

## **ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

### **FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 17, 2017

Findings Date: November 17, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: Q-11380-17

Facility: Robersonville Dialysis

FID #: 170330

County: Martin

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

Project: Develop a new 10-station dialysis facility in Martin County by relocating ten dialysis stations and the home training program (includes home hemodialysis and peritoneal dialysis training and support programs) from DC Martin 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

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 Robersonville Dialysis proposes to develop a new 10-station dialysis facility (Robersonville Dialysis) in Robersonville, Martin County by relocating ten dialysis stations from Dialysis Care of Martin County (DC Martin 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, Robersonville Dialysis will be certified for 10 dialysis stations and DC Martin County will be certified for 15 dialysis stations. DC Martin County offers a home hemodialysis and peritoneal program, which will be relocated to Robersonville Dialysis.

## **Need Determination**

The applicant is proposing to relocate existing dialysis stations within Martin County. Neither the county need nor the facility need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) are applicable to this review. Additionally, Policy GEN-3: *Basic Principles* is not applicable because neither need methodology is applicable to the review.

## **Policies**

There are two policies in the 2017 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27 and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33.

*POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* 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 is proposing to relocate existing dialysis stations within Martin County, therefore the proposed project is in compliance with Policy ESRD-2- *Relocation of Dialysis Stations*.

*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 43-44, 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.

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policies in the 2017 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**

TRC proposes to develop a new 10-station dialysis facility, Robersonville Dialysis, by relocating ten dialysis stations from DC Martin County. The existing facility and the proposed facility will be located in Martin 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, Robersonville Dialysis will be certified for 10 dialysis stations and DC Martin County will be certified for 15 dialysis stations. DC Martin County offers a home hemodialysis and peritoneal program, which will be relocated to Robersonville Dialysis.

### **Patient Origin**

On page 373, the 2017 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 Martin County. Facilities may also serve residents of counties not included in their service area.

Robersonville Dialysis will be a new facility in Martin County and therefore has no existing patient origin.

In Section C, page 13, the applicant provides the projected patient origin for Robersonville Dialysis for in-center (IC), home hemodialysis (HH) and peritoneal (PD) patients the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Martin	30	1	2	30	2	3	80.5%	81.4%
Beaufort	0	0	1	0	0	1	4.9%	4.7%
Bertie	1	0	2	1	0	2	4.9%	4.7%
Pitt	1	1	0	1	1	0	4.9%	4.7%
Washington	0	0	2	0	0	2	4.9%	4.7%
Total	32	2	7	32	3	8	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 13-18.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 17, the applicant states that it determined a need for a new dialysis facility in the western part of Martin County based on the fact that 32 in-center patients currently receiving services at DC Martin County live in the western part of Martin County. Additionally, the applicant identified one HH and six PD patients that are currently served by DC Martin County, but live in ZIP Codes “in or near” the western part of Martin County.

The only existing or approved dialysis facility in Martin County is DC Martin County. Based on the signed letters from patients currently dialyzing at DC Martin County the applicant concluded that the proposed new facility will be located closer to where a significant number of its patients reside. 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 Total 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.”*

See Exhibit C-1 which contains 40 patient letters of support which state:

*“I fully support this new dialysis facility ... to be built in Robersonville. ... Having my dialysis treatments at Robersonville 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.”*

Projected Utilization-IC Patients

In Section C, page 13, the applicant provides the projected utilization during the first two years of operation following completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Martin	30	1	2	30	2	3	80.5%	81.4%
Beaufort	0	0	1	0	0	1	4.9%	4.7%
Bertie	1	0	2	1	0	2	4.9%	4.7%
Pitt	1	1	0	1	1	0	4.9%	4.7%
Washington	0	0	2	0	0	2	4.9%	4.7%
Total	32	2	7	32	3	8	100.0%	100.0%

In Section C, pages 13-18, the applicant provides the assumptions and methodology used to project utilization. On page 13-14, the applicant illustrates how in-center patient utilization was projected, which is summarized below:

