

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 19, 2017

Findings Date: May 19, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: H-11317-17

Facility: Southern Pines Dialysis Center

FID #: 020648

County: Moore

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two stations to existing facility for a total of 17 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 d/b/a Southern Pines Dialysis Center (the applicant) or (Southern Pines Dialysis) proposes to add two dialysis stations to the existing facility for a total of 17 in-center 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 surplus of five dialysis stations; thus, there is no need for additional dialysis stations in Moore County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need

methodology, because the utilization rate reported for Southern Pines Dialysis in the January 2017 SDR is 3.66 patients per station. This utilization rate was calculated based on 55 in-center dialysis patients and 15 certified dialysis stations as of June 30, 2016 (55 patients / 15 stations = 3.66 patients per station). Application of the facility need methodology indicates that 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		91.67%
Certified Stations		15
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>15</b>
In-Center Patients as of 6/30/16 (SDR2)		55
In-Center Patients as of 12/31/15 (SDR1)		49
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.2449
(ii)	Divide the result of step (i) by 12	0.0204
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.1224
(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	61.7347
(v)	Divide the result of step (iv) by 3.2 patients per station	19.2921
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>4</b>

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

**Policies**

*Policy GEN-3: Basic Principles*, page 33 of the 2017 SMFP is applicable to this review. *Policy GEN-3* states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and*

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

The applicant addresses Policy GEN-3 as follows:

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 and Exhibits B-4 and K-1(g). The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality in the delivery of dialysis services.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 15, Section L, pages 43 – 46 and Exhibit L-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access to dialysis services.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11 and in Section N.1, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value for dialysis services.

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

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2017 SDR and with *Policy GEN-3: Basic Principles* in the 2017 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

Total Renal Care of North Carolina, LLC d/b/a Southern Pines Dialysis Center proposes to add two dialysis stations to the existing facility for a total of 17 in-center dialysis stations upon project completion.

**Patient Origin**

On page 373, the 2017 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 counties is a separate dialysis station planning area. Thus, the service area for this facility is Moore County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 18, the applicant provides the in-center patient origin for Southern Pines Dialysis Center as of June 30, 2016, as summarized in the following table:

**Southern Pines Dialysis Center**

COUNTY	# OF PATIENTS	% OF TOTAL
Moore	48	87.3%
Alamance	1	1.8%
Harnett	1	1.8%
Hoke	3	5.5%
Lee	1	1.8%
Richmond	1	1.8%
<b>Total</b>	<b>55</b>	<b>100.0%</b>

In Section C.1, page 13, the applicant identifies the in-center patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**Southern Pines Dialysis Center  
 Projected Patients First Two Operating Years**

COUNTY	OPERATING YEAR 1 (CY 2019)		OPERATING YEAR 2 (CY 2020)	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Moore	49	87.5%	50	87.8%
Alamance	1	1.8%	1	1.8%
Harnett	1	1.8%	1	1.8%
Hoke	3	5.4%	3	5.3%
Lee	1	1.8%	1	1.8%
Richmond	1	1.8%	1	1.8%
<b>Total</b>	<b>56</b>	<b>100.0%</b>	<b>57</b>	<b>100.0%</b>

Numbers may not sum due to rounding

See pages 16 - 17 for the assumptions and methodology used to project patient origin.

The applicant adequately identifies the population to be served.

### **Analysis of Need**

In Section B.2, page 7, the applicant provides a table to show the application is filed pursuant to the facility need methodology outlined in the 2017 SMFP, utilizing data from the January 2017 SDR. The applicant proposes to add two dialysis stations to the existing facility for a total of 17 certified dialysis stations upon project completion.

