

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 26, 2015

Findings Date: February 26, 2015

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Martha J. Frisone

Project ID #: H-11085-15

Facility: Southern Pines Dialysis Center

FID #: 020648

County: Moore

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add 1 dialysis station for a total of 16 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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.

NC

The applicant, Total Renal Care of North Carolina, LLC (TRC) d/b/a Southern Pines Dialysis (Southern Pines) proposes to add one dialysis station to the existing facility for a total of 16 stations upon project completion.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table B in the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of four dialysis stations in Moore County; therefore, the applicant is ineligible to apply for 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 this facility based on the facility need methodology, because the utilization rate reported for Southern Pines in the July 2015 SDR is 3.4 patients per station, or 85% (3.4 / 4 patients per station = 0.85). This utilization rate was calculated based on 51 in-center dialysis patients and 15 certified dialysis stations (51 patients / 15 stations = 3.4 patients per station).

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

| OCTOBER 1 REVIEW-JULY SDR | | |
|--|---|-----------|
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 12/31/14 | | 85.0% |
| Certified Stations | | 15 |
| Pending Stations | | 0 |
| Total Existing and Pending Stations | | 15 |
| In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2) | | 51 |
| In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1) | | 49 |
| Step | Description | Result |
| (i) | Difference (SDR2 - SDR1) | 2 |
| | Multiply the difference by 2 for the projected net in-center change | 4 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14 | 0.0816 |
| (ii) | Divide the result of Step (i) by 12 | 0.0068 |
| (iii) | Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14) | 0.0816 |
| (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 | 55.1633 |
| (v) | Divide the result of Step (iv) by 3.2 patients per station | 17.2385 |
| | and subtract the number of certified and pending stations to determine the number of stations needed | 2.2385 |

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 2 stations, rounded down from 2.2385. 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, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology applies. 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, pages 9-10 and Section O, page 49. 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, page 10, Section C, page 15, Section L, pages 42 - 45 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 to dialysis services.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 11 and Section N, page 48. However, the applicant does not adequately demonstrate that the proposed project is the least costly or most effective alternative and that the project will not result in unnecessary duplication of existing or approved dialysis stations. The discussions regarding alternatives and duplication found in Criteria (4) and (6), respectively, are incorporated herein by reference. Based on those facts, the applicant does not adequately demonstrate that the proposal will maximize healthcare value. Moreover, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended in meeting the facility need. Therefore the application is not 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 2015 SDR, however, the applicant does not adequately demonstrate that the proposed project is consistent with Policy GEN-3. Therefore, the application is nonconforming 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, proposes to add one dialysis station to the existing Southern Pines facility for a total of 16 stations upon project completion.

Population to be Served

On page 361, the 2015 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 Moore County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 17, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by Southern Pines, as shown below:

Dialysis Patients as of 12/31/2014

| COUNTY | IC PATIENTS |
|--------------|-------------|
| Moore | 43 |
| Richmond | 4 |
| Hoke | 1 |
| Scotland | 1 |
| Virginia | 1 |
| Other States | 1 |
| Total | 51 |

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

| COUNTY | OPERATING YEAR 1 | | | OPERATING YEAR 2 | | | COUNTY PATIENTS AS % OF TOTAL | |
|----------|------------------|----|----|------------------|----|----|-------------------------------|--------|
| | IC | HH | PD | IC | HH | PD | OY 1 | OY 2 |
| Moore | 46 | 0 | 0 | 47 | 0 | 0 | 85.0% | 85.0% |
| Richmond | 4 | 0 | 0 | 4 | 0 | 0 | 7.0% | 7.0% |
| Hoke | 1 | 0 | 0 | 1 | 0 | 0 | 2.0% | 2.0% |
| Scotland | 1 | 0 | 0 | 1 | 0 | 0 | 2.0% | 2.0% |
| Virginia | 1 | 0 | 0 | 1 | 0 | 0 | 2.0% | 2.0% |
| Other | 1 | 0 | 0 | 1 | 0 | 0 | 2.0% | 2.0% |
| Total | 54 | 0 | 0 | 55 | 0 | 0 | 100.0% | 100.0% |

The applicant provides the assumptions and methodology for the projections above on pages 13-17.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant projects to serve 54 in-center dialysis patients on 16 in-center stations at the end of the first operating year, which is 3.375 patients per station per week or an 84.5% utilization rate. The applicant does not project to serve any home hemodialysis patients or peritoneal dialysis patients.

