

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

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

Decision Date: January 27, 2017

Findings Date: January 27, 2017

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: A-11258-16

Facility: Waynesville Dialysis Center

FID #: 010800

County: Haywood

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 1 dialysis station for a total of 19 certified dialysis stations upon project completion

### 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 (TRC) d/b/a Waynesville Dialysis Center (WDC) proposes to add 1 dialysis station for a total of 19 certified dialysis stations upon project completion.

#### **Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need

methodology shows there is a deficit of one dialysis station in Haywood County; thus, the applicant cannot apply to add any additional stations based on the county need methodology. However, an 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%. 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 WDC in the July 2016 SDR is 3.22 patients per station per week, or 80.5 percent ( $3.22 / 4 \text{ patients per station} = 0.805$  or 80.5%). This utilization rate was calculated based on 58 in-center dialysis patients and 18 certified dialysis stations ( $58 \text{ patients} / 18 \text{ stations} = 3.22 \text{ patients per station per week}$ ).

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

<b>October 1 Review – July 2016 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		80.5%
Certified Stations		18
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>18</b>
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		58
In-Center Patients as of 6/30/15 (January 2016 SDR) (SDR1)		56
Step	Description	Result
	Difference (SDR2 - SDR1)	2
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.0714
(ii)	Divide the result of Step (i) by 12	0.0060
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0714
(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	62.1429
(v)	Divide the result of Step (iv) by 3.2 patients per station	19.4196
	and subtract the number of certified and pending stations to determine the number of stations needed*	<b>1</b>

\*Note: According to Step Two of the facility need methodology in the July 2016 SDR, "Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)(v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number."

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one. 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 one new station and, therefore, is consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles on page 39 of the 2016 SMFP. 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(a), pages 9-10, Section O, page 49, 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(b), page 10, Section L, pages 42-46, 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 Sections B.4(c)-(d), page 11, and Section N, page 48. 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 July 2016 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

TRC proposes to add 1 dialysis station to the WDC facility for a total of 19 certified dialysis stations upon project completion.

**Patient Origin**

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Haywood County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 17, the applicant provides the historical patient origin for WDC patients as of December 31, 2015, which is summarized in the following table:

<b>WDC Dialysis Patients by County/State 12/31/2015</b>	
<b>County/State</b>	<b>Number of Patients</b>
Haywood	54
Buncombe	2
Jackson	1
Other States	1
<b>Total</b>	<b>58</b>

In Section C.1, page 13, the applicant provides the projected patient origin for WDC for in-center patients for the first two operating years (OY) following completion of the project, as shown below.

<b>WDC Dialysis Patients by County/State – OYs 1 &amp; 2</b>				
<b>County</b>	<b>OY1 CY 2018</b>	<b>OY2 CY 2019</b>	<b>Patients as % of Total</b>	
	<b>In-Center</b>	<b>In-Center</b>	<b>OY1</b>	<b>OY2</b>
Haywood	71	77	94.7%	95.1%
Buncombe	2	2	2.7%	2.5%
Jackson	1	1	1.3%	1.2%
Other States	1	1	1.3%	1.2%
<b>Total</b>	<b>75</b>	<b>81</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology used to project patient origin on pages 13-14. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 14, the applicant states the need for the proposed project is based on the continued growth of the patient population at WDC. 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 Section C.1, page 13, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

<b>WDC Dialysis Patients by County/State – OYs 1 &amp; 2</b>				
<b>County</b>	<b>OY1 CY 2018</b>	<b>OY2 CY 2019</b>	<b>Patients as % of Total</b>	
	<b>In-Center</b>	<b>In-Center</b>	<b>OY1</b>	<b>OY2</b>
Haywood	71	77	94.7%	95.1%
Buncombe	2	2	2.7%	2.5%
Jackson	1	1	1.3%	1.2%
Other States	1	1	1.3%	1.2%
<b>Total</b>	<b>75</b>	<b>81</b>	<b>100.0%</b>	<b>100.0%</b>

In Section C.1, pages 13-14, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- The Haywood County patient population will grow at a rate of 9.6 percent (the Five Year AACR for Haywood County as published in the July 2016 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 Haywood County, but assumes that those patients will continue to dialyze at WDC and are added to the calculations when appropriate.
- The project is scheduled for completion on January 1, 2018. OY1 is CY 2018. OY2 is CY 2019.

