

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 10, 2017

Findings Date: March 10, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: F-11265-16

Facility: Hickory Ridge Dialysis

FID #: 160494

County: Cabarrus

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility in Cabarrus County by relocating eight stations from Harrisburg Dialysis and two stations from Copperfield Dialysis and offer home training and support for peritoneal dialysis patients

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DaVita, Inc. is the parent company of Total Renal Care of North Carolina, LLC (TRC). Total Renal Care of North Carolina, LLC d/b/a Hickory Ridge Dialysis (“the applicant”) proposes to develop a new 10-station dialysis facility in Harrisburg, a northeastern suburb of Charlotte, but located in Cabarrus County instead of Mecklenburg County. The applicant proposes to develop the new facility by relocating eight stations from Harrisburg Dialysis and two stations from Copperfield Dialysis. In addition, the applicant proposes to offer home training and support for home peritoneal dialysis (PD) patients. The two existing facilities and the proposed facility will all be located in Cabarrus County. The applicant does not propose to add dialysis stations to an existing facility or

to establish new dialysis stations. Upon completion of this project, Hickory Ridge Dialysis will be certified for 10 dialysis stations, Harrisburg Dialysis will be certified for 17 dialysis stations following completion of this project and Project I.D. # F-11088-15 (add six stations) and Copperfield Dialysis will be certified for 29 dialysis stations following completion of this project and Project I.D. # F-11019-15 (add four stations).

The project analyst notes that Harrisburg Dialysis would have been certified for 18 stations upon completion of this project and Project ID# F-11088-15 (add six stations), however, one of the six stations in that project was certified on July 20, 2016.

In Section A-9, page 5, the applicant refers to Project ID# F-11019-15 in the Copperfield chart. However, the applicant does not include the number of stations to be certified. Agency records indicate that Copperfield Dialysis will be certified for 31 stations upon completion of Project ID# F-11019-15.

### **Need Determination**

The applicant is proposing to relocate existing dialysis stations within Cabarrus County, therefore there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

### **Policies**

There are two policies in the 2016 SMFP that are applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on pages 39-40, and *Policy ESRD-2 Relocation of Dialysis Stations*, on page 33.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water*

*conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure is greater than \$2 million, but less than \$5 million. In Section B-5, pages 11-12, Section K-1, pages 45-46, and Exhibits B-5 and K-1(d) the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

*Policy ESRD-2: Relocation of Dialysis Stations*

*"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 [sic] county is currently serving residents of that contiguous [sic] 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."*

The applicant proposes to develop a new 10-station dialysis facility, Hickory Ridge Dialysis, by relocating existing dialysis stations from both Harrisburg Dialysis and Copperfield Dialysis. The two existing facilities and the proposed facility will be located in Cabarrus County, so there will be no change in the dialysis station inventory in Cabarrus County. Therefore, the application is consistent with Policy ESRD-2.

**Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with all applicable policies in the 2016 SMFP.

Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.

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

## C

The applicant proposes to develop a new 10-station dialysis facility in Harrisburg, a northeastern suburb of Charlotte, but located in Cabarrus County instead of Mecklenburg County. The applicant proposes to develop the new facility by relocating eight stations from Harrisburg Dialysis and two stations from Copperfield Dialysis. In addition, the proposed facility will offer home training and support for home PD patients. The two existing facilities and the proposed facility will be located in Cabarrus County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Hickory Ridge Dialysis will be certified for 10 dialysis stations, Harrisburg Dialysis will be certified for 17 dialysis stations following completion of this project and Project I.D. # F-11088-15 (add six stations) and Copperfield Dialysis will be certified for 25 dialysis stations following completion of this project and Project I.D. # F-11019-15 (add four stations).

The project analyst notes that Harrisburg Dialysis would have been certified for 18 stations upon completion of this project and Project ID# F-11088-15 (add six stations), however, one of the six stations in that project was certified on July 20, 2016.

### **Patient Origin**

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

Hickory Ridge Dialysis will be a new facility in Cabarrus County and therefore has no existing patient origin.

