

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 7, 2015

Findings Date: April 7, 2015

Project Analyst: Gloria C. Hale

Team Leader: Lisa Pittman

Project ID #: F-10371-15

Facility: Dialysis Care of Kannapolis

FID #: 980409

County: Rowan

Applicant(s): Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis

Project: Relocate 5 dialysis stations from Dialysis Care of Rowan County to Dialysis Care of Kannapolis for a total of 25 dialysis stations upon completion of this project, Project I.D. #F-10273-14 (add 1 station) and Project I.D. #F-10109-13 (relocate 6 stations to Copperfield Dialysis Center)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis (DC of Kannapolis) proposes to relocate five dialysis stations from Dialysis Care of Rowan County (DC of Rowan County) to DC of Kannapolis for a total of 25 dialysis stations upon completion of this project, Project I.D. #F-10273-14 (add one station) and Project I.D. F-10109-13 (relocate six stations to Copperfield Dialysis Center). Project I.D. #F-10273-14 will relocate one dialysis station from DC of Rowan County to DC of

Kannapolis, and Project I.D. #F-10109-13 will relocate six dialysis stations from DC of Kannapolis to Copperfield Dialysis Center. DC of Kannapolis and DC of Rowan County are both located in Rowan County. The applicant does not propose to establish new dialysis stations.

### **Need Determination**

The applicant is proposing to relocate dialysis stations within Rowan County; therefore, the county and facility need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) are not applicable to this review.

### **Policies**

*Policy GEN-3: Basic Principles* in the 2014 SMFP is not applicable to this review because neither the county nor the facility need methodology is applicable to this review.

However, *Policy ESRD-2: Relocation of Dialysis Stations* is applicable to this review.

*Policy ESRD-2: Relocation of Dialysis Stations* states,

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

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate five dialysis stations from DC of Rowan County to DC of Kannapolis, both of which are in Rowan County, for a total of 25 dialysis stations upon completion of this project, CON Project I.D. #F-10273-14 (add one station), and Project I.D. F-10109-13 (relocate six stations to Copperfield Dialysis Center). Since both facilities are located in Rowan County, there is no change in the number of dialysis stations in Rowan County. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

The application is consistent with Policy ESRD-2 and 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 currently operates two dialysis facilities in Rowan County. In this application, Total Renal Care of North Carolina, LLC d/b/a DC of Kannapolis proposes to relocate five dialysis stations from DC of Rowan County in Salisbury, to DC of Kannapolis in Kannapolis, both of which are in Rowan County. The applicant states that the project will be completed upon completion of two other projects currently under development, Project I.D. #F-10273-14 (relocate one station from DC of Rowan County to DC of Kannapolis) and Project I.D. #F-10109-13 (relocate six stations from DC of Kannapolis to Copperfield Dialysis Center). In Section III.3, page 19, the applicant states that no patients are projected to transfer from DC of Rowan County to DC of Kannapolis.

**Population to be Served**

In supplemental information, the applicant identifies the population of in-center and home dialysis patients served at DC of Kannapolis as of June 30, 2014, as shown in the table below:

<b>DC of Kannapolis</b>		
<b>Patient's County of Residence</b>	<b>In-Center Patients</b>	<b>Home-Trained Patients</b>
Rowan	23	11
Cabarrus	50	21
Mecklenburg	0	3
Montgomery	0	1
Stanly	0	1
<b>Total</b>	<b>73</b>	<b>37</b>

In supplemental information, the applicant provides the projected patient origin of the in-center patients to be served at DC of Kannapolis for the first two years of operation following completion of the project, as shown below. In Section III.7, page 22, the applicant provides the projected patient origin of the home dialysis patients to be served at DC of Kannapolis for the first two years of operation following completion of the project, as show below:

County	Operating Year 1 CY 2016		Operating Year 2 CY 2017		County Patients as Percent of Total	
	In-Center	Home-trained	In-Center	Home-trained	Year 1	Year 2
Rowan	28	11	29	11	31.2%	31.0%
Cabarrus	60	21	63	21	64.8%	65.1%
Mecklenburg	0	3	0	3	2.4%	2.3%
Montgomery	0	1	0	1	0.8%	0.8%
Stanly	0	1	0	1	0.8%	0.8%
<b>Total</b>	<b>88</b>	<b>37</b>	<b>92</b>	<b>37</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population to be served.