In Section C.1, pages 13 – 14, the applicant provides the assumptions and methodology to support its need to add two stations pursuant to the facility need methodology, as summarized below:

- The applicant notes the facility was dialyzing 55 in-center patients on 15 certified dialysis stations as of June 30, 2016, as reported in the January 2017 SDR, which is a 91.7% utilization rate [ $55 / 15 = 3.67$ ;  $3.67 / 4 = 0.9167$ ].
- The applicant states 48 of those patients are residents of Moore County, and the remaining seven patients are residents of Alamance, Harnett, Hoke, Lee and Richmond counties.
- The applicant uses 1.0% as the Moore County Five Year Average Annual Change Rate (AACR), reported in Table B of the January 2017 SDR to project growth of the Moore County patient population at the facility.
- The applicant projected no growth in the patient population that resides outside of Moore County; rather, these patients are added after the Moore County patient population growth is calculated.
- The applicant states Operating Year one (OY 1) is projected to begin January 1, 2019, and Operating Year two (OY 2) is projected to begin January 1, 2020. Operating Years are calendar years, as reported by the applicant on page 13.
- The applicant projects growth beginning July 1, 2016 and ending December 31, 2020.
- Based on these assumptions, the applicant projects 56 in-center patients by the end of OY 1

### **Projected Utilization**

In Section C.1, page 14, the applicant projects the following in-center utilization for Southern Pines Dialysis Center, calculating growth of only the Moore County patients and then adding the out-of-county patients at the end of each year's growth:

	START DATE	# SA PTS.	GROWTH RATE	# SA PTS	# PTS FROM OUT OF SA	TOTAL # PTS	DATE
Beginning Service Area Census	7/1/16	48.00	1.005	48.24	7	55.24	12/31/16
Current Year	1/1/17	48.24	1.01	48.72	7	55.72	12/31/17
Interim Year	1/1/18	48.72	1.01	49.21	7	56.21	12/31/18
OY 1	1/1/19	49.21	1.01	49.70	7	56.70	12/31/19
OY 2	1/1/20	49.70	1.01	50.20	7	57.20	12/31/19

The applicant rounds down to the nearest whole number and projects to serve 57 in-center patients on 17 stations or 3.29 patients per station per week [ $56 / 17 = 3.29$ ] by the end of Operating Year 1, and 57 in-center patients or 3.35 patients per station per week [ $57 / 17 = 3.35$ ] by the end of Operating Year 2 for the facility.

However, the applicant used an incorrect AACR to project utilization of the additional dialysis stations at the facility. The applicant used a 1.0% growth rate, which is actually the growth rate for Nash County, not Moore County. The counties are listed alphabetically in the table in the SDR, and Nash County appears in the line directly above Moore County. The Moore County AACR is actually 0.6%. The project analyst recalculated the growth projections using the Moore County AACR of 0.6 %, as illustrated in the following table:

	START DATE	# SA PTS.	GROWTH RATE	# SA PTS	# PTS FROM OUT OF SA	TOTAL # PTS	DATE
Beginning Service Area Census	7/1/16	48.00	1.003	48.14	7	55.14	12/31/16
Current Year	1/1/17	48.14	1.006	48.43	7	55.43	12/31/17
Interim Year	1/1/18	48.43	1.006	48.72	7	55.72	12/31/18
OY 1	1/1/19	48.72	1.006	49.01	7	56.01	12/31/19
OY 2	1/1/20	49.01	1.006	49.31	7	56.31	12/31/19

Thus, the projected utilization for OY 1 is 56 patients dialyzing on 17 in-center stations, which is a utilization of 3.29 patients per station per week, or 82.35% of capacity [ $56 / 17 = 3.29$ ;  $3.29 / 4 = 0.8235$ ]. Although the applicant used the incorrect AACR for Moore County in its projections of the number of patients to be served, utilization of the correct AACR results in a projected utilization for OY 1 that exceeds the minimum of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth, despite the use of the incorrect AACR for Moore County.

