

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 7, 2016

Findings Date: June 7, 2016

Project Analyst: Gloria C. Hale

Team Leader: Lisa Pittman

Project ID #: F-11154-16

Facility: Dialysis Care of Rowan County

FID #: 944673

County: Rowan

Applicant: Total Renal Care of North Carolina, LLC

Project: Add six dialysis stations for a total of 33 stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis)

### 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.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County proposes to add six dialysis stations for a total of 33 certified dialysis stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis).

#### Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of five dialysis stations in Rowan County. There would need to be a deficit of at least 10 stations to trigger a county need. Therefore, there is no county need for additional stations in Rowan County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Dialysis Care of Rowan County in the January 2016 SDR is 3.83 patients per station. This utilization rate was calculated based on 111 in-center dialysis patients and 29 certified dialysis stations as of June 30, 2015 (111 patients / 29 stations = 3.83 patients per station). Application of the facility need methodology indicates that six additional stations are needed for this facility, as illustrated in the following table:

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		95.69%
Certified Stations		29
Pending Stations		4
<b>Total Existing and Pending Stations</b>		<b>33</b>
In-Center Patients as of 6/30/15 (SDR2)		111
In-Center Patients as of 12/31/14 (SDR1)		98
Step	Description	Result
	Difference (SDR2 - SDR1)	13
(i)	Multiply the difference by 2 for the projected net in-center change	26
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.2653
(ii)	Divide the result of step (i) by 12	0.0221
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.1326
(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	125.71
(v)	Divide the result of step (iv) by 3.2 patients per station	39.28
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>6</b>

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

**Policies**

*Policy GEN-3: Basic Principles*, page 39, of the 2016 SMFP is applicable to this review. *Policy GEN-3* states:

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

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, and in Exhibit K. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, pages 15-16, Section L, pages 44-48, and Exhibit L. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11, and N.1, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2016 SDR and with *Policy GEN-3: Basic Principles*. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to

which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County, whose parent company is DaVita HealthCare Partners, Inc. (DaVita), proposes to add six dialysis stations for a total of 33 certified dialysis stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis).

**Population to be Served**

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Rowan County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for Dialysis Care of Rowan County for in-center and home peritoneal dialysis (PD) patients as of June 30, 2015, which is summarized in the following table:

**Dialysis Care of Rowan County  
Historical Patient Origin, June 30, 2015**

	<b># of In-Center Patients</b>	<b># of Home PD Patients</b>
Rowan	104	28
Cabarrus	2	0
Gaston	2	1
Davidson	1	0
Davie	0	1
[Iredell]	[0]	[1]
Virginia	1	0
Other States	1	0
<b>Total</b>	<b>111</b>	<b>30[31]</b>

\*Project Analyst’s corrections are in brackets and are based on the ESRD Data Collection Form for Dialysis Care of Rowan County for June 2015.

In Section C.1, page 13, the applicant provides the projected patient origin for Dialysis Care of Rowan County for in-center and home PD patients for the first two years of operation following project completion, as illustrated in the following table:

**Dialysis Care of Rowan County  
 Projected Patient Origin by County**

	Operating Year 1 CY2018		Operating Year 2 CY2019		County Patients as a Percent of Total	
	# of In-Center Patients	# of Home PD Patients	# of In-Center Patients	# of Home PD Patients	Year 1	Year 2
Rowan	138	31	150	32	94.9% [94.4%]	95.3% [94.8%]
Cabarrus	2	0	2	0	1.1%	1.0%
Gaston	2	1	2	1	1.7%	1.6%
Davidson	1	0	1	0	0.6%	0.5%
Davie	0	1	0	1	0.6%	0.5%
[Iredell]	[0]	[1]	[0]	[1]	[0.6%]	[0.5%]
Virginia	1	0	1	0	0.6%	0.5%
Other States	1	0	1	0	0.6%	0.5%
<b>Total</b>	<b>145</b>	<b>33 [34]</b>	<b>157</b>	<b>34 [35]</b>	<b>100.0%**</b>	<b>100.0%**</b>

\*Project Analyst's corrections are in brackets and are based on applicant's error in beginning census used in methodology for projecting utilization for home PD patients.

\*\*Percentages may not foot due to rounding.

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

**Analysis of Need**

The applicant proposes to add six dialysis stations to Dialysis Care of Rowan County for a total of 33 certified dialysis stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis) pursuant to the 2016 SMFP Facility Need Methodology.