In Section B, page 7, the applicant applied the facility need methodology which shows a need for two additional dialysis stations at Southern Pines. The proposed project is for one additional dialysis station at Southern Pines.

Projected Utilization

In Section C, pages 13-17, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- As of December 31, 2014, the utilization at Southern Pines was 85.0% or 3.4 patients per station per week on 15 stations. The facility was serving 51 in-center patients.
- As of December 31, 2014, there were 43 patients from Moore County dialyzing in-center at Southern Pines.
- There were 8 patients from outside the service area (Moore County) dialyzing in-center at Southern Pines as of December 31, 2014. These patients are expected to continue to use the facility but the applicant does not project any growth for these 8 patients.
- For Moore County residents using Southern Pines, the applicant assumes a growth rate of 2.5%, which is the Moore County Five Year Average Annual Change Rate as published in Table B of the July 2015 SDR.
- Operating Year 1 is CY 2017 and Operating Year 2 is CY 2018.
- The following table illustrates the applicant’s methodology:

| DATE | # SERVICE AREA PTS. | GROWTH RATE | TOTAL SERVICE AREA PTS. | # OUT OF SERVICE AREA PTS. | TOTAL IN-CENTER PATIENTS |
|-------------------|---------------------|-------------|-------------------------|----------------------------|--------------------------|
| As of 12/31/2014 | 43 | | | | |
| Current (CY 2015) | 43 | 1.025 | 44.075 | 8 | 52.075 |
| Interim (CY 2016) | 44 | 1.025 | 45.1 | 8 | 53.1 |
| OY 1 (CY 2017) | 45 | 1.025 | 46.125 | 8 | 54.125 |
| OY 2 (CY 2018) | 46.125 | 1.025 | 47.2781 | 8 | 55.2781 |

- The applicant projects that the facility will have 54 in-center patients by the end of operating year one (OY1) for a utilization rate of 84.4%, or 3.375 patients per station per week. [$54 / 16 \text{ stations} = 3.375 / 4 = 0.8437$ or 84.4%]
- The applicant projects that the facility will have 55 in-center patients by the end of operating year two (OY2), for a utilization rate of 85.9%, or 3.44 patients per station per week. [$55 / 16 \text{ stations} = 3.4375 / 4 = 0.8593$ or 85.9%]

The projected utilization of 3.375 patients per station per week at the end of OY1 exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C, page 15, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”

On page 43, the applicant projects 55% of all treatments will be covered by Medicare or Medicaid in OY2. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by Southern Pines and that the facility will conform to all federal, state and local codes and standards for handicapped access. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed 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.

NC

In Section E, page 21, the applicant discusses the alternatives considered prior to the submission of this application, which includes doing nothing or the proposed project. The applicant operates two other facilities in Moore County. One of these, Carthage Dialysis, was operating at only 58.33% of capacity, serving 28 patients on 12 stations or 2.333 patients per station per week. It would appear that one station could be relocated from Carthage Dialysis to meet the expected volume at Southern Pines without negatively impacting the patients using Carthage Dialysis. The applicant does not provide sufficient information to adequately document that the chosen alternative is actually the least costly or most effective alternative to meet the need for one additional station at Southern Pines.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (6) and (18a). An application that cannot be approved is not an effective alternative.

In summary, the applicant did not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Consequently, the application is nonconforming to this criterion.

- (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 one dialysis station to the existing Southern Pines facility for a total of 16 stations upon project completion.