### **Access to Services**

In Section C.3, page 15, the applicant states that by policy, the proposed services will be available to all persons without regard to race, sex, age or handicap. The applicant further states services will be available to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, and “*other under-served persons.*”

In addition, in Section L.1, page 44 the applicant projects that 74.6% of the patients who will dialyze at Southern Pines Dialysis Center will be covered by either Medicare or Medicaid. In Section L.1, page 44, the applicant states that its projected payor mix is based on the payor mix for the last full operating year for Southern Pines Dialysis Center. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to 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 project 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 22, the applicant discusses the alternatives considered prior to submitting this application, summarized as follows:

- Maintain the Status Quo – the applicant states that this alternative was dismissed considering the growth rate at Southern Pines Dialysis Center.
- Relocate Dialysis Stations from Another DaVita Facility – The applicant states that the Carthage Dialysis facility operates three days per week; to take stations from that facility would negatively impact its existing patients. Likewise, the other dialysis facility, Dialysis Care of Moore County, recently relocated two stations to Dialysis

Care of Richmond County; relocating additional stations would negatively impact the patients being served at that facility.

After considering the above alternatives, the applicant states that applying for two additional stations at Southern Pines Dialysis Center pursuant to the facility need methodology is the most effective alternative to meet the identified need for additional stations to serve the dialysis patients in Moore County who dialyze at that facility.

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 Southern Pines 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 Southern Pines Dialysis Center shall add no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon project completion.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Southern Pines Dialysis Center shall install plumbing and electrical wiring through the walls for no more than two dialysis stations, which shall include any isolation or home hemodialysis stations.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Southern Pines Dialysis Center 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 proposes to add two dialysis stations to the existing facility for a total of 17 dialysis stations upon project completion.

### **Capital Costs and Working Capital Costs**

In Section F.1, page 23, the applicant projects \$42,220 in capital costs to develop the proposed project. In Sections F.10 - F.12, pages 25 - 26, the applicant projects there will be no start-up expenses or initial operating expenses associated with this project, since the facility is currently operational.

### **Availability of Funds**

In Section F.2, page 24, the applicant states it will finance the capital costs with the accumulated reserves and owner's equity of DaVita, parent company to Total Renal Care of North Carolina, LLC.

Exhibit F-5 contains a letter dated March 14, 2017, from the Chief Accounting Officer of DaVita, as the parent company of TRC and also as the guarantor of the funds on behalf of Southern Pines Dialysis Center, which confirms availability and commitment of sufficient cash reserves for the capital costs of \$42,220, as well as, "*any other funds that are necessary for the development of the project.*"

Exhibit F-7 contains DaVita's Securities and Exchange Commission (SEC) Form 10-K for the fiscal year ended December 31, 2015. Those forms show that, as of December 31, 2015, DaVita 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 that sufficient funds will be available for the capital and operating needs of the project.

### **Financial Feasibility**

In Section R of the application, 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 of the project, as shown in the table below.

**Southern Pines Dialysis Center  
Revenues and Expenses**

	<b>OY 1 (CY 2019)</b>	<b>OY 2 (CY 2020)</b>
Total Treatments	8,736	8,814
Total Gross Revenues (Charges)	\$3,577,029	\$3,608,930
Total Net Revenue	\$3,514,409	\$3,545,757
Total Operating Expenses (Costs)	\$2,656,282	\$2,691,013
<b>Net Profit</b>	<b>\$ 858,128</b>	<b>\$ 854,744</b>

Source: Application Section R, Forms B and C

Because the applicant used a higher AACR to calculate the projected patient census at the facility, the number of treatments given to patients in OY 1 and OY 2 will be slightly less than what the applicant calculated. However, there will be still be a positive net revenue and thus net profit, despite the applicant's use of the incorrect AACR. See Criterion (3) for discussion. Therefore, the assumptions used by the applicant in preparation of the pro

forma financial statements are reasonable, including projected utilization, costs and charges, despite the use of the incorrect AACR. See Section R, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

**Conclusion**

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding utilization and revenues (charges 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**

Total Renal Care of North Carolina, LLC d/b/a Southern Pines Dialysis Center proposes to add two dialysis stations to the existing facility for a total of 17 in-center stations upon project completion.

