

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 6, 2018

Findings Date: June 6, 2018

Project Analyst: Tanya S. Rupp

Assistant Chief: Lisa Pittman

Project ID #: H-11494-18

Facility: Pee Dee Dialysis

FID #: 180172

County: Richmond

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Pee Dee Dialysis (PDD) proposes to develop a new 10-station dialysis facility in Richmond County by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis. Both existing facilities and the proposed facility are located in Richmond County. Upon completion of the proposed relocation of stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations and Sandhills Dialysis will be certified for 16 dialysis stations.

Need Determination

Neither the county nor the facility need methodologies in the January 2018 SDR and the 2018 SMFP are applicable to this review.

Policies

There are three policies in the 2018 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations, on page 27, Policy GEN-3: Basic Principles, on page 33 and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33.

Policy ESRD-2

Policy ESRD-2 states:

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

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

PDD proposes to develop a new 10-station dialysis facility by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis. Both existing facilities and the proposed facility are located in Richmond County, therefore there will be no change in the dialysis station inventory in Richmond County associated with this proposal.

According to Table D of the January 2018 SDR, Richmond County has a projected surplus of 2 dialysis stations. Since this project proposes a relocation of existing dialysis stations within Richmond County, the surplus will not be effected. Therefore, the application is conforming to Policy ESRD-2.

Policy GEN-3

Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 8 - 9, Section O, page 57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, pages 9 - 10, Section C, pages 19 - 20, Section L, pages 50 - 53, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, page 10, Section N, page 56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Policy GEN-4

Policy GEN-4 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 of 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 for this project is greater than \$2 million but less than \$5 million. In Section B.5, pages 11 - 12, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

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

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Pee Dee Dialysis (PDD) proposes to develop a new 10-station dialysis facility in Richmond County by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis. Both existing facilities and the proposed facility are located in Richmond County. Upon completion of the proposed relocation of stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations and Sandhills Dialysis will be certified for 16 dialysis stations.

The following tables, summarized from Section A.9, pages 4 - 5 of the application, show the proposed PDD facility, and the existing Dialysis Care of Richmond County and Sandhills Dialysis facilities from which the applicant plans to relocate 10 stations to develop the proposed new facility.

Pee Dee Dialysis

# STATIONS	DESCRIPTION	PROJECT ID # (IF APPLICABLE)
0	Total # existing stations per most recent SDR	
10	# stations to be added	N-11494-18
10	Total # stations upon completion of all projects	

Dialysis Care of Richmond County

# STATIONS	DESCRIPTION	PROJECT ID # (IF APPLICABLE)
30	Total # existing stations per most recent SDR	
0	# stations to be added	
4	# stations to be deleted	N-11494-18
26	Total # stations upon completion of all projects	

Sandhills Dialysis

# STATIONS	DESCRIPTION	PROJECT ID # (IF APPLICABLE)
16	Total # existing stations per most recent SDR	
0	# stations to be added	
6	# stations to be deleted	N-11494-18
6	# stations previously approved to be added; not certified	H-11251-16
16	Total # stations upon completion of all projects	

As shown in the table above, upon project completion, PDD will be certified for 10 dialysis stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations, and Sandhills Dialysis will be certified for 16 dialysis stations.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 Richmond County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 13, the applicant provides the projected in-center patient origin for PDD for the first two years of operation following completion, as shown in the following table:

Pee Dee Dialysis Projected Patient Origin

COUNTY	OY 1	OY 2	COUNTY PATIENTS AS A % OF TOTAL	
			OY 1	OY 2
Richmond	33	36	97.1%	97.3%
Anson	1	1	2.9%	2.7%
Total	34	37	100.0%	100.0%

On page 15, the applicant states home hemodialysis and peritoneal dialysis patients will be trained at Dialysis Care of Moore County.