Capital and Working Capital Costs

In Section F, page 22, the applicant projects the capital cost for the proposed project, as summarized in the table below:

| Southern Pines Dialysis Projected Project Capital Costs | |
|--|----------|
| Dialysis Machines | \$13,000 |
| Equipment/Furniture | \$5,098 |
| Total Capital Cost | \$18,098 |

In Section F, pages 25-26, the applicant states that there are no working capital needs for the proposed project since Southern Pines is an existing facility.

Availability of Funds

In Section F, page 23, the applicant states that the accumulated reserves of TRC will be used to finance the proposed project.

In Exhibit F-5, the applicant provides a letter dated September 10, 2015, from Jay Leibowitz, Vice President of Tax, DaVita Healthcare Partners, Inc., which owns 85% of Total Renal Care of North Carolina, LLC, confirming that DaVita Healthcare Partners, Inc. has committed cash reserves in the sum of \$18,098 for the proposed project and will make these funds and any other funds necessary for the proposed project available to Total Renal Care of North Carolina, Inc.

In addition, Exhibit K-7 contains a copy of the most recent annual report (10-K) for DaVita HealthCare Partners, Inc. for the Fiscal Year ended December 31, 2014. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in net assets (total assets less total liabilities).

The applicant adequately demonstrated that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement in Section R, Form B, the applicant projects revenues will exceed operating expenses in both of the first two Operating Years following completion of the proposed project, as shown in the table below.

| SOUTHERN PINES DIALYSIS REVENUE AND EXPENSES - TOTAL FACILITY | | |
|--|----------------------------------|----------------------------------|
| | OPERATING YR1 CY 2017 | OPERATING YR2 CY 2018 |
| Gross Patient Revenue | \$3,604,303 | \$3,671,831 |
| Deductions from Gross Patient Revenue | (\$59,570) | (\$60,672) |
| Net Patient Revenue | \$3,544,733 | \$3,611,159 |
| Operating Expenses | (\$1,793,027) | (\$1,833,817) |
| Net Income | \$1,751,707 | \$1,777,343 |

The assumptions used by the applicant in preparation of the pro formas are reasonable including projected utilization, costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon 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, proposes to add one dialysis station to the existing Southern Pines facility for a total of 16 stations upon project completion.

On page 361, the 2015 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 Moore County. Facilities may also serve residents of counties not included in their service area.

According to Table A in the July 2015 SDR, there are three existing dialysis facilities in Moore County. According to Map Quest, Southern Pines and Carthage Dialysis are approximately 18 minutes or 12.9 miles apart. Dialysis Care of Moore County is located between Southern Pines and Carthage Dialysis. All three of the facilities are ultimately operated and controlled by the same entity. The table below illustrates utilization as of December 31, 2014, as reported in the July 2015 SDR.

| DIALYSIS FACILITY | CERTIFIED STATIONS | # PATIENTS | PATIENTS PER STATION | % UTILIZATION |
|-------------------------------|--------------------|------------|----------------------|---------------|
| Carthage Dialysis | 12 | 28 | 2.333 | 58.33% |
| Dialysis Care of Moore County | 25 | 75 | 3.000 | 75.00% |
| Southern Pines Dialysis | 15 | 51 | 3.400 | 85.00% |

As shown in the table above, Carthage Dialysis is operating at only 58.33% of capacity. Moreover, according to Table B of the July 2015 SDR there is a surplus of four dialysis stations in Moore County.