In Section C.1, pages 13-14, 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>WDC</b>	<b>In-Center Dialysis</b>
Starting point of calculations is Haywood County patients dialyzing at WDC on January 1, 2016.	54
Haywood County patient population is projected forward by one year to December 31, 2016. Projection is based on the AACR for Haywood County as published in the July 2016 SDR (9.6%).	$54 \times 1.096 = 59.184$
The four patients from other counties and states are added. This is the projected census on December 31, 2016.	$59.184 + 4 = 63.184$
Haywood County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (9.6%).	$59.184 \times 1.096 = 64.866$
The four patients from other counties and states are added. This is the projected census on December 31, 2017.	$64.866 + 4 = 68.866$
Haywood County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (9.6%).	$64.866 \times 1.096 = 71.093$
The four patients from other counties and states are added. This is the projected census on December 31, 2018 (OY1).	$71.093 + 4 = 75.093$
Haywood County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (9.6%).	$71.093 \times 1.096 = 77.918$
The four patients from other counties and states are added. This is the projected census on December 31, 2019 (OY2).	$77.918 + 4 = 81.918$

The applicant projects to serve 75 in-center patients on 19 stations, which is 3.95 patients per station per week ( $75 \text{ patients} / 19 \text{ stations} = 3.95$ ), by the end of OY1 and 82 in-center patients on 19 stations, which is 4.32 patients per station per week ( $82 \text{ patients} / 19 \text{ stations} = 4.32$ ), by the end of OY2. This exceeds 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). The July 2016 SDR indicates that WDC's utilization rate was 80.6 percent (3.22 patients per station per week) as of December 31, 2015. In this application, the applicant projects the Haywood County in-center patient census will increase annually by 9.6 percent, which is the Haywood County AACR published in the July 2016 SDR.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to add one dialysis station to its existing facility for a total of 19 dialysis stations upon project completion.

### Home Hemodialysis and Peritoneal Dialysis

The applicant does not report home hemodialysis or peritoneal dialysis patients in any of its patient origin information or historical payor mix information. In Section C.2, page 14, the applicant states:

*“This application does not call for any changes to home hemo or PD services at Waynesville Dialysis.”*

### Access

In Section L.1, page 42, the applicant states that WDC provides dialysis services to all residents in its service area without qualifications and serves patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability. The table below, found in Section L.7, page 46, shows the CY 2015 payment sources of the facility, and shows that 88.6 percent of the patients had some or all of their services paid for by Medicare or Medicaid.

<b>WDC Historical Payor Mix – CY 2015</b>	
<b>Payment Source</b>	<b>% Total Patients</b>
Medicare	24.0%
Medicaid	8.3%
Commercial Insurance	4.7%
Medicare/Commercial	34.6%
Medicare/Medicaid	21.7%
VA	6.7
<b>Total</b>	<b>100.0%</b>

In Section L.1, page 43, the applicant projects 88.6 percent of its patients will have some or all of their services paid for by Medicare or Medicaid in CY 2019. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed, 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 21, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that this alternative was dismissed due to the growth rate of the patient population at WDC.
- Apply for the One Station Expansion – The applicant states the one additional station will help meet the growing demand for services at WDC.