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

<b>HICKORY RIDGE DIALYSIS PROJECTED PATIENT ORIGIN</b>						
County	<b>OY1 CY2019</b>		<b>OY2 CY2020</b>		<b>Percent of Total</b>	
	IC	PD	IC	PD	OY1	OY2
Cabarrus	19	2	19	3	60.0%	61.1%
Mecklenburg	14	0	14	0	40.0%	38.9%
<b>Total</b>	<b>33</b>	<b>2</b>	<b>34</b>	<b>3</b>	<b>100.0%</b>	<b>100.0%</b>

See pages 13-16 for the assumptions and methodology used to project patient origin including a summary of the patient support letters found in Exhibit C-1.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C-5, page 17, the applicant states that after an analysis of patient data, it determined that at least 42 in-center patients who currently live in or near the southwest part of Cabarrus County (Zip Code area 28075) receive dialysis treatment at other DaVita operated facilities in Cabarrus and Mecklenburg counties, respectively. The applicant reviewed other areas in Cabarrus County to see if there was an area with a significant population of end stage renal disease (ESRD) patients. The applicant concluded that the other areas of Cabarrus County that did have a significant number of ESRD patients were currently being served by existing DaVita facilities or would be served by new facilities currently under development. The applicant concluded that the proposed new facility would provide better access to dialysis services for the patients who reside in the southwest part of Cabarrus County rather than the facility where they are currently dialyzing.

In Section C-2, page 16, the applicant states:

*“In order to make the travel to dialysis – three times a week for in-patients and monthly for PD patients – more convenient, it was determined that TRC Renal Care of North Carolina, LLC needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.”*

On page 14, the applicant states,

*“It is assumed that at least 33 of the 42 in-center patients who signed letters of support for Hickory Ridge Dialysis will transfer their care upon certification of the new facility; including all 19 of the Cabarrus County patients and at least 14 of the Mecklenburg County patients.”*

Exhibit C-1 contains 44 patient letters of support (two letters are from PD patients), which state:

*“... I fully support this new dialysis facility ... to be built in Harrisburg. ... I could travel between home and that location more easily and quickly, which would save me time and money.”*

### Projected Utilization

In Section C-1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization for the proposed facility. The assumptions and methodology are summarized as follows:

#### In-center:

- The applicant assumes that through the second operating year (CY2020), the in-center patients who are residents of Cabarrus County will increase at a rate commensurate with Cabarrus County’s Five Year Average Annual Change Rate (AACR) of 2.1%, as published in Table B of the July 2016 Semi-Annual Dialysis Report (SDR). The applicant assumes no growth for patients residing outside of Cabarrus County.
- Exhibit C-1 includes letters from 42 in-center patients who expressed interest in transferring their care from the facility that they are currently dialyzing in Cabarrus and Mecklenburg counties to the proposed new Hickory Ridge Dialysis facility.
- The applicant assumes that 33 of the 42 in-center patients who signed letters of support for Hickory Ridge Dialysis will actually transfer their care to the proposed new facility. This includes all 19 of the Cabarrus County patients and a minimum of 14 of the Mecklenburg County patients.
- All of the letters signed by the patients state, *“... Having my dialysis treatments at Hickory Ridge Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save time and money. ... But I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.”*

In Section C-1, page 15, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Years 1 and 2, as follows:

<b>Hickory Ridge Dialysis</b>	<b>In-Center Patients</b>
January 1, 2019, the beginning of Operating Year 1, will begin with 19 in-center patients who will transfer their care from other DaVita dialysis facilities.	19
Growth is projected during OY1 by multiplying the beginning census for January 1, 2019 by the Cabarrus County Five Year AACR of 2.1% and adding 14 out of service area patients for an end of year census for December 31, 2019.	$19 \times 1.021 = 19.399 + 14 = 33.399$
Growth is projected again for OY2 by multiplying the beginning census for January 1, 2020 by the Cabarrus County Five Year AACR of 2.1% and adding 14 out of service area patients for an end of year census for December 31, 2020.	$19.399 \times 1.021 = 19.806 + 14 = 33.806$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) the facility is projected to serve 33 in-center patients and at the end of OY2 (CY2020) the facility is also projected to serve 33 in-center patients.