**In-Center Patients**

As of June 30, 2015, as reported in the January 2016 SDR, the utilization rate at Dialysis Care of Rowan County was 95.69% or 3.83 patients per station per week based on 111 in-center patients utilizing 29 certified dialysis stations.

In Section C.1, pages 13-15, the applicant provides the following assumptions used to project utilization for in-center patients:

1. Total Renal Care of North Carolina, LLC (TRC) is approved to relocate a combined total of six dialysis stations from Dialysis Care of Rowan County to Dialysis Care of Kannapolis, Project I.D. #F-10273-14 (1) and Project I.D. #F-10371-15 (5). TRC is also approved to add four dialysis stations to Dialysis Care of Rowan County, Project I.D. #F-11023-15. No patients will be transferred as a result of any of these projects.

2. The applicant projects the first two full operating years of the project will be CY2018 and CY2019.
3. The Average Annual Change Rate (AACR) for Rowan County of 8.6%, as reported in Table B of the January 2016 SDR, is used to project in-center patients from Rowan County. No growth rates are applied for the seven in-center patients from other counties and states. The period of growth for in-center patients from Rowan County begins July 1, 2015.

Projected Utilization, In-Center Patients

In Section C.1, page 14, the applicant provides its methodology for projecting utilization for in-center patients for operating years one and two, as follows:

<b>Dialysis Care of Rowan County</b>	<b>In-Center Patients</b>
Beginning census of Rowan County in-center patients only, July 1, 2015	104
The census of Rowan County in-center patients is projected forward six months to December 31, 2015, using one-half of the AACR for Rowan County, then the seven patients outside the county are added.	$(104 \times 1.043) + 7 = 115.47$
The census of Rowan County in-center patients is projected forward one year to December 31, 2016, using the AACR for Rowan County, then the seven patients outside the county are added.	$(108.47 \times 1.086) + 7 = 124.80$
The census of Rowan County in-center patients is projected forward one year to December 31, 2017, using the AACR for Rowan County of 8.6%, then the seven patients outside the county are added.	$(117.80 \times 1.086) + 7 = 134.93$
The census of Rowan County in-center patients is projected forward one year to December 31, 2018, using the AACR for Rowan County of 8.6%, then the seven patients from outside the county are added. This is the projected ending census for Operating Year 1.	$(127.93 \times 1.086) + 7 = 145.93$
The census of Rowan County in-center patients is projected forward one year to December 31, 2019, using the AACR for Rowan County of 8.6%, then the seven patients outside the county are added. This is the projected ending census for Operating Year 2.	$(138.93 \times 1.086) + 7 = 157.88$

The applicant states, on page 14, that Dialysis Care of Rowan County will have 145 in-center patients, rounded down, by the end of operating year one or 4.39 patients per station per week (145 patients/ 33 stations = 4.39). For the end of operating year two, the applicant projects Dialysis Care of Rowan County will have 157 in-center patients, rounded down, or 4.76 patients per station per week (157 patients/ 33 stations = 4.76). Therefore, the applicant's projected utilization 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).

### Home Peritoneal Dialysis (PD) Patients

The applicant currently provides home PD at Dialysis Care of Rowan County, and, as stated in Section C.1, page 15, it does not propose any changes to its PD services.

In Section C.1, page 15, the applicant states that it assumes its PD population will grow at a rate of one PD patient per year.

### Projected Utilization, Home PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, page 15, as follows:

<b>Operating Year</b>	<b>Start Date</b>	<b>Beginning Census of PD Patients</b>	<b>Ending Census of PD Patients</b>
	7/1/2015	30 [31]	31 [32]
Current Year	1/1/2016	31 [32]	32 [33]
Interim Year	1/1/2017	32 [33]	33 [34]
Operating Year 1	1/1/2018	33 [34]	34 [35]
Operating Year 2	1/1/2019	34 [35]	35 [36]

Note: The Project Analyst's corrections are in brackets.

The Project Analyst notes that the beginning census for projecting utilization for PD patients should be 31, not 30, based on the total number of PD patients reported on the June 2015 ESRD Data Collection Form for Dialysis Care of Rowan County which covers the period, January 1, 2015 – June 30, 2015.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for six additional dialysis stations at Dialysis Care of Rowan County.