**Need Analysis**

The applicant proposes to relocate five dialysis stations from DC of Rowan County to DC of Kannapolis, both in Rowan County, for a total of 25 dialysis stations upon completion of this project and two others under development. Project I.D. #F-10273-14 will relocate one dialysis station from DC of Rowan County to DC of Kannapolis and Project I.D. #F-10109-13 will relocate six dialysis stations from DC of Kannapolis to Copperfield Dialysis Center, illustrated as follows:

**DC of Kannapolis**

Current # of dialysis stations: 25  
 Relocate one (Project I.D. #F-10273-14): 1  
 Relocate five (Project I.D. #F-10371-15): + 5  
 31  
 Relocate six (Project I.D. #F-10109-13): - 6  
 Total proposed # of dialysis stations upon 25  
 project completion

In Section II.1, page 13, the applicant projects the stations will be utilized at 88.0% of capacity by the end of the first year of operation, December 31, 2016, with 88 patients dialyzing on 25 in-center dialysis stations ( $88/25 = 3.52$ ;  $3.52/4 = 88.0\%$ ).

In Section II.1, page 14, the applicant states that from December 31, 2013 to December 31, 2014, DC of Kannapolis had an increase of 16 in-center patients, or a 25% increase in the patient census. In Section III.3, page 19, the applicant states that with one dialysis station to be relocated from DC of Rowan County to DC of Kannapolis (Project I.D. #F-10273-14), and six dialysis stations to be relocated from DC of Kannapolis to Copperfield Dialysis Center (Project I.D. #F-10109-13) leaving DC of Kannapolis with a total of 20 stations, DC of Kannapolis “will need 25 stations in order to keep their patients on the

*current schedule.” The applicant further states, on page 19, that unless it can relocate five dialysis stations from DC of Rowan County to DC of Kannapolis, “...several patients will have to change shifts or even the days they receive their dialysis services. This would be a significant disruption to the lives of the patients and the transportation system that many patient [sic] rely on for transport to and from their dialysis treatments.*

...

*The purpose of the relocation is to keep the existing patients on their current treatment and transportation schedules.”*

### Projected Utilization

In Section III.7, pages 22-24, the applicant provides its assumptions and methodology used to project utilization at DC of Kannapolis. The applicant states that the in-center patient census of DC of Kannapolis increased from 64 to 80 from December 31, 2013 to December 31, 2014, an increase of 25%. However, the applicant states that it does not expect this rate of growth to continue, rather, it projects the in-center population will grow at a “conservative” annual rate of 5% during 2015, 2016 and 2017. The Average Annual Change Rate (AACR) for the past five years for Rowan County is 4.8%, according to the January 2015 Semiannual Dialysis Report (SDR). The applicant’s use of an annual growth rate of 5% to project utilization is reasonable given the 25% increase in in-center patients from December 31, 2013 to December 31, 2014. Moreover, application of the Five Year AACR for Rowan County of 4.8% to the applicant’s methodology results in the same projected utilization for project years one and two as using the 5% annual growth rate.

The applicant calculates the projected utilization for DC of Kannapolis in Section III.7, pages 23-24, as follows:

December 31, 2014 - DC of Kannapolis begins with 80 in-center patients.

January 1, 2015 – December 31, 2015 – an annual growth rate of 5% is applied for a census of 84 in-center patients ( $80 \times 1.05\% = 84$ ).

January 1, 2016 – December 31, 2016 – the patient census is increased by the annual growth rate of 5% for a census of 88.2 in-center patients for the end of Operating Year One.

January 1, 2017 – December 31, 2017 – the patient census is increased by the annual growth rate of 5% for a census of 92.61 in-center patients for the end of Operating Year Two.