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

- OY1: 3.3 patients per station per week, or 82.5% (33 patients/ 10 stations = 3.3/4 = .825 or 82.5%).
- OY2: 3.3 patients per station per week, or 82.5% (33 patients/ 10 stations = 3.3/4 = .825 or 82.5%).

The projected utilization of 3.3 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 utilization for the in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Peritoneal Dialysis:

- In Section C-1, page 16, the applicant provides the calculations used to arrive at the projected PD patient census for Operating Years 1 and 2 below in the table.
- On page 13, the applicants states that it will have two PD patients in OY1 and three PD patients in OY2; slightly different than what is below in the table. The project analyst acknowledges the discrepancy made by the applicant; however, there is no performance standard for PD patients.

<b>HICKORY RIDGE DIALYSIS PD PATIENT PROJECTIONS</b>				
		<b>Beginning Year Patients</b>	<b>End of Year Patients</b>	<b>Average # Patient per Year</b>
OY1	1/1/2019	2	3	2.5
OY2	1/1/2020	3	4	3.5

On pages 15-16 of the application, the applicant states that it received two letters of support from PD patients utilizing TRC dialysis facilities in Cabarrus County who live in Cabarrus (1) and Mecklenburg (1) counties indicating their willingness to consider transferring their care to the proposed facility. The applicant assumes the two patients having signed letters of support will actually transfer their care to the proposed new facility. The applicant assumes that Hickory Ridge Dialysis will grow at a rate of one patient per operating year.

#### Access to Services

In Section C-3, page 16, 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 addition, the applicant projects in Section L-1, page 52, that 82.1% of its total patients at Hickory Ridge Dialysis will be covered by either Medicare or Medicaid. The applicant states that the projected payor mix for the proposed facility is based on sources of payment for its DVA facilities in Cabarrus County for the last full operating year. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

#### Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Harrisburg, by relocating eight dialysis stations from Harrisburg Dialysis and two dialysis stations from Copperfield Dialysis.

Harrisburg Dialysis

In Section D-1, pages 25-26, the applicant states that as of December 31, 2015, as reported in the July 2016 Semiannual Dialysis Report (SDR), there were 73 in-center dialysis patients at Harrisburg Dialysis dialyzing on 19 dialysis stations, for a utilization rate of 96.05%. In addition, the applicant states that 59 of the 73 in-center patients lived in Cabarrus County and that 14 lived outside Cabarrus County.

Project ID# F-11088-15 was to add six stations for a total of 25; one of those six stations was certified on July 20, 2016 which is why the current SDR shows five stations awaiting certification (20 certified stations – 8 from this project + 5 awaiting certification = 17 stations, not 18).

TRC proposes to relocate eight stations from Harrisburg Dialysis to the proposed Hickory Ridge Dialysis. The applicant projects that 17 in-center patients currently receiving care/services at Harrisburg Dialysis will opt to transfer their services to Hickory Ridge Dialysis. After the period of growth in 2018, there will be 76 in-center patients, 62 of them from Cabarrus County. When the 14 Cabarrus County and three Mecklenburg County patients transfer to Hickory Ridge Dialysis, Harrisburg Dialysis is projected to have 48 Cabarrus County patients at the beginning of OY1 (CY2019).

The applicant assumes that the number of patients at Harrisburg Dialysis who live in Cabarrus County will increase at 2.1% per year based on the Five Year AACR for Cabarrus County, as reported in Table B of the July 2016 SDR. The applicant assumes that no growth will occur for the 14 in-center patients living outside of Cabarrus County.