- Operating Year One (OY1) is January 1, 2019 – December 31, 2019.
- Operating Year Two (OY2) is January 1, 2020 – December 31, 2020.
- Thirty (30) Martin County residents currently dialyzing at DC Martin County have signed letters that they would consider transferring to Robersonville Dialysis because the proposed facility would be located in the western part of Martin County and thus closer to where they reside. See also Exhibit C-1.
- Two (2) in-center patients of DC Martin County who are not residents of Martin County (one each from Bertie and Pitt Counties) have also signed letters indicating that they would consider transferring to the proposed Robersonville Dialysis based on the fact that it would be closer to where they currently live.
- The applicant projects no growth of the in-center patients who are not residents of Martin County
- In-center patient population of Martin County residents is projected to grow at 1.2%, the Five Year Average Annual Growth Rate (AAGR) for Martin County pursuant to Table D in the July 2017 Semi-Annual Dialysis Report (SDR).

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

TRC projects 30 in-center patients, all of whom reside in Martin County as of January 1, 2019.	30
TRC projects this patient population forward one year to December 31, 2019, using the 1.2% AAGR.	$1.012 \times 30 = 30.36$
TRC then adds the two in-center patients who are not residents of Martin County. This is the projected ending census for <b>Operating Year 1 (1/1/19 – 12/31/19)</b> .	$30.36 + 2 = 32.36$
TRC projects the Martin County resident patient population forward one year to December 31, 2020 using the 1.2% AAGR.	$1.012 \times 30.36 = 30.7243$
TRC then adds the two in-center patients who are not residents of Martin County. This is the projected ending census for <b>Operating Year 2 (1/1/20 – 12/31/20)</b> .	$30.7243 + 2 = 32.7243$

The applicant states on page 15 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 2019) and OY2 (CY2020) the facility is projected to serve 32 in-center patients.

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

- OY1: 3.2 patients per station per week, or 80% ( $32 \text{ patients} / 10 \text{ stations} = 3.2/4 = 0.8$  or 80%).
- OY2: 3.2 patients per station per week, or 80% ( $32 \text{ patients} / 10 \text{ stations} = 3.2/4 = 0.8$  or 80%).

The projected utilization of 3.2 patients per station per week at the end of OY1 meets 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 at Robersonville Dialysis.

*Projected Utilization-Home PD Patients*

The applicant provides projected utilization for its PD patients in Section C.1, page 16, 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	1/1/19	6	7
Operating Year 2	1/1/20	7	8

On page 16, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains six letters of support for the proposed facility from PD patients who currently receive their support at DC Martin County indicating that they would consider transferring their care to Robersonville Dialysis, if approved, based on the fact

that they either lived closer to the proposed new facility or it would be more convenient for them. The six current PD patients who signed the letters live in Martin, Beaufort, Washington and Bertie counties.

- TRC assumes the six patients who signed letters of support for the proposed facility will transfer their care to Robersonville Dialysis upon certification.
- TRC assumes that the PD patients will increase one patient each year.

Projected Utilization-HH Patients

The applicant provides projected utilization for its HH patients in Section C.1, pages 16, as follows:

<b>Operating Year</b>	<b>Start Date</b>	<b>Beginning Census of HH Patients</b>	<b>Ending Census of HH Patients</b>
Operating Year 1	1/1/2019	1	2
Operating Year 2	1/1/2020	2	3

On pages 15-16, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains one letter of support for the proposed facility from a current HH patient at DC Martin County who lives in Pitt County indicating that they would consider transferring their care to Robersonville Dialysis, if approved.
- TRC assumes that the patient who signed the letter of support for the proposed facility would transfer their care to Robersonville Dialysis upon certification.
- TRC assumes that the HH patients will increase by one patient each year.

Projected PD and HH utilization is based on reasonable and adequately supported assumptions regarding continued growth at Robersonville Dialysis.

Access to Services

In Section C.3, page 17, 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 49, that 84.6% of its patients at Robersonville Dialysis will have some or all of their expenses paid by either Medicare or Medicaid. The applicant states that the projected payor mix for the proposed facility is based on sources of payment for DaVita operated facilities in Martin 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 dialysis services at Robersonville Dialysis. 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, Robersonville Dialysis, by relocating ten dialysis stations and the home training program (includes home hemodialysis and peritoneal dialysis training and support programs) from DC Martin County. The existing facility and the proposed facility will be located in Martin 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, Robersonville Dialysis will be certified for 10 dialysis stations and DC Martin County will be certified for 15 dialysis stations (25 stations – 10 stations = 15 stations).