The applicant states that the number of patients is rounded down to the nearest whole number, resulting in 88 in-center patients for Operating Year One and 92 in-center patients for Operating Year Two. In addition, the applicant states, on page 24, that there

were 37 home-trained patients and that this number is not expected to grow since “*the patients are spread over five counties.*”

Therefore, the applicant projects to serve 88 in-center patients dialyzing on 25 stations by the end of Operating Year One for a utilization rate of 88.0% or 3.52 patients per station [ $88/25 = 3.52/4.0 = 0.880$  or 88.0%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant demonstrates that the proposed relocation of dialysis stations to DC of Kannapolis would meet the minimum performance standard requirements in the Rule.

### Access to Services

In Section VI.1, page 32, the applicant states,

*“DC of Kannapolis, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve patients without regard to race, sex, age, handicap, or other ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

...

*DC of Kannapolis does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

In Section VI.2, page 33, the applicant projects that 81.1% of its patients will have all or part of their services covered by Medicare and/or Medicaid, and 5.4% will be covered by VA. The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population projected to be served has for the proposed relocation of five dialysis stations from DC of Rowan County to the DC of Kannapolis facility, and demonstrates that all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate five existing certified dialysis stations from DC of Rowan County to DC of Kannapolis, both in Rowan County, for a total of 25 dialysis stations upon completion of this project, Project I.D. #F-10273-14 (add one station), and Project I.D. #F-10109-13 (relocate six stations to Copperfield Dialysis Center).

In Section III.3, page 20, the applicant discusses how the needs of dialysis patients at DC of Rowan County will continue to be met after the relocation of stations to DC of Kannapolis, as follows:

As of June 30, 2014, DC of Rowan County had 97 in-center dialysis patients, 29 stations, and a utilization rate of 83.62%, based on data in the January 2015 SDR.

In Project I.D. #F-10273-14, currently under development, DC of Rowan County will relocate one dialysis station to DC of Kannapolis and no in-center dialysis patients will be transferred, leaving 28 stations ( $29-1=28$ ).

The applicant proposes in this project to relocate five dialysis stations from DC of Rowan County to DC of Kannapolis, leaving DC of Rowan County with 23 stations ( $28-5=23$ ). No in-center dialysis patients will transfer to DC of Kannapolis.

The applicant uses the Five Year Average Annual Change Rate (AACR) for Rowan County of 4.8% in the January 2015 SDR to calculate the number of in-center patients projected at DC of Rowan County as follows:

July 1, 2014 – December 31, 2014 – 97 in-center patients  $\times 1.024 = 99.33$

January 1, 2015 – December 31, 2015 – 99.33 in-center patients  $\times 1.048 = 104.10$

The expected date of completion for this project is January 1, 2016. The applicant states that it intends to submit a CON application for the April 1, 2015 review cycle to add four dialysis stations to DC of Rowan County using the Facility Need Methodology. The additional four dialysis stations would be added by January 1, 2016 for a total of 27 stations ( $23+4=27$ ).

The applicant states that if the Five Year AACR is 4.8% for Rowan County for July 1, 2014 – January 1, 2015, DC of Rowan County will have 104 in-center patients and 27 dialysis stations as of January 1, 2016 for a utilization rate of 96% [96.3%] or 3.85 patients per station ( $104/27 = 3.85/4 = 96.3\%$ ).

To summarize, the applicant states that it intends to file a CON application for the April 1, 2015 review cycle to add four dialysis stations to DC of Rowan County based on the Facility Need Methodology. The applicant projects that DC of Rowan County will have a utilization rate of 96% [96.3%], with 104 in-center patients dialyzing on 27 stations as of January 1, 2016, which is the projected certification date for the proposed project.

Therefore, the applicant demonstrates that the needs of the population presently served at DC of Rowan County will continue to be adequately met following the proposed relocation of five dialysis stations from DC of Rowan County to DC of Kannapolis and that access for medically underserved groups will not be negatively impacted.

In summary, the applicant proposes to relocate five dialysis stations from DC of Rowan County to DC of Kannapolis, both in Rowan County, upon completion of this project and Project I.D. #F-10273-14 (add one station), and Project I.D. #F-10109-13 (relocate six stations to Copperfield Dialysis Center). The applicant adequately demonstrates that DC of Rowan County, the facility from which dialysis stations would be relocated, would have sufficient capacity following the relocation of stations to DC of Kannapolis. Thus, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. Therefore, the application is conforming to this criterion.