The applicant does not discuss why it could not relocate one of the existing certified stations at Carthage Dialysis to address the need for one additional certified station at Southern Pines. Approval of the application's proposal would increase the surplus of stations in Moore County. Relocating one from Carthage Dialysis would not. The applicant does not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved certified dialysis stations in Moore County. Consequently, the application is nonconforming 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, page 29, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for Southern Pines. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

| POSITION | CURRENT # FTEs | # FTEs TO BE ADDED | PROJECTED # FTEs |
|--------------------------|----------------|--------------------|------------------|
| Registered Nurse | 2.0 | - | 2.0 |
| Technician (PCT)) | 6.0 | - | 6.0 |
| Dietician | 0.5 | - | 0.5 |
| Social Worker | 0.5 | - | 0.5 |
| Bio-med Technician | 0.5 | - | 0.5 |
| Administrative Assistant | 1.0 | - | 1.0 |
| Total | 10.5 | 0.0 | 10.5 |

In Section H, page 32, the applicant provides the projected direct care staff for Southern Pines in Operating Year 2, as shown below in the table:

| DIRECT CARE POSITIONS | # FTEs | HOURS PER YEAR PER FTE | TOTAL ANNUAL FTE HOURS | TOTAL ANNUAL HOURS OF OPERATION | # FTE HOURS PER HOUR OF OPERATION |
|-----------------------|----------|------------------------|------------------------|---------------------------------|-----------------------------------|
| Registered Nurse | 2 | 2,080 | 4,160 | 3,120 | 1.3 |
| Technician (PCT) | 6 | 2,080 | 12,480 | 3,120 | 4.0 |
| Total | 8 | 2,080 | 16,640 | 3,120 | 5.3 |

In Section I, page 34, the applicant identifies Dr. Edward Hoehn-Saric as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by Dr. Hoehn-Saric of Pinehurst Nephrology Associates, supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 30-31, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

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, page 33, the applicant lists the providers of the necessary ancillary and support services that are being provided and will continue to be provided at the existing facility. The applicant discusses coordination with the existing health care system on page 35. Also on page 35, the applicant states that the clinical staff at Southern Pines has established relationships with other

health care providers and social service agencies in the county and that these agencies are aware of and support the proposed project. Exhibits I-1, and I-3 contain supporting documents from Total Renal Laboratories, Inc. d/b/a DaVita Laboratory Services, Inc. and Dr. Hoehn-Saric (Medical Director), respectively. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (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, page 42, the applicant states,

“Southern Pines Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.

Southern Pines Dialysis makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility provides dialysis six days per week with two patient shifts per day to accommodate patient need.”

In addition, on pages 43-45, the applicant discusses its financial policies to help underserved groups. In Section L, page 46, the applicant provides the historical payor mix for Southern Pines, as follows:

| PAYOR TYPE | PERCENT PATIENTS |
|----------------------|------------------|
| Private Pay | 0.0% |
| Commercial Insurance | 15.7% |
| Medicare | 5.9% |
| Medicaid | 21.6% |
| VA | 27.5% |
| Other | 21.6% |
| Total | 92.3% |

Based on the projected payor mix, which the applicant states is based on historical, and the fact that the percentages in the table do not total 100%, the data on page 46 is not correct. The applicant inadvertently omitted a row and the percentages ended up on the wrong row. The correct Medicare/Medicaid percentage of the total is 55%.

The *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

| Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 | | |
|--|---------------------------|---------------------------------|
| | # of ESRD Patients | % of Dialysis Population |
| Age | | |
| 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% |
| Gender | | |
| Female | 7,064 | 44.2% |
| Male | 8,934 | 55.8% |
| Race | | |
| African-American | 9,855 | 61.6% |
| White | 5,778 | 36.1% |
| Other, inc. not specified | 365 | 2.3% |
| Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report. ² | | |

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The applicant demonstrates that it currently provides adequate access to medically underserved groups. 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, page 45, the applicant states:

“Southern Pines Dialysis 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.”

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In Section L, page 45, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

The application is conforming to this criterion.

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

C

In Section C, page 15, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...

...