In Section D.1, pages 24-25, the applicant discusses how the needs of dialysis patients at DC Martin County will continue to be met following the relocation of stations to Robersonville Dialysis. In Section D.1, page 23, the applicant states that as of December 31, 2016, as reported in the July 2017 SDR, there were 69 in-center dialysis patients at DC Martin County dialyzing on 25 dialysis stations, for a utilization rate of 69.0%. In addition, the applicant states that 65 of the 69 in-center patients lived in Martin County and that four lived outside Martin County.

In Section C.1, page 13, the applicant projects that 30 in-center patients currently receiving services at DC Martin County and who also live in Martin County will transfer to Robersonville Dialysis. The applicant also projects that 2 in-center patients who are not residents of Martin County (Bertie and Pitt Counties) currently dialyzing at DC Martin County will transfer to Robersonville Dialysis.

The applicant assumes that the number of in-center patients at DC Martin County who live in Martin County will increase at 1.2% per year based on the Five Year AACR for Martin County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the two in-center patients currently living in Bertie and Pitt Counties.



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

TRC projects 65 in-center patients, all of whom reside in Martin County as of January 1, 2017.	65
TRC projects this patient population forward one year to December 31, 2017, using the 1.2% AAGR. .	$1.012 \times 65 = 65.78$
TRC then adds the four in-center patients who are not residents of Martin County. This is the projected ending census for 2017.	$65.78 + 4 = 69.78$
TRC projects this patient population forward one year to December 31, 2018, using the 1.2% AAGR	$1.012 \times 65.78 = 66.56936$
TRC then adds the four in-center patients who are not residents of Martin County. This is the projected ending census for 2018.	$66.56936 + 4 = 70.56936$
TRC projects this patient population forward one year to December 31, 2019 by first subtracting out the 30 patients from Martin County who will be transferring to Robersonville Dialysis and using the 1.2% AAGR.	$66 - 30 = 36$ $1.012 \times 36 = 36.432$
TRC then adds the four patients who are not residents of Martin County less the two who are transferring to Robersonville Dialysis. This is the projected ending census for <b>Operating Year 1 (1/1/19 – 12/31/19)</b> .	$4 - 2 = 2$ $36.432 + 2 = 38.432$
TRC projects this patient population forward one year to December 31, 2020, using the 1.2% AAGR	$1.012 \times 36.432 = 36.86918$
TRC then adds the two in-center patients who are not residents of Martin County. This is the projected ending census for <b>Operating Year 2 (1/1/20 – 12/31/20)</b> .	$36.86918 + 2 = 38.86918$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 and OY2, DC Martin County is projected to serve 38 in-center patients.

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

- OY1: 2.53 patients per station per week, or 63.25% (38 patients/ 15 stations = 2.53/4 = 0.6325 or 63.25%).
- OY2: 2.53 patients per station per week, or 63.25% (38 patients/ 15 stations = 2.53/4 = 0.6325 or 63.25%).

This utilization for DC Martin County is consistent with its historical utilization as reported in the most recent SDR (July 2017). The applicant states the following on page 25:

*“Given this projected growth of the in-center patient population, the needs of the population presently served at this location will be adequately met. ...”*

The home training program (includes home hemodialysis and peritoneal dialysis training and support programs) at DC Martin County will continue to operate *“for a period of time because some of the home patients will not transfer their care while Robersonville Dialysis secures*

*approval for all private insurance providers. That is why not all home-trained patients did not sign support letters for this application.” (See application page 3.)*

In Section D, page 25, the applicant states that DC Martin County, by policy, will continue to make dialysis services available to all residents in the service area without qualifications.

### **Conclusion**

The applicant demonstrates that the needs of the populations presently served at DC Martin County will continue to be adequately met following the proposed relocation of ten dialysis stations from the facility to Robersonville Dialysis and that access for medically underserved groups will not be negatively impacted by the relocation.