After considering those alternatives, the applicant states the alternative represented in the application 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 the 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 Waynesville Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Waynesville Dialysis Center shall develop and operate no more than 1 additional dialysis station for a total of no more than 19 certified stations which shall include any isolation or home hemodialysis stations.**

3. **Total Renal Care of North Carolina, LLC d/b/a Waynesville Dialysis Center shall install plumbing and electrical wiring through the walls for no more than 19 dialysis stations which shall include any isolation stations.**
  4. **Total Renal Care of North Carolina, LLC d/b/a Waynesville Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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

TRC proposes to add 1 dialysis station to the WDC facility for a total of 19 certified dialysis stations upon project completion.

**Capital and Working Capital Costs**

In the table in Section F.1, page 22, the applicant states that the projected capital cost is \$5,773, for equipment and furniture. The applicant states that WDC is an existing dialysis facility with an ongoing operation; therefore, in Sections F.10-12, pages 24-25, it does not project any working capital needs.

**Availability of Funds**

Exhibit F-7 contains DaVita's Form 10-K for the fiscal year ended December 31, 2014, not 2015, as stated by the applicant. The 2014 financials were more than 20 months old on the application submission date. However, the Agency has DaVita's Form 10-K for the year ended December 31, 2015 on file from Project I.D. #F-11154-16, which indicates that as of December 31, 2015, it had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds, should the need arise, for the capital and working 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>WDC</b>	<b>Operating Year 1 CY 2018</b>	<b>Operating Year 2 CY 2019</b>
Total Treatments	10,600	11,563
Total Gross Revenues (Charges)	\$2,859,944	\$3,119,396
Total Net Revenue	\$2,742,722	\$2,991,529
Total Operating Expenses (Costs)	\$2,687,148	\$2,883,230
<b>Net Income/Profit</b>	<b>\$55,574</b>	<b>\$108,299</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See the financial section 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 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

TRC proposes to add 1 dialysis station to the WDC facility for a total of 19 certified dialysis stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Haywood County. Facilities may also serve residents of counties not included in their service area.

WDC is the only dialysis center in Haywood County. There are no other providers of dialysis services in Haywood County. According to the July 2016 SDR, the applicant was serving 58 patients on 18 existing certified stations. Based on that data, the applicant demonstrates that as of December 31, 2015, the facility was operating at 80.5 percent of capacity or 3.22 patients per station per week (58 patients / 19 stations = 3.22 / 4 = .805 or

80.5%). Over a three year period, the applicant projects an increase of 17 in-center patients from 58 in-center patients as of December 31, 2015 to 75 in-center patients as of December 31, 2018, the end of Operating Year One.

In Section C.1, pages 13-14, the applicant demonstrates that WDC will serve a total of 75 in-center patients at the end of Operating Year One (CY 2018) for a utilization rate of 98.8 percent or 3.95 patients per station per week (75 patients / 19 stations = 3.95 / 4 = .988 or 98.8%). The projected utilization of 3.95 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C.2203(b).

The applicant adequately demonstrates the need to add one additional station to WDC based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Haywood 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.

C

In Section H.1, page 29, the applicant provides the following table to illustrate the projected staffing for WDC at the end of OY2.

<b>WDC – Proposed Facility Staffing</b>	
<b>Position</b>	<b>Projected # of FTEs</b>
Medical Director*	
RN	3.0
Patient Care Technician	8.0
Administrator	2.0
Dietician	0.5
Social Worker	0.5
Admin Assistant	1.0
Biomed Technician	0.5
<b>Total</b>	<b>15.5</b>

\*The Medical Director is a contract position and is not an employee of the facility.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. In Section I.3, page 34, the applicant identifies Dr. Blake Pruitt as the current Medical Director for the facility.

In Section H.3, pages 30-31, the applicant describes its experience and process for recruiting and retaining staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel, including the 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, pages 33-35, the applicant discusses the providers of the necessary ancillary and support services for the proposed facility, as well as coordination with the existing health care system. Exhibits I-1 through I-3 contain documents from the facility administrator, a copy of an agreement between WDC and Asheville Kidney Center for home hemodialysis and peritoneal dialysis patient training and support, and a letter of support from Dr. William Durham, a local nephrologist, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information found in Section I and referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
  - (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
    - (i) would be available under a contract of at least 5 years duration;
    - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

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

C

In Section L.7, page 46, the applicant reports that 88.6 percent of the patients who received treatments at WDC had some or all of their services paid for by Medicare or Medicaid in CY 2015. The historical payor mix for patients dialyzing at WDC is shown in the table below.