In Section D-1, page 26, the applicant calculates the in-center patient census for Harrisburg Dialysis starting January 1, 2016 through OY1 (CY2019) and OY2 (CY2020). The table below shows the applicant's methodology to project the patient census at Harrisburg Dialysis after the period of growth that began January 1, 2016 and ends December 31, 2020 (OY2), illustrated as follows:

<b>HARRISBURG DIALYSIS Projected Patient Census</b>	<b>In-Center Patients</b>
Beginning census for January 1, 2016 for Cabarrus County patients only, increased by the Five Year AACR for Cabarrus County of 2.1%. Add 14 patients from outside Cabarrus County to arrive at the ending census for December 31, 2016.	$59 \times 1.021 = 60.2.39 + 14 = 74.239$
Cabarrus County patient census for CY2017 increased by 2.1%. Five Year AACR for Cabarrus County. Add 14 patients from outside Cabarrus County to arrive at ending census for December 31, 2017.	$60.2.39 \times 1.021 = 61.504 + 14 = 75.504$
Cabarrus County patient census for CY2018 increased by 2.1%. Five Year AACR for Cabarrus County. Add 14 patients from outside Cabarrus County to arrive at ending census for December 31, 2018.	$61.504 \times 1.021 = 62.796 + 14 = 76.796$
<b>OY1 (CY2019)</b> Cabarrus County patient census for CY2019 increased by 2.1%. Five Year AACR for Cabarrus County. (After subtracting 14 Cabarrus County and 3 Mecklenburg County patients who are projected to transfer to the proposed Hickory Ridge Dialysis facility). Arrive at ending census for December 31, 2019.	$62 - 14 = 48 \times 1.021 = 49.008 + 14 - 3 = 11 = 60.008$
<b>OY2 (CY2020)</b> Cabarrus County patient census for CY2019 increased 2.1%. Five Year AACR for Cabarrus County. Add 11 patients from outside Cabarrus County to arrive at ending census for December 31, 2020.	$49.008 \times 1.021 = 50.037 + 11 = 61.037$

The applicant rounds down the ending census numbers for OY1 and OY2 (See page 26). Harrisburg Dialysis is projected to have 60 in-center patients at the end of OY1 dialyzing on 17 stations for a utilization rate of 83.3%, or 3.33 patients per station (60 patients/17 stations =  $3.53/4 = 0.88.2$  or 88.2%). The applicant states the following on page 26:

*“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”*

Copperfield Dialysis

In Section D-1, pages 26-27, the applicant states that as of December 31, 2015, as reported in the July 2016 SDR, there were 73 in-center dialysis patients at Copperfield Dialysis dialyzing on 21 dialysis stations, for a utilization rate of 86.9%. In addition, the applicant states that 58 of the 73 in-center patients lived in Cabarrus County and that 15 lived outside Cabarrus County.

TRC proposes to relocate two stations from Copperfield Dialysis to the proposed Hickory Ridge Dialysis. TRC projects that one in-center patient currently receiving care/services at Copperfield Dialysis will opt to transfer those services to Hickory Ridge Dialysis. The applicant states on page 26, that TRC was approved in Project I.D. # F-10109-13 to relocate six dialysis stations from Dialysis Care of Kannapolis to resulting in 27 certified stations at Copperfield Dialysis.

The applicant assumes that the number of in-center patients at Copperfield Dialysis who live in Cabarrus County will increase at 2.1% per year based on the Five Year AACR for Cabarrus County, as reported in Table B of the July 2016 SDR. The applicant assumes that no growth will occur for the 15 in-center patients living outside of Cabarrus County. The applicant projects that one current in-center patient from Copperfield Dialysis will transfer to Hickory Ridge Dialysis. The applicant assumes there will be 76 in-center patients, 61 of them from Cabarrus County and when the one patient transfers to Hickory Ridge Dialysis, Copperfield Dialysis will have 60 Cabarrus County patients at the beginning of OY1 (CY2019).

In Section D-1, page 27, the applicant calculates the in-center patient census for Copperfield Dialysis starting January 1, 2016 through OY1 (CY2019) and OY2 (CY2020), illustrated as follows:

<b>COPPERFIELD DIALYSIS Projected Patient Census</b>	<b>In-Center Patients</b>
Beginning census for January 1, 2016 for Cabarrus County patients only, increased by the Five Year AACR for Cabarrus County of 2.1%. Add 15 patients from outside Cabarrus County to arrive at the ending census for December 31, 2016.	$58 \times 1.021 = 59.189 + 15 = 74.189$
Cabarrus County patient census for CY2017 increased by 2.1%. Five Year AACR for Cabarrus County. Add 15 patients from outside Cabarrus County to arrive at ending census for December 31, 2017.	$59.189 \times 1.021 = 60.432 + 15 = 75.432$
Cabarrus County patient census for CY2018 increased by 2.1%. Five Year AACR for Cabarrus County. Add 15 patients from outside Cabarrus County to arrive at ending census for December 31, 2018.	$60.432 \times 1.021 = 61.701 + 15 = 76.701$
<b>OY1 (CY2019)</b> Cabarrus County patient census for CY2019 increased by 2.1%. Five Year AACR for Cabarrus County. (After subtracting one Cabarrus County and who is projected to transfer to the proposed Hickory Ridge Dialysis facility). Arrive at ending census for December 31, 2019.	$61 - 1 = 60 \times 1.021 = 61.26 + 15 = 76.26$
<b>OY2 (CY2020)</b> Cabarrus County patient census for CY2019 increased 2.1%. Five Year AACR for Cabarrus County. Add 15 patients from outside Cabarrus County to arrive at ending census for December 31, 2020.	$61.26 \times 1.021 = 62.55 + 15 = 77.546$

The applicant rounds down the ending census numbers for OY1 and OY2. (See page 27) Copperfield Dialysis is projected to have 76 in-center patients at the end of OY1 for a utilization rate of 76.0%, or 3.04 patients per station (76 patients/ 25 stations = 3.04/4 = .76 or 76.0%). The applicant states the following on page 27:

*“... If necessary, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”*

The applicant demonstrates that the needs of the populations presently served at Harrisburg Dialysis and Copperfield Dialysis will continue to be adequately met following the proposed relocation of eight dialysis stations from Harrisburg Dialysis and two dialysis stations from Copperfield Dialysis to Hickory Ridge Dialysis, and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

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

CA

In Section E-1, page 28, the applicant discusses the alternatives considered prior to submitting this application, which include maintaining the status quo or developing the new facility in another area of Cabarrus County. The applicant discusses the fact that dialysis can be a time consuming and physically demanding process and that the proposed location in southwestern Cabarrus County would place the facility in close proximity to existing dialysis patients who currently utilize other existing DVA owned facilities in Cabarrus County, and the fact that these patients residing in southwestern Cabarrus County have signed letters of support for the proposed project.

After considering the above alternatives, the applicant states that development of the new Hickory Ridge Dialysis facility would reduce the transportation demands faced by existing patients and increase the patients' quality of life and compliance with treatment schedules. Therefore, DVA believes that developing the new Hickory Ridge Dialysis facility will address the growing dialysis populations at both Harrisburg and Copperfield dialysis facilities in Cabarrus County and is, therefore, the most effective alternative to meet the identified need.

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

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Hickory Ridge Dialysis shall materially comply with all representations made in the certificate of need application except as modified by the conditions of approval.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Hickory Ridge Dialysis shall relocate no more than eight dialysis stations from Harrisburg Dialysis and no more than two dialysis stations from Copperfield Dialysis.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Hickory Ridge Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation stations and home hemodialysis stations.**

4. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify eight dialysis stations at Harrisburg Dialysis for a total of no more than 17 dialysis stations at Harrisburg Dialysis upon completion of this project and Project F-11088-15 (add six stations).**
  5. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify two dialysis stations at Copperfield Dialysis for a total of no more than 25 dialysis stations at Copperfield Dialysis upon completion of this project and Project I.D. # F-11019-15 (add four stations).**
  6. **Total Renal Care of North Carolina, LLC d/b/a Hickory Ridge Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Harrisburg, by relocating eight dialysis stations from Harrisburg Dialysis and two dialysis stations from Copperfield Dialysis.

**Capital and Working Capital Costs**

In Section F-1, page 30, the applicant provides the capital cost of the project as summarized in the following table:

<b>HICKORY RIDGE DIALYSIS Project Capital Costs</b>	
Site Costs	\$11,500
Construction Contract	\$1,864,139
Dialysis Machines	\$151,580
Water Treatment Equipment	\$129,075
Equipment/Furniture	\$551,606
Architect & Engineering Fees	\$129,320
<b>Total Capital Cost</b>	<b>\$2,837,220</b>

In Section F-10 and Section F-11, page 33, the applicant estimates start-up expenses of \$197,533 and initial operating expenses of \$801,409, respectively, for \$998,942 in total working capital needed.