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, pages 26-27, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintaining the status quo – the applicant concluded that maintaining the status quo did not meet the growing need for dialysis services in the western portion of Martin County. Therefore, this is not an effective alternative.
- Locating the facility in another area of Martin County – the applicant states that it analyzed the patient population currently being served at DaVita operated facilities in Martin County and determined that western Martin County was in need of a dialysis center, as based on the letters of support. Building the facility in another part of the county would not provide better geographic access to patients currently being served. Therefore, this is not an effective alternative.

After considering these alternatives to its proposal, the applicant states that development of the new Robersonville Dialysis facility would reduce the transportation demands faced by existing patients and increase the patients’ quality of life and compliance with treatment schedules. Therefore, the proposed project is 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 Robersonville Dialysis shall materially comply with all representations made in the certificate of need application.**
  2. **Total Renal Care of North Carolina, LLC d/b/a Robersonville Dialysis shall relocate no more than ten dialysis stations from DC Martin County for a total of no more than 10 dialysis stations at Robersonville Dialysis.**
  3. **Total Renal Care of North Carolina, LLC d/b/a Robersonville Dialysis shall relocate the home training program (includes home hemodialysis and peritoneal dialysis training and support programs) from Dialysis Care of Martin County to Robersonville Dialysis.**
  4. **Total Renal Care of North Carolina, LLC d/b/a Robersonville Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
  5. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify ten dialysis stations at Dialysis Care of Martin County for a total of no more than 15 dialysis stations at Dialysis Care of Martin County upon project completion.**
  6. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify the home training program (includes home hemodialysis and peritoneal dialysis training and support programs) at Dialysis Care of Martin County upon project completion and approval of all private insurance providers.**
  7. **Total Renal Care of North Carolina, LLC d/b/a Robersonville 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

TRC proposes to develop a new 10-station dialysis facility in Robersonville by relocating ten dialysis stations from DC Martin County.

### **Capital and Working Capital Costs**

In Section F.1, page 28, the applicant provides the capital cost of the project as summarized in the following table:

**Robersonville Dialysis  
 Project Capital Costs**

Site Costs	\$40,510
Construction Contract	\$1,276,155
Dialysis Machines	\$165,360
Water Treatment Equipment	\$160,560
Equipment/Furniture	\$390,857
Architect & Engineering Fees	\$107,800
<b>Total Capital Costs</b>	<b>\$2,141,242</b>

In Section F.10, pages 30-31, and Section F.11, page 31, the applicant estimates start-up expenses of \$191,283 and initial operating expenses of \$765,644, respectively, for a total working capital \$956,927.

**Availability of Funds**

In Section F.2, page 29, the applicant states that accumulated reserves/owner's equity will be used to finance the project's capital costs. In Section F.13, page 32, the applicant states that the working capital costs will be financed with cash reserves. Exhibit F-5 contains a letter from DaVita Inc.'s Chief Accounting Officer, dated July 17, 2017, 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 DaVita HealthCare Partners, Inc. (DaVita) United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2016. As of December 31, 2016, DaVita had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets, and \$5,822,999,000 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 provided pro forma financial statements for the first two full fiscal years of operation following completion 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 in the table below.

	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Treatments	5,927	6,225
Total Gross Revenues (Charges)	\$1,705,377	\$1,791,242
Total Net Revenue	\$1,633,127	\$1,711,343
Average Net Revenue per Treatment	\$275.54	\$274.91
Total Operating Expenses (Costs)	\$1,531,287	\$1,580,117
Average Operating Expenses per Treatment	\$258.36	\$252.83
Net Income	\$101,840	\$131,226

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 financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. 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

TRC proposes to develop a new 10-station dialysis facility, Robersonville Dialysis, by relocating ten dialysis stations from DC Martin County. The existing facility is and the proposed facility will be located in Martin 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, Robersonville Dialysis will be certified for 10 dialysis stations and DC Martin County will be certified for 15 dialysis stations.

On page 373, the 2017 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 Martin County. Facilities may also serve residents of counties not included in their service area.