<b>WDC Historical Payor Mix – CY 2015</b>	
<b>Payment Source</b>	<b>% Total Patients</b>
Medicare	24.0%
Medicaid	8.3%
Commercial Insurance	4.7%
Medicare/Commercial	34.6%
Medicare/Medicaid	21.7%
VA	6.7
<b>Total</b>	<b>100.0%</b>

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>
Haywood	24%	52%	7%	15%	11%	19%
Statewide	15%	51%	36%	17%	10%	15%

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

\*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 *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

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

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

The applicant demonstrates that it currently provide 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 L.3(d), page 45, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 45, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 43, the applicant projects that 88.6 percent of the patients who will receive treatments at WDC in the second operating year (CY 2019) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility.

<b>Payment Source</b>	<b>% Total Patients</b>
Medicare	24.0%
Medicaid	8.3%
Commercial Insurance	4.7%
Medicare/Commercial	34.6%
Medicare/Medicaid	21.7%
VA	6.7
<b>Total</b>	<b>100.0%</b>

The applicant's projected OY2 payor mix for the facility is the same as the historical payor mix reported by the applicant in Section L.7, page 46. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at WDC. 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 45, the applicant describes the range of means by which a person will have access to the dialysis services at WDC, including admissions from nephrologists with medical privileges at the facility or via referral from a different provider to a nephrologist with medical privileges. 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.2, page 47, the applicant states that WDC has offered the facility as a clinical learning site for medical assistant students from Haywood Community College. Exhibit M-2 contains a letter dated August 31, 2016, from the applicant to Haywood Community

College. 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

TRC proposes to add 1 dialysis station to the WDC facility for a total of 19 certified dialysis stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Haywood County. Facilities may also serve residents of counties not included in their service area.

WDC is the only dialysis center in Haywood County. There are no other providers of dialysis services in Haywood County. According to the July 2016 SDR, the applicant was serving 58 patients on 18 existing certified stations. Based on that data, the applicant demonstrates that as of December 31, 2015, the facility was operating at 80.5 percent of capacity or 3.22 patients per station per week ( $58 \text{ patients} / 19 \text{ stations} = 3.22 / 4 = .805$  or 80.5%). Over a three year period, the applicant projects an increase of 17 in-center patients from 58 in-center patients as of December 31, 2015 to 75 in-center patients as of December 31, 2018, the end of Operating Year One.

In Section N.1, page 48, the applicant discusses how the proposed project would have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

*“The expansion of Waynesville Dialysis will have no effect on competition in Haywood 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 Waynesville 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 project 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 WDC 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 WDC 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 Section B.4, pages 9-10, Section O, page 49, and Exhibits O-2 and O-3, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-3, the applicant identifies four kidney disease treatment centers located in North Carolina, owned and operated by the applicant or its parent company, that were 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. See the table below.

<b>TRC Quality Care</b>		
<b>Facility</b>	<b>Survey Date</b>	<b>Back in Compliance</b>
Southeastern Dialysis Center – Kenansville	3/22/2016	Yes
Durham Dialysis	3/22/2016	Yes
Marshville Dialysis	2/29/2016	Yes
Durham West Dialysis	10/7/2015	Yes

In Section O.3, page 49, the applicant states that all facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has 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- WDC 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 13-14, the applicant documents the need for the project and demonstrates that it will serve a total of 75 in-center patients on 19 stations at the end of the first operating year, which is 3.95 patients per station per week or a utilization rate of 98.8 percent. 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 13-14, 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.