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section L, page 45, the applicant states:

“Southern Pines Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

In Section L, page 43, the applicant projects that 55.0% of all patients who will receive dialysis treatment at Southern Pines will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below.

| PAYOR TYPE | PERCENT PATIENTS |
|----------------------|------------------|
| Private Pay | 0.0% |
| Commercial Insurance | 15.7% |
| Medicare | 5.9% |
| Medicaid | 21.6% |
| Medicare/ Medicaid | 27.5% |
| VA | 21.6% |
| Other | 7.8% |
| Total | 100.0% |

On page 43, the applicant also states that the projected payor mix for Southern Pines is based upon the experience of the facility and no change is anticipated.

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, page 45, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Southern Pines Dialysis ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

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, page 47, the applicant states that Southern Pines has been offered as a clinical training site for dialysis technicians and nursing students from Richmond Community College.

Exhibit M-2 contains a copy of the applicant’s existing agreement with Richmond Community College for student clinical rotations at Southern Pines. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity 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.

NC

The applicant, TRC, proposes to add one dialysis station to the existing Southern Pines facility for a total of 16 stations upon project completion.

On page 361, the 2015 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 Moore County. Facilities may also serve residents of counties not included in their service area.

According to Table A in the July 2015 SDR, there are three existing dialysis facilities in Moore County. All three of the facilities are ultimately operated and controlled by the same entity. The table below illustrates utilization as of December 31, 2014, as reported in the July 2015 SDR.

| DIALYSIS FACILITY | CERTIFIED STATIONS | # PATIENTS | PATIENTS PER STATION | % UTILIZATION |
|-------------------------------|--------------------|------------|----------------------|---------------|
| Carthage Dialysis | 12 | 28 | 2.333 | 58.33% |
| Dialysis Care of Moore County | 25 | 75 | 3.000 | 75.00% |
| Southern Pines Dialysis | 15 | 51 | 3.400 | 85.00% |

In Section N, page 48, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Southern Pines Dialysis will have no effect on competition in Moore County. This project 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 d/b/a [sic]

The expansion of Southern Pines 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 others involved in the dialysis process to receive services.”

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

However, the applicant did not adequately demonstrate that any enhanced competition in the service area will have a positive impact on the cost-effectiveness of the proposed services.

The applicant did not adequately demonstrate that the proposed project is the least costly or most effective alternative to meet the identified need. The discussion regarding alternatives found in Criterion (4) is incorporated herein by reference. Moreover, the applicant did not adequately demonstrate that the proposal to develop a new certified dialysis station would not result in an unnecessary duplication. The discussion regarding duplication found in Criterion (6) is incorporated herein by reference. Therefore, the application is not 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(a), pages 9-10, the applicant describes the methods it uses to ensure and maintain quality. In Section O, page 49, the applicant states:

“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look back period. Each facility is currently in compliance.”

See the table below which shows the survey dates and the dates the facilities were found to be back in compliance with CMS.

| Facility Name | Survey Date | Back in Compliance | |
|-----------------------------------|-------------|--------------------|------------|
| Burlington Dialysis | 6/16/2014 | Yes | 7/29/2014 |
| Dialysis Care of Edgecombe County | 7/1/2014 | Yes | 7/30/2014 |
| Dialysis Care of Rowan County | 9/17/2014 | Yes | 10/22/2014 |

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In the July 2015 SDR the historical utilization rate for Southern Pines as of December 31, 2014 was 85.0% with 51 in-center patients dialyzing on 15 stations.

.2202(a)(2) Mortality rates;

- C- In Section C, page 18, the applicant provides the mortality rates for Southern Pines as follows: 22.68%; 17.20% and 16.16% for the years 2012, 2013, and 2014 respectively.

.2202(a)(3) The number of patients that are home-trained and the number of patients on home dialysis;

- C- In Section C, page 17, the applicant states that Southern Pines does not provide home-training or home dialysis and that all home dialysis patients are referred to Dialysis of Moore County.

.2202(a)(4)

The number of transplants performed or referred;

- C- In Section C, page 18, the applicant states that Southern Pines had two patients who either had transplants or were referred for a transplant during 2014.