**Availability of Funds**

On page 13, the applicant states that it will have two PD patients in OY1 and three PD patients in OY2; slightly different than what is stated in the table on page 16. In the table on page 16, the applicant states four PD patients at the end of OY2. The project analyst acknowledges the discrepancy made by the applicant. In Section R, the pro forma assumptions, the applicant stated three PD patients at the end of OY2. However, without calculating in the revenue from PD patients, the proposed project is still financially feasible.

In Section F-2, page 31, the applicant states that accumulated reserves/owner’s equity will be used to finance the project’s capital costs. In Section F-13, page 34, the applicant states that the working capital costs will be financed with cash reserves. Exhibit F-5 contains a letter from DaVita’s Chief Accounting Officer, dated October 13, 2016, confirming DaVita’s commitment to funding the project’s capital costs and working capital costs with cash reserves.

In Exhibit F-7, the applicant provides a copy of the United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2015 from DaVita HealthCare Partners, Inc. (DaVita). DaVita is TRC’s parent company. DaVita had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets, and \$5,948,238,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown below in the table.

<b>HICKORY RIDGE DIALYSIS PROJECTED REVENUES &amp; EXPENSES</b>		
	<b>Operating Year 1 CY2019</b>	<b>Operating Year 2 CY2020</b>
Total Treatments*	4,891	4,891
Total Gross Revenues (Charges)	\$1,745,935	\$1,820,773
Total Net Revenue	\$1,685,803	\$1,759,719
Total Operating Expenses (Costs)	\$1,602,818	\$1,648,226
Net Income	\$82,986	\$111,493

\*Adjusted for missed treatments.

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. 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.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital, working capital and operating needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project 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 develop a new 10-station dialysis facility in Harrisburg, by relocating eight dialysis stations from Harrisburg Dialysis and two dialysis stations from Copperfield Dialysis.

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

The July 2016 SDR indicates there are two dialysis facilities in Cabarrus County, as shown in the following table:

<b>CABARRUS COUNTY DIALYSIS FACILITIES</b>						
<b>December 31, 2015</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Copperfield Dialysis	TRC	73	Concord	21	21	86.90%
Copperfield Dialysis*	TRC	0	Concord	0	31	0.00%
Harrisburg Dialysis Center	TRC	73	Concord	19	6	96.05%

\*New Site Under development.

As illustrated in the table above, there are two existing dialysis facilities located in Cabarrus County and one of those facilities is a site change under development. Both facilities are operated by TRC. The proposed site for Hickory Ridge Dialysis is in the southwestern part of Cabarrus County. The two existing facilities operate with a utilization rate over 85.0%. Thus, both of the operational dialysis facilities in the county are reasonably well utilized.

The applicant is not increasing the number of dialysis stations in Cabarrus County, rather it is relocating 10 existing stations pursuant to Policy ESRD 2 in the 2016 SMFP to develop a new facility that is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C-1, page 14, the applicant demonstrates that Hickory Ridge Dialysis will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 87.5% ( $33/10 = 3.3$ ;  $3.3/4 = 0.825$  or 82.5%). The applicant provides documentation in Exhibit C-1 from 42 in-center patients at its Cabarrus County facilities indicating their willingness to consider transferring to Hickory Ridge Dialysis upon completion because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate stations to develop a new dialysis facility in Cabarrus County. The discussion on the needs of the population presently served at both Harrisburg Dialysis and Copperfield Dialysis, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Cabarrus 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

The applicant provides the projected staffing for Hickory Ridge Dialysis in Section H-1, page 37, illustrated as follows:

<b>HICKORY RIDGE DIALYSIS PROPOSED STAFFING</b>	
<b>Position</b>	<b>Projected Number of FTEs</b>
Medical Director*	*
Registered Nurse	2.0
Patient Care Technician (PCT)	4.0
Administrator	1.0
Home Training RN	0.5
Dietitian	0.5
Social Worker	0.5
Administrative Assistant	1.0
Biomedical Technician	0.3
<b>Total</b>	<b>9.8</b>

\*The Medical Director is an independent contractor, not an employee of the facility.

