

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 25, 2018

Findings Date: May 25, 2018

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11452-18

Facility: Cannon Dialysis

FID #: 180049

County: Cabarrus

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

Project: Develop a new eleven-station facility in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County.

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 (TRC and/or the applicant), d/b/a Cannon Dialysis proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. In addition to in-center (IC) dialysis, Cannon Dialysis would offer a peritoneal dialysis (PD) program but does not propose to initially offer a home hemodialysis (HH) program. Dialysis Care of Kannapolis will be certified for 20 dialysis stations upon completion of this project and Project ID#F-11264-16 (relocate two stations) and North Charlotte Dialysis will be certified for 29 dialysis stations upon completion of this project, Project ID#F-11019-15

(relocate 4 stations), Project ID# F-11108-15 (relocate 10 stations), Project ID#F-11252-16 (add 9 stations), Project ID#F-11288-17 (relocate 4 stations). The parent company of TRC is DaVita, Inc. (DaVita).

### **Need Determination**

The county and facility need methodologies in the January 2018 Semiannual Dialysis Report (SDR) and the 2018 State Medical Facilities Plan (SMFP) are not applicable to this review.

### **Policies**

There are one policy in the 2018 SMFP applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*, on page 27.

### **Policy ESRD-2**

*Policy ESRD-2* states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing 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*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing 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.”*

TRC proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. Cabarrus county is contiguous to both Rowan and Mecklenburg counties. In Section B.3, page 8, and Section C.2, page 18, the applicant states that Dialysis Care of Kannapolis (44 Cabarrus County IC patients) and North Charlotte Dialysis (1 Cabarrus County IC patient) are both currently serving residents of Cabarrus County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

According to Table D of the January 2018 SDR, Rowan County has a projected surplus of 8 dialysis stations. Following the applicant’s proposed relocation of eight existing stations from

Dialysis Care of Kannapolis to Cabarrus County, Rowan County would have a surplus of 0 dialysis stations ( $8-8 = 0$ ). Therefore, the proposal will not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations.

According to Table D of the January 2018 SDR, Mecklenburg County has a projected surplus of 44 dialysis stations. Following the applicant's proposed relocation of three existing stations from North Charlotte Dialysis to Cabarrus County, Mecklenburg County would have a surplus of 41 dialysis stations ( $44-3 = 41$ ). Therefore, the proposal will not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations.

According to Table D of the January 2018 SDR, Cabarrus County has a projected deficit of eleven dialysis stations. Following the applicant's proposed relocation of eight existing stations from Dialysis Care of Kannapolis and three existing stations from North Charlotte Dialysis to Cabarrus County, Cabarrus County would have a deficit of zero dialysis stations ( $11 - (8+3) = 0$ ). Therefore, the proposal will not result in a surplus, or increase an existing surplus in the number of dialysis stations in the county that would be gaining stations. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the proposal is consistent with Policy ESRD 2 for the following reasons:
  - The existing dialysis stations are being relocated from counties that are contiguous to Cabarrus County.
  - The relocation of existing dialysis stations from Rowan and Mecklenburg counties will not result in a deficit, or increase an existing deficit in the number of dialysis stations in either of the counties that would be losing dialysis stations.
  - The relocation of existing dialysis stations from contiguous counties to Cabarrus county will not result in a surplus, or increase an existing surplus in the number of dialysis stations in Cabarrus county.
  - The applicant demonstrates that both of the facilities (Dialysis Care of Kannapolis and North Charlotte Dialysis) from which dialysis stations are being relocated to Cabarrus county currently serve residents of Cabarrus county.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

TRC proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. In addition to in-center dialysis, Cannon Dialysis would offer a PD program but does not propose to initially offer a HH program. Dialysis Care of Kannapolis will be certified for 20 dialysis stations upon completion of this project and Project I.D. #F-11264-16 (relocate two stations) and North Charlotte Dialysis will be certified for 29 dialysis stations upon completion of this project, Project ID#F-11019-15 (relocate 4 stations), Project ID# F-11108-15 (relocate 10 stations), Project ID#F-11252-16 (add 9 stations), Project ID#F-11288-17 (relocate 4 stations).