The applicant provides the assumptions and methodology used to project patient origin on pages 13 - 15. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.1, page 15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“In doing an analysis of the patients served by Total Renal Care of North Carolina, LLC in Richmond County, it was determined that DaVita is serving many patients who live in the City of Rockingham and the Town of Ellerbe. We have identified in this application twenty-one in-center patients who live in the City of Rockingham who travel to the Dialysis Care of Richmond County facility that is located in Hamlet. All of those patients can be better served with a second facility located in the City of Rockingham.”

The applicant thus proposes to develop a new dialysis facility by relocating existing dialysis stations, to serve its existing Richmond County patients who currently travel to another DaVita facility in another town to dialyze. The relocation of these stations to develop a new facility would better serve DaVita’s existing patient population who indicated, in letters provided in Exhibit C-1, that the proposed location would be more convenient to them. In addition, the applicant states on page 15 that peritoneal and home hemo-dialysis patients are served by Dialysis Care of Moore County.

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

- The applicant demonstrates the need to develop a new dialysis facility by relocating existing dialysis stations consistent with Policy ESRD-2. The discussion regarding Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.
- The applicant demonstrates, through signed patient letters, that existing DaVita dialysis patients would be better served by a new facility located in Rockingham.

Projected Utilization

In Section C.1, pages 13 - 15, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The January 2018 SDR shows that currently, 140 in-center dialysis patients receive their treatment at DaVita operated facilities in Richmond County.
2. The applicant states that 33 of those patients who live in Richmond County have signed letters that indicate each patient’s intent to transfer his/her care to the proposed Pee Dee Dialysis facility. The applicant states there is one in-center dialysis patient currently being treated at a DaVita operated facility in Richmond County who resides in Anson County, who has also signed a letter indicating he/she would consider transferring dialysis care to PDD. Exhibit C-1 contains copies of the 34 signed letters.
3. The applicant assumes that 31 of the 34 patients identified above will transfer their care to the proposed facility. The applicant assumes that the Richmond County patient population will increase at a rate that is consistent with the Five Year Average Annual Change Rate (AACR) for Richmond County published in the January 2018 SDR, which is 8.5%.
4. Operating Year (OY) One is projected to be calendar year (CY) 2020; and OY 2 is projected to be CY 2021.

The applicant’s methodology for serving in-center patients is shown in the following table, from page 15:

Beginning Period	Start Date	# Service Area Pts.	Five Year AACR	# Service Area Pts. End	# Out of Service Area Pts.	End Pt. Census
Current Year	1/1/2018	0	0	0	0	0
Interim Period	1/1/2019	0	0	0	0	0
OY 1 (CY 2020)	1/1/2020	31	8.5%	33.635	1	34.635
OY 2 (CY 2021)	1/1/2021	33.635	8.5%	36.494	1	37.494

The applicant rounds down to the nearest whole number and projects to serve 34 in-center patients or 3.4 patients per station per week ($34 / 10 = 3.4$) by the end of Operating Year 1 and 37 in-center patients or 3.7 patients per station per week ($37 / 10 = 3.7$) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Projected utilization for in-center dialysis patients at PDD is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing patients who live in Richmond County and currently dialyze at a DaVita facility, each of whom has signed a letter expressing an intent to transfer dialysis care to the proposed PDD facility.
- The applicant's growth projections are based on an assumption that the dialysis patient census will increase annually by 8.5%, which is consistent with the Five Year AACR for Richmond County, reported in the January 2018 SDR, Table D.

Access

In Section C.3, page 16, the applicant states that, by policy, dialysis services will be available to all residents in the service area, and that the facility will serve all patients without regard to race, sex, age, handicap or socioeconomic situation. In Section L.1(b), page 51, the applicant projects the following payor mix during the second full fiscal year of operation (CY 2020) following completion of the project, as illustrated in the following table.