### Access to Services

In Section L.1(a), pages 44-45, the applicant states that Dialysis Care of Rowan County makes its services available to all persons without qualifications, including racial and ethnic minorities, women, low-income persons, persons with disabilities, elderly and “*other under-served persons.*” The applicant projects, in Section L.1(b), page 45, that 86.9% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service 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, demonstrates the need the population has for six additional stations at Dialysis Care of Rowan County, and demonstrates the extent to which all residents of the area, including 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.

NA

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

CA

In Section E.1, page 23, the applicant states that the only other alternative to the proposed project that was considered prior to submitting this application was to maintain the status quo. However, the applicant states that maintaining the status quo is not an effective alternative due to the growth rate at the facility.

The applicant states the alternative represented in the application is the most effective alternative to meet the growing demand for dialysis services.

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

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall materially comply with all representations made in the certificate of need application and in clarifying information provided. In those instances where representations conflict, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall materially comply with the last made representation.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall develop and operate no more than six additional dialysis stations for a total of no more than 33 certified stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis), which shall include any isolation or home hemodialysis stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall acknowledge acceptance of and agree to comply with all conditions stated**



**herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

**C**

The applicant proposes to add six dialysis stations for a total of 33 certified dialysis stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis).

In Section F.1, page 24, the applicant states that it projects \$1,747,835 in capital costs to develop this project. The applicant's projected capital costs are as follows:

**Dialysis Care of Rowan County  
Proposed Project Capital Costs**

Construction costs	\$1,325,000
Architect/Engineering fees	\$102,000
Miscellaneous costs*	\$320,835
<b>Total</b>	<b>\$1,747,835</b>

\*Includes dialysis machines, (RO) water treatment equipment, and equipment and furniture

In Sections F.10 and F.11, pages 26-27, the applicant states there will be no start-up expenses or initial operating expenses for this project.

**Availability of Funds**

In Section F.2, page 25, the applicant states it will finance the capital costs with accumulated reserves/owner's equity. Exhibit F-5 contains a letter dated March 10, 2016 from the Chief Accounting Officer for DaVita HealthCare Partners, Inc. (DaVita), the parent company of the applicant, which states that DaVita has committed cash reserves in the amount of \$1,747,835 for the proposed project. Exhibit F-7 contains the Securities and Exchange Commission Form 10-K for DaVita which indicates that as of December 31, 2015, it had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

In Section R, page 60, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

**Allowable Charges**

<b>Payor</b>	<b>In-Center Charge</b>
Medicare	\$230.39
Medicaid	\$143.00
Commercial Insurance	\$1,275.00
Medicare/Commercial	\$230.39
Medicare/ Medicaid	\$230.39
VA	\$193.00

In Section C.1, pages 14-15, and in the pro formas, the applicant provides tables for its projected beginning census, ending census, and average census for in-center patients and home PD patients, respectively, for operating years one and two. The applicant uses the average census for in-center and home PD patients to calculate its financial projections. The following table summarizes the census counts and census averages for each of the first two operating years of the project:

	<b>Operating Year One</b>	<b>Operating Year Two</b>
<b># of In-Center Patients</b>		
Beginning Census	134.0	145.0
Ending Census	145.0	157.0
Average Census	139.5	151.0
<b># of PD Patients</b>		
Beginning Census	33.0 [34.0]	34.0 [35.0]
Ending Census	34.0 [35.0]	35.0 [36.0]
Average Census	33.5 [34.5]	34.5 [35.5]

\*Project Analyst's corrections are in brackets.

The applicant states, in Section C.1, page 15, that the number of home PD patients are projected to increase by one home PD patient per year. The applicant's methodology for projecting home PD patient utilization begins with 30 patients on July 1, 2015, but should have started with 31 patients, adding one patient each subsequent year based on the number of home PD patients reported in the June 2015 ESRD Facilities Data Collection Form. The discussion regarding need found in Criterion (3) is incorporated herein by reference. The applicant's pro formas were calculated based on the average census totals for in-center and home PD patients. Therefore, the pro formas are also inaccurate. However, due to the calculation of home PD patients being short by only one patient, the pro formas still provide a reasonable estimation of revenues, operating expenses, and net income for the proposed project.