**Patient Origin**

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 14, the applicant provides the projected patient origin for Cannon Dialysis for IC and PD patients for the first two years of operation following completion of the project as follows:

County	OY1 (CY2020)		OY2 (CY2021)		County Patients as a Percent of Total	
	IC	PD	IC	PD	OY1	OY2
Cabarrus	37	3	39	4	100%	100%
Total	37	3	39	4	100%	100%

The applicant provides the assumptions and methodology used to project its patient origin on pages 14-17. The applicant’s assumptions are reasonable and adequately supported.

## **Analysis of Need**

In Section C.2, pages 17-18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 14-18, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- 35 Cabarrus County residents who are currently in-center patients at Dialysis Care of Kannapolis, a DaVita dialysis facility in Rowan County, and 1 Cabarrus County resident who is currently an in-center patient at North Charlotte Dialysis, a DaVita dialysis facility in Mecklenburg County, have signed letters indicating that the proposed Cannon Dialysis facility will be more convenient for them and, in many cases, will be closer to their home and that they would consider transferring their care to Cannon Dialysis.
- Two PD patients who reside in Cabarrus County both of whom currently receive their dialysis support at Dialysis Care of Kannapolis have signed letters indicating that the proposed Cannon Dialysis facility will be more convenient for them and they would consider transferring to the proposed Cannon Dialysis facility.
- There are three existing or approved dialysis facilities in Cabarrus County – Copperfield Dialysis, Harrisburg Dialysis Center and an approved new site, Hickory Ridge Dialysis. Based on the signed letters from patients currently dialyzing at Dialysis Care of Kannapolis and North Charlotte Dialysis, the applicant concludes that the proposed new facility will be located closer to where a significant number of its patients who currently receive dialysis services outside the county, reside. In Section C.2, page 18, the applicant states that the development of Cannon Dialysis will reduce the number of DaVita in-center patients living in Cabarrus County and receiving dialysis treatments at DaVita facilities outside of Cabarrus County from 54 patients to 18 patients (54-36 = 18).

The information is reasonable and adequately supported for the following reasons:

- See Exhibit C-1 which contains 38 patient letters of support, 36 from IC patients and two from PD patients. The letters state:

*In-Center:*

*“I fully support this new dialysis facility ... to be built in Kannapolis. ... Having my dialysis treatments at Cannon Dialysis would be more convenient for me. I could travel between home and that location more easily and quickly, which would save me time and money.”*

*Peritoneal Dialysis:*

*“... Having support for my home training at Cannon Dialysis would be closer to my home and much more convenient for me. ...”*

*Projected Utilization*

*Projected Utilization – In-center*

On pages 14-16, the applicant illustrates how in-center patient utilization was projected, which is summarized as follows:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021
- Thirty-five (35) Cabarrus County residents currently dialyzing in-center at Dialysis Care of Kannapolis, a DaVita facility in Rowan County, have signed letters that they would consider transferring to Cannon Dialysis because the proposed facility would be located in Cabarrus County making it more convenient and closer to where they reside. See Exhibit C-1.
- One (1) Cabarrus County resident currently dialyzing in-center at North Charlotte Dialysis, a DaVita facility in Mecklenburg County, has also signed a letter indicating that they would consider transferring to Cannon Dialysis because the proposed facility would be located in Cabarrus County making it more convenient and closer to where they reside. See Exhibit C-1.
- The applicant only projects in-center patients from Cabarrus County.
- In-center patient population of Cabarrus County residents is projected to grow at 5.4% (the Five-Year Average Annual Growth Rate (AAGR) for Cabarrus County) pursuant to Table D in the January 2018 Semi-Annual Dialysis Report (SDR).

The following table illustrates application of these assumptions and the methodology used.