The applicant provides the projected direct care staffing for Hickory Ridge Dialysis in Section H-1, page 40, illustrated as follows:

<b>HICKORY RIDGE DIALYSIS PROJECTED DIRECT CARE STAFF HOURS – YEAR 2</b>					
<b>Direct Care Positions</b>	<b># FTEs</b>	<b>Hours/Year/FTE</b>	<b>Total Annual FTE Hours</b>	<b>Total Annual Operating Hours</b>	<b>FTE Hours/ Operating Hours</b>
	<b>[a]</b>	<b>[b]</b>	<b>[c] = [a] x [b]</b>	<b>[d]</b>	<b>[e] = [c]/[d]</b>
RN	2	2,080	4,160	3,120	1.3
Technician (PCT)	4	2,080	8,320	3,120	2.7
Total	6	2,080	12,480	3,120	4.0

In Section H-3, pages 38-39, the applicant states that it will fill positions by using a DaVita Teammate Recruiter, the Teammate Referral Program, and it's Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract candidates for positions.

In Section H-2, page 37, the applicant states that the Medical Director for Hickory Ridge Dialysis will be Dr. Charles Stoddard. In Exhibit I-3, the applicant provides a letter signed by Dr. Stoddard, dated October 13, 2016, confirming his commitment to serve as Medical Director.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary

and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, pages 41-43, the applicant discusses the provision of necessary ancillary and support services to be provided for the proposed facility and provides a list of service providers on page 41. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1, I-2 and I-3 including letters from several providers such as Copperfield Dialysis agreeing to provide home training, DaVita Laboratory Services, Inc., Metrolina Nephrology, Cabarrus County Department of Human Services, the NC Division of Vocational Rehabilitation Services, and Carolinas Healthcare System. The information in Section I and Exhibits I-1, I-2 and I-3 is reasonable and adequately supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K-2, page 46, the applicant states there will be 6,066 square feet of treatment area, which will include space for an isolation room. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). The drawing depicts office space, nine dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 10 stations. In Section F-1, page 30, the applicant lists its project costs, including \$11,500 for site work and \$1,864,139 for construction and \$961,581 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,837,220. The capital cost in this section agrees with the total proposed capital expenditure in Section F, page 30 and in the October 2016 letter from DaVita's chief financial officer in Exhibit F.

In Section B-5, pages 11-12, the applicant describes its plans to assure improved energy-efficiency and water conservation, including the following:

- The use of full LED lighting packages with occupancy and vacancy sensors, dimmers, and a full lighting control system that will provide 28% energy reduction.
- Adopt water optimization protocols to reduce the volume of water required to provide patient care, including adjusting the recovery rate for reverse osmosis devices and utilizing water-conserving plumbing fixtures.
- Interior finishes and materials will be used based on sustainable design and "*Indoor Environmental Quality criteria...defined in the US Green Building Council's LEED Rating system.*"
- The HVAC system will be selected for its high performance and energy efficiency.
- All appliances, when possible, and most information technology equipment will be Energy Star rated.

Costs and charges are described by the applicant in Section F, pages 30-34, and in Section R, the pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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

Hickory Ridge Dialysis would be a new facility, thus, it has no historical payor mix. In Section L-7, page 55, the applicant provides the payor mix for both Harrisburg Dialysis and Copperfield Dialysis for CY2015. These are the facilities that will be contributing stations to develop the proposed facility and from which at least some patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payor mix is illustrated as follows:

<b>HARRISBURG DIALYSIS Payor Mix CY2015</b>	
<b>Payor Type</b>	<b>Percent of Total Patients</b>
Medicare	28.0%
Medicaid	2.4%
Commercial Insurance	13.4%
Medicare/Commercial	30.5%
Medicare/Medicaid	20.7%
VA	4.9%
<b>Total</b>	<b>100.0%</b>