The applicant provided pro forma financial statements for the first two operating years of the project in Section R. In Form B of the pro formas, the applicant projects that revenues will exceed operating expenses in each of the first two operating years of the project, as shown in the following table:

	<b>CY2018</b>	<b>CY2019</b>
Gross Patient Revenue	\$7,075,740	\$7,575,392
Deductions from Gross Patient Revenue	\$450,643	\$483,681
Net Patient Revenue	\$6,625,097	\$7,091,711
Operating Expenses	\$4,608,432	\$4,831,415
<b>Net Income</b>	<b>\$2,016,665</b>	<b>\$2,260,295</b>

However, the Project Analyst notes that there are discrepancies in some of the line items of the operating expenses in Form A of the pro formas as compared to calculations for those line items using the assumptions provided for Form A. Using the applicant’s assumptions, the total operating expenses are much higher than stated. In clarifying information, the applicant states that it erroneously used a different income tax rate than what was stated in the assumptions for calculating the amount of income taxes. For other line items, the applicant states that the assumptions were misstated and should have been based on historical values for Dialysis Care of Rowan County and then increased by three percent annually. However, based on clarifying information, the applicant’s proposed project still projects a positive net income in operating years one and two.

Therefore, the assumptions used by the applicant in preparation of the pro forma financial statements 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 on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add six dialysis stations for a total of 33 certified dialysis stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis).

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Rowan County. Facilities may serve residents of counties not included in their service area.

Table A in the January 2016 SDR indicates that there are two dialysis facilities in Rowan County, as follows:

**Rowan County Dialysis Facilities  
June 30, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>
Dialysis Care of Kannapolis	DaVita	76	25	76.00%
Dialysis Care of Rowan County	DaVita	111	29	95.69%

As illustrated above, DaVita, the parent company of the applicant, owns both of the dialysis facilities in Rowan County. Both of the dialysis facilities are well utilized with Dialysis Care of Kannapolis operating at over 75% of capacity and Dialysis Care of Rowan County operating at over 95% of capacity.

In this application, the applicant is proposing to add six dialysis stations based on the facility need methodology. In Section C.1, page 14, the applicant demonstrates that Dialysis Care of Rowan County will serve a total of 145 in-center patients on 33 dialysis stations at the end of the first operating year (CY2018), for a utilization rate of 4.39 patients per station per week, or 110% of capacity ( $145/33 = 4.39$ ;  $4.39/4 = 110\%$ ). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Rowan County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 31, the applicant provides the current and proposed staffing for the facility, as illustrated in the table below:

<b>Dialysis Care of Rowan County Current and Proposed FTEs</b>			
Position	Current	Additional	Total
Medical Director*			
Registered Nurse	4	1	5
Patient Care Technician	11	2	13
Administrator	1	0	1
Dietitian	1	0	1
Social Worker	1	0	1
Home Training RN	2	0	2
Administrative Assistant	1	0	1
Biomed Technician	1	0	1
<b>Total FTEs</b>	<b>22</b>	<b>3</b>	<b>25</b>

\*This is an independent contractor, not an employee.

In Exhibit I-1, the applicant provides a letter from Dr. Ernest Johnson, Medical Director of Dialysis Care of Rowan County, dated February 15, 2016, indicating his support of the project and his willingness to continue to serve as Medical Director of the facility. In Section H.3, pages 32-33, the applicant describes its methods for filling staff positions, including a competitive salary structure and range of benefits to attract qualified employees. 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.

C

In Section I.1, page 35, the applicant includes a list of providers of the necessary ancillary and support services for the proposed project. Exhibit I-1 contains a copy of a letter from the Facility Administrator for Dialysis Care of Rowan County which states that the facility has established relationships with various healthcare providers and that it will continue to provide necessary services through existing agreements with them. A copy of the facility's existing laboratory services agreement and an agreement with Dialysis Care of Kannapolis for home training for hemodialysis are also included in Exhibit I-1. The letter in Exhibit I-1 from the Facility Administrator, and letters from the facility's Medical Director and another nephrology provider in Exhibit I-3, demonstrate support for the project and coordination with the existing health care system. Therefore, 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 L.1, pages 44-45, the applicant states that its policy is to make dialysis services available to all persons, *“without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.”* In addition, the applicant states that it *“helps uninsured or underinsured patients with identifying and applying for financial assistance.”* The applicant provides additional information regarding its financial policies for uninsured or underinsured patients on page 46.