<b>Cannon Dialysis</b>	<b>In-Center Patients</b>
Begin with Cannon Dialysis in-center ESRD patient population as of January 1, 2020. This is the beginning patient census for OY1.	36
Project the in-center ESRD population forward one year to December 31, 2020, using the Five Year AACR for Cabarrus County. <b>This is the patient census at the end of OY1.</b>	$36 \times 1.054 = \mathbf{37.944}$
Project the in-center ESRD population forward one year to December 31, 2021, using the Five Year AACR for Cabarrus County. <b>This is the patient census at the end of OY1.</b>	$37.944 \times 1.054 = \mathbf{39.993}$

The applicant states on page 16 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of both OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 37 and 39 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.36 patients per station per week, or 84.1% (37 patients/11 stations = 3.3636/4 = 0.8409 or 84.1%).
- OY2: 3.5 patients per station per week, or 88.64% (39 patients/11 stations = 3.5454/4 = 0.8864 or 88.64%).

The projected utilization of 3.36 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected in-center utilization is based on reasonable and adequately supported assumptions regarding projected growth.

Projected Utilization-Home PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, page 17, as follows:

<b>Operating Year</b>	<b>Start Date</b>	<b>Beginning Census of PD Patients</b>	<b>Ending Census of PD Patients</b>
Operating Year 1	1/1/20	2	3
Operating Year 2	1/1/21	3	4

On page 17, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains two letters of support for the proposed facility from PD patients who currently receive their support at a DaVita facility indicating that they would consider transferring their care to Cannon Dialysis, if approved, based on the fact that they either live closer to the proposed new facility or it would be more convenient for them.
- TRC assumes the two patients who signed letters of support for the proposed facility will transfer their care to Cannon Dialysis upon certification.
- TRC assumes that the PD patients will increase one patient each year.

Projected utilization for the IC and PD dialysis programs at Cannon Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing Dialysis Care of Kannapolis and North Charlotte Dialysis patients who have signed letters expressing their intention to transfer their care to the proposed Cannon Dialysis facility.
- The applicant’s growth projections are based on an assumption that patient census will increase at an annual rate of 5.4%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Cabarrus County, as reported in Table D of the January 2018 SDR.

**Access**

In Section C.3, page 19, the applicant states, “*By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*”

In Section L.1, page 50, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	9.0%
Medicare	27.6%
Medicare/Medicaid	22.6%
Medicare/Commercial	23.8%
VA	5.0%
Commercial Insurance	12.0%
<b>Total</b>	<b>100.0%</b>

Source: Table, page 50 of the application.

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.



- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

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The following table shows the projected relocation of stations from Dialysis Care of Kannapolis and North Charlotte Dialysis to the proposed Cannon Dialysis facility and identifies the number of patients projected to transfer from the existing facility to the proposed new facility.

<b>Proposed Cannon Dialysis Project</b>		
<b>Facility</b>	<b>Number of Stations to be Relocated</b>	<b>Number of Patients Transferring</b>
Dialysis Care of Kannapolis	8	35
North Charlotte Dialysis	3	1
<b>Total Relocated and Transferred</b>	<b>11</b>	<b>36</b>

In Section D.1, pages 23-26, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

Dialysis Care of Kannapolis

According to the January 2018 SDR, there were 97 patients dialyzing at Dialysis Care of Kannapolis and 25 certified dialysis stations for a utilization rate of 97.0%, or 3.3636 patients per station per week ( $97/25 = 3.88/4 = .97$  or 97.0%) as of June 30, 2017. In Section D.1, page 23, the applicant states that 44 of the 97 in-center patients reside in Cabarrus County, and the remaining patients originate from Rowan County (46 patients), Anson County (1 patient), Iredell County (1 patient), Mecklenburg County (1 patient), Stanly County (1 patient), Wake (1 patient), and Other States (2 patients).

The applicant assumes that the number of in-center patients at Dialysis Care of Kannapolis who reside in Rowan County will increase at a rate of 6.5% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Rowan County, as reported in Table D of the January 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that 35 Dialysis Care of Kannapolis patients, all of whom reside in Cabarrus County, will transfer their care to Cannon Dialysis upon certification of that facility on December 1, 2019.

