender – 2014 and 2015</b>						
	<b>2014 Patients and Percentages*</b>				<b>2015 Patients and Percentages**</b>	
	<b>NC Patients</b>	<b>NC Percentage</b>	<b>Total Network 6 Patients</b>	<b>Total Network 6 Percentage</b>	<b>Total Network 6 Patients</b>	<b>Total Network 6 Percentage</b>
<b>Age</b>						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
<b>Gender</b>						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
<b>Race</b>						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

\*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

\*\*2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at [http://esrd.ipro.org/wp-content/uploads/2016/11/2015\\_NW-6\\_Annual-Report\\_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf](http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf)

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

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

<sup>2</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

- (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 L.3(d), page 49, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service except those federal requirements of the Rehabilitation Act of 1973 and subsequent amendments. The applicant states that the facility has no Hill-Burton obligations.

In Section L.6, pages 49-50, the applicant states there have been no civil rights complaints filed against any TRC-NC facilities in North Carolina within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 47, the applicant provides the projected payor mix for the proposed project for the second operating year (CY 2020). The applicant states on page 47 that the projected payor mix for New River is based on the sources of payment received by the existing facility during the last full operating year. The projected payor mix is illustrated as follows:

<b>New River Projected Payor Mix – OY 2 (CY 2020)</b>				
<b>Payor Type</b>	<b>% of Total Patients</b>	<b>% of IC Patients</b>	<b>% of HH Patients</b>	<b>% of PD Patients</b>
Medicare	24.4%	28.4%	0.0%	15.0%
Medicaid	1.1%	1.5%	0.0%	0.0%
Commercial Insurance	4.4%	3.0%	33.3%	5.0%
Medicare/Commercial	37.8%	35.7%	0.0%	50.0%
Medicare/Medicaid	25.6%	23.9%	66.7%	25.0%
VA	6.7%	7.5%	0.0%	5.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

As illustrated in the table above, the applicant projects that 88.9 percent of all of the patients receiving dialysis services at New River in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at New River. 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 L.4, page 49, the applicant describes the range of means by which a person will have access to the dialysis services at New River. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from patients themselves, family, or friends. In Exhibit I-3, the applicant provides a letter signed by Dr. George Thomas, indicating his willingness to serve as Medical Director. Exhibit I-3 also contains letters of support from local nephrologists who state they plan to refer patients to New River. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 51, the applicant states it has offered the facility as a clinical learning site to nursing students at Coastal Carolina Community College. Exhibit M-2 contains a letter from the applicant to Coastal Carolina Community College's president, inviting the school to use the facility for clinical rotations for nursing students at its facility. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

C

The applicant, TRC-NC, proposes to add two stations to the existing New River facility for a total of 20 stations upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis stations as the "*planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*" Thus, the service area is Onslow County. Facilities may serve residents of counties not included in their service area.



The applicant operates two dialysis facilities in Onslow County. The Onslow County dialysis facilities are shown below:

<b>Onslow County Dialysis Facilities as of June 30, 2016</b>				
<b>Dialysis Facility</b>	<b>Certified Stations</b>	<b>CON Issued Not Certified</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
SEDC – Jacksonville	25	5	96.0%	3.84
New River Dialysis	18	0	87.5%	3.50

Source: Table A, January 2017 SDR.

As shown in the table above, both operational facilities in Onslow County were operating at a capacity of greater than 80 percent (3.2 patients per station) as of June 30, 2016.

In Section N, page 52, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

*“The expansion of New River Dialysis will have no effect on competition in Onslow County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC.*

*The expansion of 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.”*

See also Sections B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

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

- The applicant adequately demonstrates the need for the proposed dialysis stations and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that New River will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicant demonstrates that New River will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3), and (13) are incorporated herein by reference.

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

In Exhibit O-3, the applicant identifies four of its 70+ North Carolina facilities (Southeastern Dialysis Center – Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West Dialysis) as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all four facilities are back in full compliance with CMS Guidelines as of the date of submission of this application and provides copies of letters to each facility from the Agency’s Acute and Home Care Licensure and Certification Section that state each facility is back in compliance. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 application is conforming to all applicable criteria, as discussed below.

#### **10 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- New River is an existing 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- In Section C.1, pages 13-15, the applicant adequately demonstrates that New River will serve at least 66 patients on 20 dialysis stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5 percent ( $66 / 20 = 3.3$ ;  $3.3 / 4 = 0.825$  or 82.5%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.