The July 2017 SDR indicates there is one dialysis facility in Martin as follows:

**Martin County Dialysis Facilities  
December 31, 2016**

<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>
Dialysis Care of Martin Country	DaVita	69	Williamston	25	0	69.0%

Source: July 2017 SDR

As illustrated above, there is one existing dialysis facility located in Martin County as of December 31, 2016 which is operated by DaVita. The proposed site for Robersonville Dialysis is in the western part of Martin County. DC Martin County operated with a utilization rate of 69.0% as of December 31, 2016.

The applicant is not increasing the number of dialysis stations in Martin County, rather it is relocating 10 of them to develop a new facility that is closer to patients living in the western part

of the area where the new facility will be located. Therefore, the applicant 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, pages 13-15, the applicant demonstrates that Robersonville Dialysis will serve a total of 32 in-center patients on 10 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80% ( $32/10 = 3.2$ ;  $3.2/4 = 0.80$  or 80%). The applicant provides documentation in Exhibit C-1 from 32 in-center patients at its DC Martin County facility indicating their willingness to consider transferring to Robersonville Dialysis upon project completion because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Table D: ESRD Dialysis Station Need Determination by Planning Area in the July 2017 SDR shows a deficit of one dialysis stations in Martin County. However, the applicant is not proposing to add any new (or additional) dialysis stations in the Martin County Planning Area. The applicant is only proposing to relocate ten existing dialysis stations from one DaVita facility in Martin County to a new DaVita facility in Martin County.

The applicant adequately demonstrates the need to relocate ten stations to develop a new dialysis facility in Martin County. The discussion on analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at DC Martin County, 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 Martin County. Consequently, the application is conforming to this criterion.

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

## C

In Section H.1, page 35, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for Robersonville Dialysis. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

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

In Section H.7, page 38, the applicant provides the projected Direct Care Staff Hours for OY2, as shown below in the table:

<b>Robersonville Dialysis</b>					
<b>DIRECT CARE POSITIONS</b>	<b># FTEs</b>	<b>HOURS PER YEAR PER FTE</b>	<b>TOTAL ANNUAL FTE HOURS</b>	<b>TOTAL ANNUAL HOURS OF OPERATION</b>	<b># FTE HOURS PER HOUR OF OPERATION</b>
Registered Nurse	2	2,080	4,160	3,120	1.3
Patient Care Tech	4	2,080	8,320	3,120	2.7
<b>Total</b>	<b>6</b>	<b>2,080</b>	<b>12,480</b>	<b>3,120</b>	<b>4</b>

In Section H.2, page 36, the applicant states that the Medical Director for Robersonville Dialysis will be Dr. Cynthia Christiano, a board certified nephrologist. In Exhibit I-3, the applicant provides a letter signed by Dr. Christiano dated May 11, 2017, confirming her commitment to serve as Medical Director. In Section H.3, pages 36-37, 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.

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

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

C

In Section I, page 38, 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. The

applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-2 including letters from several providers such as DaVita Laboratory Services, Inc., NC DHHS Division of Vocational Rehabilitation Services, Brody School of Medicine for vascular services and transplant services and Vidant Health for acute care services. The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

TRC is proposing to develop Robersonville Dialysis at 825 North Main Street, Robersonville, in Martin County. (See application page 4.) A dialysis facility is a permitted use at this location under the zoning code and power, sewer and water are available at the site. (See Exhibit K-4.)



In Section K.2, page 44, the applicant states, the proposed facility is projected to consist of a 3,877 square foot treatment space 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 an 8,800 square foot facility, including office space, nine dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 10 in-center stations. In Section F.1, page 28, the applicant lists its projected costs, including \$40,510 for site work, \$1,276,155 for construction and \$824,577 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,141,242. In Section B.5, pages 11-12, the applicant describes its plans to assure improved energy-efficiency and water conservation. Costs and charges are described by the applicant in Section F, pages 28-32, and in Section R 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

Robersonville Dialysis would be a new facility, thus, it has no historical payor mix.