In Section D.1, page 24, the applicant calculates the in-center patient census for Dialysis Care of Kannapolis starting June 30, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

<b>Dialysis Care of Kannapolis</b>	<b>In-Center Patients</b>
Begin with Dialysis Care of Kannapolis's in-center ESRD patient population from Rowan County, as of June 30, 2017.	46
Project the Rowan County population forward six months to December 31, 2017, using the Five Year AACR for Rowan County.	$46 \times 1.0325 = 47.495$
Project the Rowan County population forward one year to December 31, 2018, using the Five Year AACR for Rowan County.	$47.495 \times 1.065 = 50.582$
Subtract 1 Rowan County patient projected to transfer to Spencer Dialysis in Rowan County (Project ID #F-11264-16)	$50.582 - 1 = 49.582$
Project the Rowan County population forward one year to December 31, 2019, using the Five Year AACR for Rowan County.	$49.582 \times 1.065 = 52.805$
Add the 51 non-Rowan County patients. This is the beginning census for the proposed project.	$52.805 + 51 = 103.805$
Project the Rowan County population forward one year to December 31, 2020, using the Five Year AACR for Rowan County.	$52.805 \times 1.065 = 56.237$
Add the 51 non-Rowan County patients minus the 35 Cabarrus County patients projected to transfer to Cannon Dialysis. ( $51 - 35 = 16$ ). <b>This is the patient census at the end of OY1.</b>	$56.237 + 16 = 72.237$
Project the Rowan County population forward one year to December 31, 2021, using the Five Year AACR for Rowan County.	$56.237 \times 1.065 = 59.89$
Add the 16 non-Rowan County patients. <b>This is the patient census at the end of OY2.</b>	$59.89 + 16 = 75.88$

Thus, on December 31, 2020, Dialysis Care of Kannapolis is projected to have 20 certified dialysis stations with an in-center patient population of 72, which is equivalent to a utilization rate of 3.6 patients per station per week ( $72 / 20 = 3.6/4 = 0.9$  or 90.0%). In Section D.1, page 24, the applicant states that given this projected in-center growth, as the facility approaches full capacity additional Certificate of Need applications based on facility need will be submitted to ensure that the needs of the facility's patients continue to be met.

Projected utilization for Dialysis Care of Kannapolis is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for Dialysis Care of Kannapolis based on existing Dialysis Care of Kannapolis patients, and those patients who have signed letters expressing their intention to transfer their care to the proposed Cannon Dialysis facility.
- The applicant's growth projections are based on an assumption that the Rowan County patient census will increase at an annual rate of 6.5%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Rowan County, as reported in Table D of the January 2018 SDR.

#### North Charlotte Dialysis

According to the January 2018 SDR, there were 115 patients dialyzing at North Charlotte Dialysis and 41 certified dialysis stations for a utilization rate of 70.12%, or 2.8049 patients per station per week ( $115/41 = 2.8049/4 = 0.7012$  or 70.12%) as of June 30, 2017. In Section D.1, page 25, the applicant states that on June 30, 2017, 112 of the 115 in-center patients reside in Mecklenburg County, and 3 reside outside of Mecklenburg County.

The applicant assumes that the number of in-center patients at North Charlotte Dialysis who reside in Mecklenburg County will increase at a rate of 5.1% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Mecklenburg County, as reported in Table D of the January 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that one North Charlotte Dialysis patient, who resides in Mecklenburg County, will transfer their care to Cannon Dialysis upon certification of that facility on December 1, 2019.

In Section D.1, pages 25-26, the applicant calculates the in-center patient census for North Charlotte starting June 30, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