PAYMENT SOURCE	% OF TOTAL
Medicare	31.0%
Medicaid	6.3%
Commercial Insurance	7.7%
Medicare / Commercial Insurance	19.0%
Medicare / Medicaid	33.2%
VA	2.8%
Total	100.00%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

C

TRC proposes to develop a new 10-station dialysis facility in Richmond County by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis, both of which are existing dialysis facilities in Richmond County. Upon completion of the proposed relocation of stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations and Sandhills Dialysis will be certified for 16 dialysis stations.

The following table shows the projected relocation of stations from the two existing dialysis facilities to the proposed Pee Dee Dialysis facility, and the number of stations remaining after the relocation to the proposed new facility:

PEE DEE DIALYSIS NEW FACILITY				
FACILITY	CURRENT # STATIONS	# STATIONS TO BE RELOCATED	CURRENT # RICHMOND COUNTY PATIENTS	# RICHMOND COUNTY PATIENTS TO TRANSFER
Dialysis Care of Richmond County	30	-4	73	-18
Sandhills Dialysis Center*	16	6	60	-13
Pee Dee Dialysis	0	+10	0	+31

*Project ID #H-11251-16 proposed to add six dialysis stations to Sandhills Dialysis Center, so the net affect after this project and Project ID #H-11251-16 would be 16 stations at Sandhills Dialysis Center.

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

Dialysis Care of Richmond County

According to the January 2018 Semiannual Dialysis Report (SDR), there were 80 patients dialyzing at Dialysis Care of Richmond County on 30 certified dialysis stations for a utilization rate of 66.67%, or 2.67 patients per station per week ($80 / 30 = 2.67$) as of June 30, 2017. The proposed relocation of stations will leave DC of Richmond County with 26 certified stations. The applicant projects that a total of 19 in-center patients (18 residents of Richmond County and one resident of Anson County) will transfer their care from DC of Richmond County to the new facility. The applicant projects growth of the remaining patients at DC of Richmond County using the Richmond County Five Year AACR found in the January 2018 SDR, as shown in the following table:

Dialysis Care of Richmond County Projected Utilization

Beginning Period	Start Date	# Service Area Pts.	Five Year AACR	# Service Area Pts. End	# Out of Service Area Pts.	End Pt. Census
Current (6/30/17)	7/1/2017	73	1.0425*	76.103	7	83.103
Current Year	1/1/2018	76.103	8.5%	82.572	7	89.572
Interim Period	1/1/2019	85.572	8.5%	89.591	7	96.591
OY 1 (CY 2020)	1/1/2020	$89 - 18 = 71$	8.5%	77.035	$7 - 1 = 6$	83.035
OY 2 (CY 2021)	1/1/2021	77.035	8.5%	83.583	6	89.586

*This growth rate represents one-half of the Richmond County AACR, since growth in this step is projected for six months.

DC of Richmond County is projected to serve 83 patients on 26 in-center stations in OY 1 following completion of this project, which is 3.19 patients per station; and 89 patients on 26 in-center stations in OY 2, which is 3.42 patients per station per week. The applicant states on page 24 that the facility will be able to adequately serve its patients following the transfer of patients and relocation of stations as proposed in this application.

Sandhills Dialysis

According to the January 2018 Semiannual Dialysis Report (SDR), there were 60 patients dialyzing at Sandhills Dialysis Center on 16 certified dialysis stations for a utilization rate of 93.75%, or 3.75 patients per station per week ($60 / 16 = 3.75$) as of June 30, 2017. The applicant states Project ID #H-11251-16 proposed to add six stations to Sandhills Dialysis, and the station relocation proposed in this application will leave Sandhills Dialysis with 16 certified stations. The applicant projects that a total of 13 in-center patients from Richmond County will transfer their care from Sandhills Dialysis to the new facility. The applicant projects growth of the remaining patients at Sandhills Dialysis using the Richmond County Five Year AACR found in the January 2018 SDR, as shown in the following table:

Sandhills Dialysis Projected Utilization

Beginning Period	Start Date	# Service Area Pts.	Five Year AACR	End Pt. Census
Current (6/30/17)	7/1/2017	60	1.0425*	62.55
Current Year	1/1/2018	62.55	8.5%	67.867
Interim Period	1/1/2019	67.867	8.5%	73.636
OY 1 (CY 2020)	1/1/2020	73 – 13 = 60	8.5%	65.1
OY 2 (CY 2021)	1/1/2021	65.1	8.5%	70.634

*This growth rate represents one-half of the Richmond County AACR, since growth in this step is projected for six months.