.2202(a)(5) The number of patients currently on the transplant waiting list;

- C- In Section C, page 18, the applicant states that Southern Pines had four patients on the transplant list as of December 31, 2014.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

- C- In Section C, page 18, the applicant states that in calendar year 2014, 77 patients were admitted to the hospital as follows: Dialysis related - 5 or 6.5%; Non-dialysis related - 72 or 93.5%.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- In Section C, page 18, the applicant states that there were no patients with infectious disease as of 12/31/2014 and that no patients converted to infectious status during 2014.

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

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).

-NA- This application is to add one station and does not propose a new facility.

.2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This application is to add one station and does not propose a new facility.

.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- This application is to add one station and does not propose a new or replacement facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- In Exhibit K-1(f), the applicant provides a copy of policies and procedures for back up electrical service in the event of a power outage.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- This application is to add one station and does not propose a new facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section K-1(g), page 38, the applicant states: “*Southern Pines will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements*”
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section C-1, page 13, the applicant provides projected patient origin by county which is based on the patients who currently dialyze at the facility. The applicant’s assumptions and methodology used to project patient origin are provided on pages 13 - 17. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- This application is to add one station and does not propose a new facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section L, page 44, the applicant states, “*Southern Pines Dialysis admits and provides dialysis services to patients who have no insurance or other source of*

payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

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- This application is to add one station and does not propose a new 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, pages 13 - 17, the applicant documents the need for the project and demonstrates that it will serve a total of 54 in-center patients on 16 stations at the end of the first operating year, which is 3.375 patients per station per week, or a utilization rate of 84.4%. 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 - 17, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

-C- In Section I, page 33, the applicant states that diagnostic and evaluation services will be provided by FirstHealth Moore Regional. See also Exhibit I-3.

.2204(2) Maintenance dialysis;

-C- In Section I, page 33, the applicant states that in-center maintenance dialysis will be provided by Southern Pines.

.2204(3) Accessible self-care training;

- C- In Section I, page 33, the applicant states that self-care training will be provided by Southern Pines.

.2204(4) Accessible follow-up program for support of patients dialyzing at home;

- C- In Section I, page 3, the applicant states that an accessible follow-up program for support of patients dialyzing at home will be provided by Dialysis Care of Moore County. See also Exhibit I-1.

.2204(5) X-ray services;

- C- In Section I, page 33, the applicant states that x-ray services will be will be provided by FirstHealth Moore Regional. See also Exhibit I-3.

.2204(6) Laboratory services;

- C- In Section I, page 33, the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc. See also Exhibit I-1.

.2204(7) Blood bank services;

- C- In Section I, page 33, the applicant states that blood bank services will be provided by FirstHealth Moore Regional. See also Exhibit I-3.

.2204(8) Emergency care;

- C- In Section I, page 33, the applicant states that emergency care will be provided by FirstHealth Moore Regional. See also Exhibit I-3.

.2204(9) Acute dialysis in an acute care setting;

- C- In Section I, page 33, the applicant states that patients in need of acute dialysis services will be referred to FirstHealth Moore Regional. See also Exhibit I-3.

.2204(10) Vascular surgery for dialysis treatment patients;

- C- In Section I, page 33, the applicant states that vascular surgery for dialysis treatment patients is provided by FirstHealth Moore Regional.

.2204(11) Transplantation services;

- C- In Section I, page 33, the applicant states that transplantation services are provided by Carolinas Medical Center. See also Exhibit I-3.

.2204(12) Vocational rehabilitation counseling and services; and

- C- In Section I, page 33, the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) Transportation

- C- In Section I, page 33, the applicant states that transportation services will be provided by Moore County DSS.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.

- C- In Section H-2, page 30, the applicant states that it will comply with 42 CFR Part 494 (formerly 42 C.F.R. Section 405.2100). The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section H-4, page 31, the applicant discusses staff training at TRC facilities. See also Exhibit H-4, which contains DaVita's in-service training calendar and a training outline of DaVita's continuing education program courses.