<b>North Charlotte Dialysis</b>	<b>In-Center Patients</b>
Begin with Dialysis Care of Kannapolis’s in-center ESRD patient population from Mecklenburg County, as of June 30, 2017.	112
Project the Mecklenburg County population forward six months to December 31, 2017, using the Five Year AACR for Mecklenburg County.	$112 \times 1.0255 = 114.856$
Subtract 11 Mecklenburg County patients projected to transfer to University City Dialysis (Project ID #F-11252-16) as of January 1, 2018.	$114.856 - 11 = 103.856$
Project the Mecklenburg County population forward one year to December 31, 2018, using the Five Year AACR for Mecklenburg County.	$103.856 \times 1.051 = 109.153$
Project the Mecklenburg County population forward one year to December 31, 2019, using the Five Year AACR for Mecklenburg County.	$109.153 \times 1.051 = 114.72$
Add the 3 non-Mecklenburg County patients. This is the beginning census for the proposed project.	$114.72 + 3 = 117.72$
Project the Mecklenburg County population forward one year to December 31, 2020, using the Five Year AACR for Mecklenburg County.	$114.72 \times 1.051 = 120.571$
Add the 3 non-Mecklenburg County patients minus the 1 Cabarrus County patients projected to transfer to Cannon Dialysis. (3-1=2). <b>This is the patient census at the end of OY1.</b>	$120.571 + 2 = \mathbf{122.571}$
Project the Mecklenburg County population forward one year to December 31, 2021, using the Five Year AACR for Mecklenburg County.	$120.571 \times 1.051 = 126.72$
Add the 2 non-Mecklenburg County patients. <b>This is the patient census at the end of OY2.</b>	$126.72 + 2 = \mathbf{128.72}$

Thus, on December 31, 2020, North Charlotte Dialysis is projected to have 29 certified dialysis stations with an in-center patient population of 122, which is equivalent to a utilization rate of 3.6 patients per station per week ( $122 / 29 = 4.2 / 4 = 1.05$  or 105.0%). In Section D.1, page 26, the applicant states that the given this projected in-center growth, as the facility approaches full capacity additional Certificate of Need applications based on facility need will be submitted to ensure that the needs of the facility’s patients continue to be met.

Projected utilization for North Charlotte Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for North Charlotte Dialysis based on existing North Charlotte Dialysis patients, and a patient who has signed a letter expressing their intention to transfer their care to the proposed Cannon Dialysis facility.
- The applicant’s growth projections are based on an assumption that the Mecklenburg County patient census will increase at an annual rate of 5.1%, which is consistent with

the Five Year Average Annual Change Rate (AACR) for Mecklenburg County, as reported in Table D of the January 2018 SDR.

Further, in Section D.2, pages 26-27, the applicant states that the proposed relocation of stations will not will not adversely affect 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.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

TRC proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. In addition to in-center dialysis, Cannon Dialysis would offer a PD program but does not propose to initially offer a HH program. Dialysis Care of Kannapolis will be certified for 20 dialysis stations upon completion of this project and Project I.D. #F-11264-16 (relocate two stations) and North Charlotte Dialysis will be certified for 29 dialysis stations upon completion of this project, Project ID#F-11019-15 (relocate 4 stations), Project ID# F-11108-15 (relocate 10 stations), Project ID#F-11252-16 (add 9 stations), Project ID#F-11288-17 (relocate 4 stations).

In Section E, page 28, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

*Maintain the Status Quo-* The applicant states that this is not the most effective alternative because if the status quo is maintained the patients will continue to have to travel outside

their home county for dialysis. In addition, maintaining the status quo would not effectively erase the dialysis station deficit in Cabarrus County.

*Locate a Facility in a Different Location in Cabarrus County-* The primary and secondary sites proposed for Cannon Dialysis are locations where the majority of the residents who currently leave Cabarrus County for dialysis reside. The sites were specifically selected because they offer the better geographic access to the patient population identified in the patient letters.

On page 28, the applicant states that its proposal is the most effective alternative because the proposed project offers Cabarrus County residents who live in the City of Kannapolis a facility located in their home county close to where they live. The proposed Cannon Dialysis will be closer to these residents than the Dialysis Care of Kannapolis facility.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new kidney disease treatment center to be known as Cannon Dialysis by relocating eight dialysis stations from Dialysis Care of Kannapolis and three dialysis stations from North Charlotte Dialysis.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Cannon Dialysis shall install plumbing and electrical wiring through the walls for no more than 11 dialysis stations which shall include any isolation stations.**
- 4. Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify eight dialysis stations at Dialysis Care of Kannapolis for a total of no more than 20 dialysis stations at Dialysis Care of Kannapolis.**