On page 373, the 2017 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 counties is a separate dialysis station planning area. Thus, the service area for this facility is Moore County. Facilities may also serve residents of counties not included in their service area.

The applicant currently operates three dialysis facilities in Moore County, and is the only provider of dialysis services in the county. See the following table, which illustrates those facilities and their utilization:

**Utilization TRC Moore County Facilities / January 2017 SDR**

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Carthage Dialysis	12	28	58.33%
Dialysis Care of Moore County	25	69	69.00%
Southern Pines Dialysis Center	15	55	91.67%

Source: January 2017 SDR, Application page 29

In Section G, page 29, the applicant states that transferring stations from either of the two additional dialysis facilities in Moore County would negatively impact the patients who currently dialyze at those facilities. Furthermore, the applicant states that while it does

propose to increase the inventory of dialysis stations in Moore County, the increase serves to increase needed capacity at the particular facility, rather than duplicate any existing or approved services in the county.

In Section C.1, pages 13 - 14, the applicant provides reasonable projections for the in-center patient population it proposes to serve at Southern Pines Dialysis Center. The applicant's growth projections are based on the Moore County Five Year AACR as published in the January 2017 SDR.

The applicant adequately demonstrates the need to add two stations to the existing facility. 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 Moore 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 30, the applicant provides the current staffing for the facility and the projected staffing following the addition of two dialysis stations. The following table illustrates current and projected staffing at Southern Pines Dialysis Center:

**Southern Pines Dialysis Center Current and Projected Staffing**

POSITION	CURRENT FTES	# FTES TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	2.0	1.0	3.0
Patient Care Technician	6.0	1.0	7.0
Administrator	1.0	0.0	1.0
Dietician	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Administrative Assistant	1.0	0.0	1.0
Biomedical Technician	0.5	0.0	0.5
<b>Total</b>	<b>11.5</b>	<b>2.0</b>	<b>13.5</b>

Source: Application page 30

As shown in the table above, the applicant proposes to add 2.0 full-time equivalent (FTE) positions upon project completion. In Section H.2, page 31, the applicant states that the Medical Director for Southern Pines Dialysis Center will be Dr. Edward Hoehn-Saric. In Exhibit I-3, the applicant provides a letter signed by Dr. Hoehn-Saric, dated February 15, 2017, confirming his commitment to continue to serve as Medical Director. In Section H.3, page 31, the applicant describes its method for recruiting and retaining staff at the facility.

In Section H.7, page 33, the applicant projects the following direct care staff for the second operating year:

DIRECT CARE POSITIONS	# FTES	HOURS/YEAR/ FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	FTE HOURS/HOURS OF OPERATION
RN	3	2,080	6,240	3,120	2.0
Patient Care Technician	7	2,080	14,560	3,120	4.7
Total	10	2,080	20,800	3,120	6.7

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

C

In Section I, pages 24 - 36, the applicant includes a list of providers of the necessary ancillary and support services to be provided for the patients who dialyze at Southern Pines Dialysis Center. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-3, including letters from DaVita Laboratory Services, Inc. and several nephrologists. The information in Section I and Exhibits I-1 and 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;

C

In Section L.7, page 47, the applicant provides the historical payor mix for Southern Pines Dialysis Center for CY 2016, as follows:

**Southern Pines Dialysis Center  
Historical Payor Mix CY 2016**

<b>PAYOR TYPE</b>	<b>% OF TOTAL PATIENTS</b>
Medicare	16.4%
Medicaid	7.3%
Commercial Insurance	20.0%
Medicare/Commercial	29.1%
Medicare/Medicaid	21.8%
VA	5.5%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

As the table above indicates, 74.6% of Southern Pines Dialysis Center’s patients were covered by Medicare or Medicaid in CY 2018. In addition, the applicant describes its admission and financial policies in Section L.3, pages 43 – 46, and provides a copy of its admission policy which states that patients will be admitted “without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability” in Exhibit L-3.