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

#### CA

In Section III.9, pages 24-25, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintaining the status quo - the applicant states that it dismissed this alternative because the facility is growing rapidly, increasing by 25% in 2014.
- 2) The proposed alternative, relocating five dialysis stations from DC of Rowan County to DC of Kannapolis - the applicant states that this alternative would *“help meet the growing demand for dialysis services at the DC of Kannapolis facility, to keep current patient treatment schedules intact as well as patient transportation schedules.”*

After considering the above alternatives, the applicant states that the second alternative, to relocate five dialysis stations from DC of Rowan County to DC of Kannapolis, is the most effective alternative.

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 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 Dialysis Care of Kannapolis shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC shall relocate no more than five certified (5) dialysis stations to Dialysis Care of Kannapolis for a total of no more than 25 certified dialysis stations, which shall include any isolation or home hemodialysis stations, upon the completion of this project, Project I.D. #F-10273-14 and Project I.D. #F-10109-13.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall install plumbing and electrical wiring through the walls for no more than five (5) dialysis stations, which shall include any isolation or home hemodialysis stations.**
  - 4. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify five (5) dialysis stations at Dialysis Care of Rowan County for a total of no more than 23 dialysis stations at Dialysis Care of Rowan County upon project completion.**
  - 5. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis 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

In Section VIII.1, page 41, the applicant states that there will be no capital cost for the proposed project and that both dialysis machines and chairs will be transferred to DC of Kannapolis from DC of Rowan County.

In Exhibit 17, the applicant provides a copy of the most recent United States Securities and Exchange Commission Form 10-K filed by DaVita Healthcare Partners, Inc. (DaVita), the parent company of Total Renal Care of North Carolina, LLC. Included in Form 10-K are the audited financial statements for the years ended December 31, 2012 and 2013. The form shows that as of December 31, 2013, DaVita had \$946,249,000 in cash and cash equivalents with \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). (See page F-6 of Exhibit 17.) The applicant adequately demonstrates the immediate and long-term financial feasibility of the proposal.

In Section X.1, page 48, the applicant provides its allowable charges per treatment for each payment source for DC of Kannapolis, as illustrated below:

**Dialysis Care of Kannapolis**

Source of Payment	In-Center Charge Per Treatment
Private Pay	\$239.43
Commercial Insurance	\$1,275.00
Medicare	\$239.43
Medicaid	\$143.00
VA	\$193.00
Medicare/Medicaid	\$239.43
Medicare/Commercial	\$239.43

In Sections X.2-X.4, pages 49-52, the applicant projects revenues and operating expenses for DC of Kannapolis, as illustrated below:

DC of Kannapolis	Operating Year 1 CY 2016	Operating Year 2 CY 2017
Total Net Revenue	\$5,467,964	\$5,630,421
Total Operating Expenses	\$4,451,016	\$4,579,463
<b>Net Profit</b>	<b>\$1,016,948</b>	<b>\$1,050,957</b>

However, the applicant projected its revenues, in part, on a total of 86 in-center patients for Operating Year One and 90 in-center patients in Operating Year Two, rather than the 88 and 92 in-center patients it projected for Operating Years One and Two, respectively. The discussion regarding projected utilization found in Criterion 3, is incorporated herein by reference. The Project Analyst concludes that both projected total net revenue and net profit would be higher if 88 and 92 in-center patients were used to project revenues than that stated by the applicant.

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including

the number of projected treatments, are reasonable and adequately supported. See Section X, pages 48-53, for the applicant's assumptions.

The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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.

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The applicant proposes to relocate five existing certified dialysis stations from DC of Rowan County to DC of Kannapolis, both in Rowan County, for a total of 25 dialysis stations upon completion of this project, Project I.D. #F-10273-14 (add one station), and Project I.D. #F-10109-13 (relocate six stations to Copperfield Dialysis Center). According to the January 2015 SDR, DC of Kannapolis and DC of Rowan County are the only dialysis facilities in Rowan County, discussed as follows:

**Rowan County Dialysis Facility Data  
June 30, 2014**

<b>Rowan County Dialysis Facilities</b>				
<b>Facility</b>	<b>Owner</b>	<b>Location</b>	<b>Number of Stations</b>	<b>Utilization</b>
DC of Kannapolis	Total Renal Care of North Carolina, LLC	Kannapolis	25	73.0%
DC of Rowan County	Total Renal Care of North Carolina, LLC	Salisbury	29	83.6%

Total Renal Care of North Carolina, Inc. d/b/a DC of Kannapolis is not adding dialysis stations in Rowan County, rather it is relocating stations from an existing facility, DC of Rowan County, to DC of Kannapolis. The project will not change the total number of dialysis stations in Rowan County. As shown in the Rowan County Dialysis Facility Data table above, DC of Rowan County was operating at over 83% of capacity as of June 30, 2014.

In Section III.7, page 23, the applicant demonstrates that DC of Kannapolis will serve a total of 88 in-center patients on 25 dialysis stations at the end of the first operating year, which is 3.52 patients per station per week, or a utilization rate of 88.0% ( $88/25 = 3.52$ ;  $3.52/4 = 88.0\%$ ). On page 24, the applicant states that the number of home-trained patients receiving services at DC of Kannapolis as of June 30, 2014, will not change. On June 30, 2014 there were 37 home-trained patients.

Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Rowan County. Therefore, 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 VII.1, page 37, the applicant projects no change in the number of FTE positions following completion of the proposed project. The number of projected FTE positions is illustrated in the table below.

<b>Position</b>	<b>Projected # of FTEs</b>
Registered Nurse	4.0
Home Training Registered Nurse	2.0
Patient Care Technician	11.0
Bio-Medical Technician	0.7
Medical Director*	N/A
Administrator	1.0
Dietitian	1.0
Social Worker	1.0
Unit Secretary	1.0
Other-Reuse	1.0
<b>Total</b>	<b>22.7</b>

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

In Section V.4, page 30, the applicant states that the Medical Director for DC of Kannapolis, Dr. John Gerig, has indicated his willingness to continue to serve in that capacity. In Exhibit 12, the applicant provides a letter from Dr. John Gerig, dated January 12, 2015, confirming his support for the additional dialysis stations proposed for DC of Kannapolis and his role as Medical Director of the facility. In Section VII.4, page 38, the applicant states they anticipate no difficulty in hiring staff for any openings that may occur at the DC of Kannapolis dialysis facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section V.1, page 28, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicant discusses coordination with the existing health care system on page 30, stating that it has “...over the years established relationships with other agencies in Kannapolis and Concord”. In addition, in Exhibit 9, the applicant provides a copy of a signed transfer agreement with

Northeast Medical Center (currently named Carolinas Medical Center-NorthEast) to provide acute hemodialysis. In Exhibit 10, the applicant provides a copy of an agreement with Carolinas Medical Center to provide transplantation services. 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. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (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 VI.1, page 32, the applicant states,

*“DC of Kannapolis, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

In Section VI.1, pages 32-33, the applicant states that 91.3% of the in-center patients and 81.1% of the home dialysis patients who received services at DC of Kannapolis, had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the historical payment sources for the existing facility:

<b>CURRENT PAYOR MIX</b>		
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE FOR IN-CENTER</b>	<b>PERCENTAGE FOR HOME-TRAINED</b>
Medicare	33.8%	24.3%
Medicaid	12.5%	5.4%
Medicare/Medicaid	22.5%	29.8%
Commercial Insurance	6.2%	13.5%
VA	2.5%	5.4%
Medicare/Commercial	22.5%	21.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Rowan County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Rowan County	18.7%	7.6%	18.9%
Statewide	16.5%	6.7%	19.7%

\* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2013 – 12/31/2013*, page 99).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services.