5. **Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify three dialysis stations at North Charlotte Dialysis for a total of no more than 29 dialysis stations at North Charlotte Dialysis.**
  6. **Total Renal Care of North Carolina, LLC 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

TRC proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. In addition to in-center dialysis, Cannon Dialysis would offer a PD program but does not propose to initially offer a HH program. Dialysis Care of Kannapolis will be certified for 20 dialysis stations upon completion of this project and Project I.D. #F-11264-16 (relocate two stations) and North Charlotte Dialysis will be certified for 29 dialysis stations upon completion of this project, Project ID#F-11019-15 (relocate 4 stations), Project ID# F-11108-15 (relocate 10 stations), Project ID#F-11252-16 (add 9 stations), Project ID#F-11288-17 (relocate 4 stations).

**Capital and Working Capital Costs**

In Section F, page 29, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$1,160,000
Miscellaneous Costs	\$797,000
<b>Total</b>	<b>\$1,957,000</b>

In Section F.1, page 29, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 31-32, the applicant projects that start-up costs will be \$186,017 and initial operating expenses will be \$886,806 for a total working capital of \$1,072,823. On page 32, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F.2, page 30, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	Total Renal Care of North Carolina	Total
Accumulated reserves or OE *	\$1,957,000	\$1,957,000
<b>Total Financing</b>	<b>\$1,957,000</b>	<b>\$1,957,000</b>

\* OE = Owner's Equity

In Section F.13, pages 32-33, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(b)	Cash Reserves	\$1,072,823
(e)	<b>Total *</b>	<b>\$1,072,823</b>

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year
Total Treatments*	5,780	6,151
Total Gross Revenues (Charges)	\$2,032,111	\$2,180,071
Total Net Revenue	\$1,959,400	\$2,103,259
Average Net Revenue per treatment	\$338.99	\$341.94
Total Operating Expenses (Costs)	\$1,773,612	\$1,863,593
Average Operating Expense per treatment	\$306.85	\$302.97
Net Income	\$185,788	\$239,666

\*Includes both IC and PD treatments from Form C of Section R.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:



- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

TRC proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. In addition to in-center dialysis, Cannon Dialysis would offer a PD program but does not propose to initially offer a HH program. Dialysis Care of Kannapolis will be certified for 20 dialysis stations upon completion of this project and Project I.D. #F-11264-16 (relocate two stations) and North Charlotte Dialysis will be certified for 29 dialysis stations upon completion of this project, Project ID#F-11019-15 (relocate 4 stations), Project ID# F-11108-15 (relocate 10 stations), Project ID#F-11252-16 (add 9 stations), Project ID#F-11288-17 (relocate 4 stations).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

DaVita operates the all three of the dialysis facilities in Cabarrus County. The three (2 existing and 1 approved) Cabarrus County dialysis facilities are shown below:

### Existing and Approved Cabarrus County Dialysis Facilities

Dialysis Facility	Owner	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
Copperfield Dialysis*	DaVita	27	-27	75.93%	3.0370
Copperfield Dialysis*	DaVita	0	29	0.0%	0.0000
Harrisburg Dialysis	DaVita	25	-8	77.0%	3.0800
Hickory Ridge**	DaVita	0	10	0.0%	0.000

Source: January 2018 SDR, Table B.

\*Copperfield Dialysis is listed twice in the table above because it is in the process of relocating sites per Project ID#F-11019-15 [Relocate the facility to a new location and add four stations relocated from North Charlotte Dialysis Center for a total of 31 stations upon completion of this project and Project I.D. #F-10109-13, (add 6 stations by relocation from Dialysis Care of Kannapolis in Rowan County)]

\*\*Hickory Ridge is an approved new facility per Project ID# F-11265-16 [Develop a new 10-station facility by relocating 8 stations from Harrisburg Dialysis and 2 stations from Copperfield Dialysis]

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cabarrus County. The applicant states:

*“The January 2018 Semiannual Dialysis Report indicated in Table D that Cabarrus County has a Projected Station Deficit of 11 stations. Since there is a station deficit in Cabarrus County, then the development of a new dialysis facility in Cabarrus County will not unnecessarily duplicate the two existing operating facilities and the new facility under development ... the development of Cannon Dialysis will offer the opportunity for thirty-six in-center patients to receive their treatment at a facility in their home county and closer to where they live.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- Although the proposal will result in an increase in the number of dialysis stations in Cabarrus County, it will reduce the projected deficit of dialysis stations in Cabarrus County reported in the January 2018 SDR from eleven to zero.
- The applicant adequately demonstrates that the proposed facility is needed in addition to the existing or approved facilities in Cabarrus County.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, pages 36-37, the applicant provides projected staffing for the proposed services as illustrated in the following table.

**Projected Staffing: Cannon Dialysis OY2 (CY2021)**

<b>Position</b>	<b>Projected Total FTE Positions</b>
Medical Director	NA*
RN	2.0
Technician (PCT)	4.0
Administrator	1.0
Dietician	0.5
Social Worker	0.5
Home Training RN	0.5
Admin Assistant	1.0
Biomed Tech	0.3
<b>TOTAL</b>	<b>9.8</b>

\*Medical Director is an independent contractor, not an employee.

The assumptions and methodology used to project staffing are provided in Section H.1, page 36 and Sections H.6 and H.7, page 39. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3, H-4 and I-3, the applicant provides supporting documentation. In Section I.3, page 41, the applicant identifies the proposed medical director. In Exhibit I-3, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 40, the applicant identifies the ancillary and support services necessary for the proposed services.

<b>CANNON DIALYSIS Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	Cannon Dialysis
Self-care training (in-center)	Cannon Dialysis
Home training HH PD Accessible follow-up program	Dialysis Care of Kannapolis (HH) Cannon Dialysis (PD) Cannon Dialysis
Psychological counseling	Cannon Dialysis
Isolation – hepatitis	Cannon Dialysis
Nutritional counseling	Cannon Dialysis
Social Work services	Cannon Dialysis
Acute dialysis in an acute care setting	Northeast Medical Center
Emergency care	Northeast Medical Center
Blood bank services	Northeast Medical Center
Diagnostic and evaluation services	Northeast Medical Center
X-ray services	Northeast Medical Center
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Northeast Medical Center
Vascular surgery	Northeast Medical Center
Transplantation services	Carolinas Healthcare System
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	Cabarrus County Transportation Services

On page 40, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1 and I-2.

In Section I, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1, I-2(a), I-2(b) and I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

## Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicants are not a HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

C

In Section K.2, page 45, the applicant states that the project involves construction and up-fitting of 8,665 square feet in leased space in a building to be constructed by a developer at 267 North Cannon Boulevard in Kannapolis. A line drawing of the proposed facility is provided in Exhibit K-1.

On page 44, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On page 46, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. See also Exhibit K-4.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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

Cannon Dialysis is not an existing facility. The applicant projects a total of 36 IC patients and 2 PD patients transferring to Cannon Dialysis upon project completion. These 36 patients are projected to be transferring from Dialysis Care of Kannapolis and North Charlotte Dialysis.

In Section L.7, page 53, the applicant reports that 84.5% of the patients who received treatments at Dialysis Care of Kannapolis had some or all of their services paid for by Medicare or Medicaid, and that 88.1% of the patients who received treatments at North Charlotte Dialysis had some or all of their services paid for by Medicare or Medicaid, in CY2017. The table below shows the historical (CY2017) payment source for Dialysis Care of Kannapolis and North Charlotte Dialysis:

Payment Sources CY2017	Dialysis Care of Kannapolis Patients as Percent of Total	North Charlotte Dialysis Patients as Percent of Total
Medicaid	12.6%	9.9%
Medicare	31.2%	29.7%
Medicare/Medicaid	20.0%	22.8%
Medicare/Commercial	20.7%	25.7%
VA	5.9%	4.0%
Commercial Insurance	9.6%	7.9%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</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.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Cabarrus	13%	51%	33%	11%	7%	11%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

\*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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>1</sup> percentages for North Carolina and the aggregate data for all three

<sup>1</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>2</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

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

### C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 52, the applicant states

*“Cannon Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”*

In Section L.6, page 52, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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<sup>2</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)



- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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 50, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	9.0%
Medicare	27.6%
Medicare/Medicaid	22.6%
Medicare/Commercial	23.8%
VA	5.0%
Commercial Insurance	12.0%
<b>Total</b>	<b>100.0%</b>

Source: Table, page 50 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 83.0% of total services will be provided to Medicaid/Medicare patients.