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.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Moore	24%	52%	23%	16%	10%	17%
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 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 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

<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)

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

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 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 applicants;

C

In Section L.3(d) page 46, the applicant states,

*“Southern Pines Dialysis Center has 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. The facility has no obligation under the Hill Burton Act.”*

In Section L.6, page 46, the applicant states that there have been no civil rights equal access complaints filed within the last five years against the existing facility or any facilities owned by the parent corporation.

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 44, the applicant states that the projected payor mix is based on historical payor mix for the facility for the last full operating year, illustrated as follows:

**Southern Pines Dialysis Center  
Projected Payor Mix OY 2 (CY 2020)**

<b>PAYOR TYPE</b>	<b>% OF TOTAL PATIENTS</b>
Medicare	16.4%
Medicaid	7.3%
Commercial Insurance	20.0%
Medicare/Commercial	29.1%
Medicare/Medicaid	21.8%
VA	5.5%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

The applicant projects that 74.6% of its patients will be covered by Medicare or Medicaid. In Section L, page 44, the applicant states projected payor mix is based on the historical payor mix at Southern Pines Dialysis Center.

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 L.4, page 46, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients who contact the facility directly or indirectly will be referred to “*a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary.*” In Exhibit I-3, the applicant provides letters of support from area Nephrologists who indicate they have referred patients to the facility for dialysis and will continue to do so following the addition of two stations.

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to 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.

C

In Section M.1, page 48, the applicant states that it has offered Southern Pines Dialysis Center as a clinical training site for nursing students from Richmond Community College. A copy of a letter sent by the applicant to the college, dated February 10, 2015, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately supports a finding of conformity with 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

Total Renal Care of North Carolina, LLC d/b/a Southern Pines Dialysis Center proposes to add two dialysis stations to the existing facility for a total of 17 in-center dialysis stations upon project completion.

On page 373, the 2017 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 counties is a separate dialysis station planning area. Thus, the service area for this facility is Moore County. Facilities may also serve residents of counties not included in their service area.

The applicant currently operates three dialysis facilities in Moore County, and is the only provider of dialysis services in the county. See the following table, which illustrates those facilities and their utilization:

**Utilization TRC Moore County Facilities / January 2017 SDR**

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Carthage Dialysis	12	28	58.33%
Dialysis Care of Moore County	25	69	69.00%
Southern Pines Dialysis Center	15	55	91.67%

Source: January 2017 SDR, Application page 29

In Section N.1, page 49, the applicant states

*“The expansion of Southern Pines Dialysis Center will have no effect on competition in Moore 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 Southern Pines Dialysis Center 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 involved in the dialysis process to receive services.”*

See also Sections B, C, D, F, 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 referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 a cost-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 Southern Pines Dialysis Center will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that Southern Pines Dialysis Center 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 O.2, page 50, and Section B.4, pages 9 - 10, the applicant describes the methods by which Southern Pines Dialysis Center will ensure the provision of quality care. In Exhibit O-3, the applicant provides a list of four dialysis facilities operated by the applicant that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. In Exhibit O-2, the applicant provides documentation to confirm that each facility is back in compliance as of the date of the 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**

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

-NA- The applicant is not proposing to establish a new end stage renal disease facility.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C-1, pages 13 – 14 the applicant demonstrates the need for two additional stations at Southern Pines Dialysis Center based on 56 in-center patients dialyzing on 17 in-center stations as of the end of the first operating year. The applicant incorrectly applied the Nash County AACR rather than the Moore County AACR in its calculations, thus projecting 57 in-center patients at the end of OY 1. The project analyst recalculated the growth projections using the Moore County AACR of 0.6%; thus, the projected utilization for OY 1 is 56 in-center patients dialyzing on 17 stations, which is a utilization of 3.29 patients per station per week, or 82.35% of capacity [ $56 / 17 = 3.29$ ;  $3.29 / 4 = 0.8235$ ]. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

*.2203(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.