In Section L.7, page 52, the applicant provides the payor mix for DC Martin County for CY2016. DC Martin County is the facility that will be contributing ten dialysis stations to develop the proposed facility and from which some of the projected patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payor mix for DC Martin County is illustrated as follows:

**DC Martin County Payor Mix CY2016**

Payor Type	Percent of Total Patients	Percent of In-Center Patients	Percent of PD Patients	Percent of HH Patients
Medicare	25.4%	25.8%	12.5%	100.0%
Medicaid	1.4%	1.6%	0.0%	0.0%
Commercial Insurance	5.6%	4.8%	12.5%	0.0%
Medicare/Commercial	25.4%	24.2%	37.5%	0.0%
Medicare/Medicaid	32.4%	33.9%	25.0%	0.0%
VA	9.9%	9.7%	12.5%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	

As the tables above indicate, 84.6% of DC Martin County patients had some or all of their services covered by Medicare or Medicaid. 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 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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Martin	22%	53%	48%	23%	12%	12%
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 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 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

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

<sup>2</sup>[http://esrd.ipro.org/wp-content/uploads/2016/11/2015\\_NW-6\\_Annual-Report\\_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf](http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf)

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

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

C

Robersonville Dialysis would be a new facility, it has no past performance to reference.

In Section L.3(e) page 51, the applicant states:

*“Robersonville 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 51, 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 49, the applicant states that the projected payor mix for Robersonville Dialysis is based on sources of payment for its DaVita facility in Martin County for the last full operating year, as follows:

**Robersonville Dialysis Projected Payor Mix OY2**

<b>Payor Type</b>	<b>Percent of Total Patients</b>	<b>Percent of In-Center Patients</b>	<b>Percent of PD Patients</b>	<b>Percent of HH Patients</b>
Medicare	25.4%	25.8%	12.5%	100.0%
Medicaid	1.4%	1.6%	0.0%	0.0%
Commercial Insurance	5.6%	4.8%	12.5%	0.0%
Medicare/Commercial	25.4%	24.2%	37.5%	0.0%
Medicare/Medicaid	32.4%	33.9%	25.0%	0.0%
VA	9.9%	9.7%	12.5%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	

The applicant projects that 84.6% of Robersonville Dialysis’ patients will have some or all of their services covered by Medicare or Medicaid.

In Section C.3, page 17, the applicant states:

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

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

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 51, the applicant states

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

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

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

C

In Section M.1, page 53, the applicant states that it has offered Robersonville Dialysis as a clinical training site for nursing students from Martin Community College. A copy of a letter sent by the applicant to the college, dated July 1, 2017, 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

TRC proposes to develop a new 10-station dialysis facility, Robersonville Dialysis, by relocating ten dialysis stations from DC Martin County. The existing facility and the proposed facility will be located in Martin 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, Robersonville Dialysis will be certified for 10 dialysis stations and DC Martin County will be certified for 15 dialysis stations. . DC Martin County offers a home hemodialysis and peritoneal program, which shall be relocated to Robersonville Dialysis.

On page 373, the 2017 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 Martin County. Facilities may also serve residents of counties not included in their service area.

The July 2017 SDR indicates there is one dialysis facility in Martin as follows:

**Martin County Dialysis Facilities  
December 31, 2016**

<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>
Dialysis Care of Martin Country	DaVita	69	Williamston	25	0	69.0%

Source: July 2017 SDR

As illustrated above, there is one existing dialysis facility located in Martin County as of December 31, 2016 which is operated by DaVita. The proposed site for Robersonville Dialysis is in the western part of Martin County. DC Martin County operated with a utilization rate of 69.0% as of December 31, 2016.

In Section N.1, page 54, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

*“The proposed 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.*

*... Robersonville 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, E, F, G, I, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- ◆ The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will provide access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC, whose parent company is DaVita, Inc., owns and operates 73 facilities in North Carolina as of the July 2017 SDR. In Section O, page 55 and Exhibit O-3, the applicant identifies the three kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. However, all three facilities are back in compliance with the Medicare conditions of participation. 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, pages 13-14, the applicant adequately demonstrates that Robersonville Dialysis will serve at least 32 in-center patients on 10 stations at the end of OY1 (CY2019) for a utilization rate of 80% or 3.2 patients per station per week ( $32/10 = 3.2$ ;  $3.2/4 = 0.8$ ). 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 13-15, the applicant provides the assumptions and methodology used to project utilization of Robersonville Dialysis. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.