Additionally, the United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis...”*<sup>2</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which shows that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native Americans (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”* (p. 216)

<sup>1</sup> <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.3%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

<b>ESRD SPENDING BY PAYOR*</b>		
<b>PAYOR</b>	<b>SPENDING IN BILLIONS</b>	<b>% OF TOTAL SPENDING</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

\*Source: 2013 USRDS Annual Data Report, page 332.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is therefore 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

<sup>3</sup> <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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 VI.1, page 35, the applicant states,

*“DC of Kannapolis 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.”*

In Section VI.6, page 36, 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 VI.1, page 34, the applicant provides the projected payor mix for DC of Kannapolis for both in-center and home-trained dialysis patients, as follows,

**DC of Kannapolis  
Projected Patient Payor Mix**

<b>Payor Source</b>	<b>In-Center Patients</b>	<b>Home-Trained Patients</b>
Medicare	33.8%	24.3%
Medicaid	12.5%	5.4%
Medicare/Medicaid	22.5%	29.8%
Commercial Insurance	6.2%	13.5%
VA	2.5%	5.4%
Medicare/Commercial	22.5%	21.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 91.3% of in-center patients and 81.1% of home-trained patients will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 35, the applicant states that patients have access to services upon referral to a Nephrologist who has privileges at DC of Kannapolis and that the referrals typically come from primary care physicians or specialty physicians. In addition, patients, friends or families may contact a Nephrologist with privileges at the facility directly and the patient will be evaluated and admitted for dialysis services if medically necessary.

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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 V.3, page 29, the applicant states that it has offered DC of Kannapolis as a clinical training site for nursing students from Rowan-Cabarrus Community College. In Exhibit 11, the applicant provides a copy of a letter, dated March 10, 2014, to the President of Rowan-Cabarrus Community College offering DC of Kannapolis as a clinical training site. In addition, the applicant states, on page 30, that it is open to any other clinical training programs that may be interested in utilizing DC of Kannapolis as a training site. The information provided in Section V.3 and Exhibit 11 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.

C

The applicant proposes to relocate five existing certified dialysis stations from DC of Rowan County to DC of Kannapolis, both in Rowan County, for a total of 25 dialysis stations upon completion of this project, Project I.D. #F-10273-14 (add one station), and Project I.D. #F-10109-13 (relocate six stations to Copperfield Dialysis Center). According to the January 2015 SDR, there are two dialysis facilities in Rowan County and both are operated by Total Renal Care of North Carolina, LLC, as follows:

<b>Rowan County Dialysis Facilities</b>				
<b>Facility</b>	<b>Owner</b>	<b>Location</b>	<b>Number of Stations</b>	<b>Utilization</b>
DC of Kannapolis	Total Renal Care of North Carolina, LLC	Kannapolis	25	73.0%
DC of Rowan County	Total Renal Care of North Carolina, LLC	Salisbury	29	83.6%

In Section V.7, page 31, 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 proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. DC of Kannapolis is one of two dialysis facilities in Rowan County. The other facility, located in Salisbury in Rowan County, is owned and operated by Total Renal Care of North Carolina, LLC.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application 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 it 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 it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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

The applicant proposes to relocate five existing certified dialysis stations from DC of Rowan County to DC of Kannapolis, both in Rowan County, for a total of 25 dialysis stations upon completion of this project, Project I.D. #F-10273-14 (add one station), and Project I.D. #F-10109-13 (relocate six stations to Copperfield Dialysis Center). According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, both DC of Kannapolis and DC of Rowan County have operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, 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, which 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- Section II.1, page 12, and in Exhibit 7 (copy of the January 2015 SDR, Table A), the applicant provides the utilization rate for DC of Kannapolis.

- .2202(a)(2) *Mortality rates;*  
-C- In Section IV.2, page 26, the applicant reports 2012, 2013 and 2014 facility mortality rates for DC of Kannapolis.
- .2202(a)(3) *The number of patients that are home-trained and the number of patients on home dialysis;*  
-C- In Section IV.3, page 26, the applicant states that DC of Kannapolis had 37 home trained patients as of December 31, 2014.
- .2202(a)(4) *The number of transplants performed or referred;*  
-C- In Section IV.4, page 27, the applicant reports that DC of Kannapolis referred 7 patients for transplant evaluation in 2014, and 5 patients received transplants in 2013.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 27, the applicant states that DC of Kannapolis has 6 patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- In Section IV.6, page 27, the applicant reports a total of 235 hospital admissions in 2014; 78.7% were non-dialysis related and 21.3% were dialysis-related.
- .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 IV.7, page 27, the applicant reports that there were no patients with infectious disease or who converted to infectious status at DC of Kannapolis 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- DC of Kannapolis is an existing 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- DC of Kannapolis is an existing facility.