<b>COPPERFIELD DIALYSIS Payor Mix CY2015</b>	
<b>Payor Type</b>	<b>Percent of Total Patients</b>
Medicare	21.3%
Medicaid	8.0%
Commercial Insurance	10.7%
Medicare/Commercial	34.7%
Medicare/Medicaid	18.7%
VA	6.7%
<b>Total</b>	<b>100.0%</b>

As the tables above indicate, 81.6% of Harrisburg Dialysis' patients and 82.7% of Copperfield Dialysis' patients were covered by Medicare or Medicaid in CY2015. The applicant provides a copy of DaVita's policy on acceptance of patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability in Exhibit L-3.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Cabarrus	13%	51%	31%	12%	7%	16%
Mecklenburg	10%	52%	51%	15%	6%	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."

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:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
<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 applicants;

C

In Section L-3(e) page 54, the applicant states:

*“Hickory Ridge 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 54, the applicant states in reference to any facilities owned by DaVita in the state, that there have been no civil rights equal access complaints filed within the last five years.

The application is conforming to this criterion.

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

C

In Section L-1, page 52, the applicant states that the projected payor mix for Hickory Ridge Dialysis is based on sources of payment for its DaVita facilities in Cabarrus County for the last full operating year, and the projected payor mix is illustrated as follows:

<b>HICKORY RIDGE DIALYSIS Projected Payor Mix OY2</b>	
<b>Payor Source</b>	<b>Percent of Total Patients</b>
Medicare	24.8%
Medicaid	5.1%
Commercial Insurance	12.2%
Medicare/Commercial	32.5%
Medicare/Medicaid	19.7%
VA	5.7%
<b>Total</b>	<b>100.0%</b>

The applicant projects that 82.1% of Hickory Ridge Dialysis' patients will be covered by Medicare or Medicaid.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 54, the applicant states that patients will have access to the facility for dialysis services upon referral from Nephrologists with admitting privileges at the facility. Patients, family, and friends who contact the facility seeking access to services will be referred to *“a qualified nephrologist for evaluation and subsequent admission...”*

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M-1, page 56, the applicant states that it has offered Hickory Ridge Dialysis as a clinical training site for nursing students from Rowan-Cabarrus Community College. A copy of a letter sent by the applicant to the college, dated October 3, 2016, is included in Exhibit M-2.

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in Harrisburg, by relocating eight dialysis stations from Harrisburg Dialysis and two dialysis stations from Copperfield Dialysis.

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

The July 2016 SDR indicates there are two dialysis facilities in Cabarrus County, as follows:

<b>CABARRUS COUNTY DIALYSIS FACILITIES</b>						
<b>December 31, 2015</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Copperfield Dialysis	TRC	73	Concord	21	21	86.90%
Copperfield Dialysis*	TRC	0	Concord	0	31	0.00%
Harrisburg Dialysis Center	TRC	73	Concord	19	6	96.05%

\*New Site Under development.

As illustrated above, there are two existing dialysis facilities located in Cabarrus County and one of those facilities is a site change under development. Both facilities are operated by TRC. The proposed site for Hickory Ridge Dialysis is in the southwestern part of

Cabarrus County. The two existing facilities operate with a utilization rate over 85.0%. Thus, both of the operational dialysis facilities in the county are reasonably well utilized.

In Section N-1, page 57, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

*“The development of Hickory Ridge Dialysis will have no effect on any dialysis facilities located in Cabarrus County or in counties contiguous to it. DaVita operates the other two facilities in the 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 one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed. ...*

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

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that TRC will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that TRC will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section B, pages 8-9, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. However, each facility is back in compliance as of the date of this decision.

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

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

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

- C- In Section C-1, page 14, the applicant adequately demonstrates that Hickory Ridge Dialysis will serve at least 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5% ( $33/10 = 3.3$ ;  $3.3/4 = 0.825$ ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- NA- The applicant is seeking to develop a new 10-station dialysis facility.

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C-1, pages 13-16, the applicant provides the assumptions and methodology used to project in-center and peritoneal dialysis home training utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.