On page 50, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on historical payor mix from DaVita facilities both in Cabarrus County and from Dialysis Care of Kannapolis County in Rowan County since there are a significant number of in-center and peritoneal dialysis patients receiving services both in Dialysis Care of Kannapolis (located just outside Cabarrus County) and in Cabarrus County.

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 54, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.

- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

TRC proposes to develop a new eleven-station facility, Cannon Dialysis, in Cabarrus County by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County. In addition to in-center dialysis, Cannon Dialysis would offer a PD program but does not propose to initially offer a HH program. Dialysis Care of Kannapolis will be certified for 20 dialysis stations upon completion of this project and Project I.D. #F-11264-16 (relocate two stations) and North Charlotte Dialysis will be certified for 29 dialysis stations upon completion of this project, Project ID#F-11019-15 (relocate 4 stations), Project ID# F-11108-15 (relocate 10 stations), Project ID#F-11252-16 (add 9 stations), Project ID#F-11288-17 (relocate 4 stations). On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

DaVita operates the all three of the dialysis facilities in Cabarrus County. The three (2 existing and 1 approved) Cabarrus County dialysis facilities are shown below:

**Existing and Approved Cabarrus County Dialysis Facilities**

Dialysis Facility	Owner	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
Copperfield Dialysis*	DaVita	27	-27	75.93%	3.0370
Copperfield Dialysis*	DaVita	0	29	0.0%	0.0000
Harrisburg Dialysis	DaVita	25	-8	77.0%	3.0800
Hickory Ridge**	DaVita	0	10	0.0%	0.000

Source: January 2018 SDR, Table B.

\*Copperfield Dialysis is listed twice in the table above because it is in the process of relocating sites per Project ID#F-11019-15 [Relocate the facility to a new location and add four stations relocated from North Charlotte Dialysis Center for a total of 31 stations upon completion of this project and Project I.D. #F-10109-13, (add 6 stations by relocation from Dialysis Care of Kannapolis in Rowan County)]

\*\*Hickory Ridge is an approved new facility per Project ID# F-11265-16 [Develop a new 10-station facility by relocating 8 stations from Harrisburg Dialysis and 2 stations from Copperfield Dialysis]

In Section N, page 55, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 55, the applicant states:

*“DaVita operates the other two facilities in Cabarrus County. ...The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from ne DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed. There are no other dialysis facilities in the proposed service area; therefore there can be no effect on competition.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section A, page 6, the applicant states DaVita operates more than 70 dialysis facilities in North Carolina. Exhibit A-11 contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 56, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. Furthermore, in Project I.D. # F-11490-18, the applicant, in Section O, page 50, and Exhibit O-3, states that a survey conducted on February 21, 2018 led to the identification of an Immediate Jeopardy for Southeastern Dialysis Center-Wilmington, which is also a dialysis facility that is ultimately owned and operated by DaVita. Southeastern Dialysis Center-Wilmington submitted a plan of correction to CMS on March 6, 2018 and the Southeastern Dialysis Center-Wilmington is waiting for a resurvey by the North Carolina State Survey Agency on or about March 16, 2018. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

## **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

### **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.*

- C- In Section C.1, page 14, the applicant projects to serve 37 in-center patients by the end of OY1 (CY2020) for a utilization rate of 84.09% or 3.3636 patients per station per week (37patients / 11 stations =  $3.3636 / 4 = 0.8409$  or 84.09%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*(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.*

- NA- The applicant is not proposing to increase the number of dialysis stations in an existing facility or one that was not operational prior to the beginning of the review period.

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

- C- In Section C, pages 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.