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

-NA- DC of Kannapolis is an existing facility.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit 8 contains excerpts from DaVita Inc.'s Hemodialysis Policies, Procedures & Guidelines, Vol. 1, which includes a procedure for performing operational checks on backup generators.

.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- DC of Kannapolis is an existing 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- The applicant states, in Section XI.6, page 58, that it will comply with all applicable laws and regulations listed above and that "...the Office of Licensure and Certification inspects each dialysis facility under CMS guidelines on a regular basis to ensure compliance with all applicable laws and regulations." See also Section VII.1, page 37.

.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 supplemental information, the applicant provides projected patient origin for DC of Kannapolis. In supplemental information and in Section IV.7, pages 22-24, the applicant provides its assumptions and methodology for its projections.

.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- DC of Kannapolis is an existing 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 II.9, page 12, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Dialysis Care Kannapolis will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

### **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 facility. DC of Kannapolis is an existing 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 II.1, pages 12-13, the applicant demonstrates the need for five additional dialysis stations for a total of 25 stations, projecting 88 in-center patients at the end of the first operating year for a utilization rate of 3.5 patients per station.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility.

### **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- The applicant states, in Section V, page 28, that diagnostic and evaluation services will be provided by Northeast Medical Center [Carolinas Medical Center-NorthEast].
- .2204(2) *Maintenance dialysis;*
- C- The applicant states, in Section V, page 28, that DC of Kannapolis will provide

maintenance dialysis.

.2204(3) *Accessible self-care training;*

- C- The applicant states, in Section II.2, page 17, that the facility provides full support for hemodialysis patients. In Section V.1, page 28, the applicant states that self-care training is provided for hemodialysis patients and intermittent peritoneal dialysis patients.

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

- C- The applicant states, in Section V.2, page 29, that follow-up of patients dialyzing at home is provided by facility staff using facility protocols and routines. In addition, monitoring of home-trained patients is done by the Quality Management team.

.2204(5) *X-ray services;*

- C- The applicant states, in Section V.1, page 28, that x-ray services will be provided by Northeast Medical Center [Carolinas Medical Center-NorthEast].

.2204(6) *Laboratory services;*

- C- The applicant states, in Section V.1, page 28, that laboratory services will be provided off-site by Dialysis Laboratories.

.2204(7) *Blood bank services;*

- C- The applicant states, in Section V.1, page 28, that blood bank services will be provided by Northeast Medical Center [Carolinas Medical Center-NorthEast].

.2204(8) *Emergency care;*

- C- The applicant states, in Section V.1, page 28, that emergency care will be provided by Northeast Medical Center [Carolinas Medical Center-NorthEast].

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

- C- The applicant states, in Section V.1, page 28, that acute dialysis in an acute care setting will be provided by Northeast Medical Center [Carolinas Medical Center-NorthEast].

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

- C- The applicant states, in Section V.1, page 28, that vascular surgery will be provided by Northeast Medical Center [Carolinas Medical Center-NorthEast].

.2204(11) *Transplantation services;*

- C- The applicant states, in Section V.1, page 28, that transplantation services will be provided by Carolinas Medical Center. A copy of an agreement between DC of Kannapolis and Carolinas Medical Center for these services is provided in Exhibit 10.

- .2204(12) *Vocational rehabilitation counseling and services; and*  
-C- These services will be provided by North Carolina Vocational Rehabilitation, as stated in Section V.1, page 28.
- .2204(13) *Transportation*  
-C- The applicant states, in Section V.1, page 28, that transportation services will be provided by Cabarrus and Rowan Transportation Services.

#### **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 (Replaced with 42 CFR Part 494).*  
-C- In Section VII.1, pages 37-38, the applicant states the proposed facility will comply with all staffing requirements set forth in the federal code. In addition, in Section VII.1, page 37, the applicant provides a proposed staffing chart, and on page 40, provides a table showing the number of direct care staff for each shift to be offered at the facility. 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- The applicant states, in Section II.3, page 17, that it provides continuous updates to staff to ensure high quality patient care as part of its “*Quality Management Program.*” Exhibit 22 contains an outline of the annual in-service training program utilized at the facility.