In Section L.7, page 48, the applicant provides the historical payor mix for Dialysis Care of Rowan County, as follows:

**Dialysis Care of Rowan County  
 CY 2015**

<b>Payor Source</b>	<b>Percentage of In-Center Patients</b>	<b>Percentage of PD Patients</b>	<b>Percentage of Total Patients</b>
Medicare	39.0%	34.4%	38.0%
Medicaid	2.9%	3.1%	2.9%
Commercial Insurance	3.8%	9.4%	5.1%
Medicare/Commercial	23.8%	34.4%	26.3%
Medicare/Medicaid	22.9%	9.3%	19.7%
VA	7.6%	9.4%	8.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

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

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority</b>	<b>% Persons in Poverty*</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance*</b>
Rowan	16%	51%	27%	18%	12%	19%
Statewide	15%	51%	36%	17%	10%	15%

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

\*Excludes “White alone” who are “not Hispanic or Latino”

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

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

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

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

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

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;



In Section L.3, page 47, the applicant states,

*“DC of Rowan County 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 L.6, page 47, the applicant states that there have not been any 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 L.1, page 45, the applicant provides the projected payor mix for the proposed services at Dialysis Care of Rowan County for the second operating year (CY2019), as shown in the table below:

**Dialysis Care of Rowan County  
Projected Payor Mix, CY2019**

<b>Payor Source</b>	<b>Percentage of In-Center Patients</b>	<b>Percentage of PD Patients</b>	<b>Percentage of Total Patients</b>
Medicare	39.0%	34.4%	38.0%
Medicaid	2.9%	3.1%	2.9%
Commercial Insurance	3.8%	9.4%	5.1%
Medicare/Commercial	23.8%	34.4%	26.3%
Medicare/Medicaid	22.9%	9.3%	19.7%
VA	7.6%	9.4%	8.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 86.9% of total patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 45, the applicant provides its assumptions used to project payor mix, stating that it is *“based on the sources of patient payment that have been received by the existing facility in the last full operating year.”* The projected payor mix is the same as the applicant's historical payor mix provided in Section L.7, page 48. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 47, the applicant describes the range of means by which a person will have access to the dialysis services at Dialysis Care of Rowan County, including referrals from nephrologists with privileges at the facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 49, the applicant states that Dialysis Care of Rowan County has been offered as a clinical training site for medical assistant students at Brookstone College. Exhibit M-2 contains a copy of an agreement between Brookstone College of Business and several DaVita dialysis facilities, including Dialysis Care of Rowan County, to offer the dialysis facilities as clinical training sites for students enrolled in the college's Medical Assistant and Medical Office Assistant programs. The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately 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 add six dialysis stations for a total of 33 certified dialysis stations upon completion of this project and all of the following projects: I.D. #F-11023-15 (add four stations), I.D. #F-10273-14 (relocate one station to Dialysis Care of Kannapolis), and I.D. #F-10371-15 (relocate five stations to Dialysis Care of Kannapolis).

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Rowan County. Facilities may serve residents of counties not included in their service area.

Table A in the January 2016 SDR indicates that there are two dialysis facilities in Rowan County, as follows:

**Rowan County Dialysis Facilities  
June 30, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>
Dialysis Care of Kannapolis	DaVita	76	25	76.00%
Dialysis Care of Rowan County	DaVita	111	29	95.69%

As illustrated above, DaVita, the parent company of the applicant, owns both of the dialysis facilities in Rowan County. Both of the dialysis facilities are well utilized with Dialysis Care of Kannapolis operating at over 75% of capacity and Dialysis Care of Rowan County operating at over 95% of capacity.

In Section N.1, page 50, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states that the proposed project will have no effect on competition, and, that while it could serve as an alternative for dialysis patients “*to select a provider that gives them the highest quality service and better meets their needs...*,” it is primarily seeking to serve existing patients and accommodate projected growth.

In addition, the applicant states, on page 50,

*“The expansion of the DC of Rowan County will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”*

See also Sections B, C, E, F, H and L 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 the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the 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 it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit O-3, the applicant provides information on quality of care provided at DaVita's ESRD facilities, including citations received during the 18 months immediately preceding the submittal of the application through the date of the decision, and their resolution. One of the facilities had an immediate jeopardy citation and the other had two standard level deficiencies of the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities, 42 CFR Part 494. In Section O.3, page 51, the applicant states that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

**10A NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- Dialysis Care of Rowan County is an existing facility.

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

-C- In Section C.1, pages 13-14, the applicant projects 145 in-center patients dialyzing on 33 stations at the end of the first operating year for a utilization rate of 4.39 patients per station per week, thereby documenting the need for the additional stations. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 13-15, and Section C.7, pages 17-19. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.