Sandhills Dialysis is projected to serve 65 patients on 16 in-center stations in OY 1 following completion of this project, which is 4.06 patients per station per week; and 70 patients on 16 in-center stations in OY 2, which is 4.38 patients per station per week. The applicant states on page 25 that Sandhills Dialysis will be able to adequately serve its patients following the transfer of patients and relocation of stations as proposed in this application.

Projected utilization for DC of Richmond County and Sandhills Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for DC of Richmond County and Sandhills Dialysis based on existing patients who will remain at each facility, as well as those patients who have signed letters expressing their intention to transfer their care to the proposed Pee Dee Dialysis facility.
- The applicant’s growth projections are based on an assumption that patient census will increase at an annual rate of 8.5%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Richmond County, as reported in Table D of the January 2018 SDR.

Further, in Section D.2, pages 25 - 26, the applicant states that the proposed relocation of stations will not will not adversely affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

Conclusion

The Agency reviewed the:

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

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

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.

- The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to develop a new 10-station dialysis facility in Richmond County by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis. Both existing facilities and the proposed facility are located in Richmond County. Upon completion of the proposed relocation of stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations and Sandhills Dialysis will be certified for 16 dialysis stations.

In Section E, pages 32-33, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because the projected growth in patient census at both of the DaVita facilities in Richmond County would necessitate a third shift or additional stations at each facility. The applicant states a third shift is not convenient for patients, and a facility operating at maximum capacity eliminates the choice for patients to continue to dialyze at a DaVita facility.
- Locate the Proposed Facility in Another area of the County – The applicant states that, based on patient preference as reflected in the patient letters in Exhibit C-1, the selected location is most consistent with expressed patient choice.

On page 28, the applicant states that its proposal is the most effective alternative because the proposed facility is convenient to the patients currently served and will be large enough to accommodate the projected need for the projected growth in in-center patient population currently served by the existing Richmond County facilities.

Conclusion

The Agency reviewed the:

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

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

1. **Total Renal Care of North Carolina, LLC d/b/a Pee Dee Dialysis shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new kidney disease treatment center to be known as Pee Dee Dialysis by relocating four dialysis stations from Dialysis Care of Richmond County and six dialysis stations from Sandhills Dialysis.**
 3. **Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify four dialysis stations at Dialysis Care of Richmond County for a total of no more than 26 dialysis stations at Dialysis Care of Richmond County.**
 4. **Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify six dialysis stations at Sandhills Dialysis for a total of no more than 16 dialysis stations at Sandhills Dialysis following completion of this project and Project ID #H-11251-16.**
 5. **Total Renal Care of North Carolina, LLC d/b/a Pee Dee Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
 6. **Total Renal Care of North Carolina, LLC d/b/a Pee Dee 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 Richmond County by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis.

Capital and Working Capital Costs

In Section F.1, page 29, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$1,616,717
Miscellaneous Costs	\$958,152
Total	2,574,869

In Section F.10, page 32, the applicant projects that start-up costs will be \$172,729 and initial operating expenses will be \$703,113 for a total working capital of \$875,842. On pages 32 - 33, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

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

Sources of Capital Cost Financing

TYPE	PEE DEE DIALYSIS	TOTAL
Loans	\$0	0\$
Accumulated reserves or OE *	\$2,574,869	\$2,574,869
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,574,869	\$2,574,869

*OE = Owner's Equity

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

Sources of Working Capital Financing

TYPE	PEE DEE DIALYSIS	TOTAL
Loans	\$0	0\$
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Cash Reserves)	\$875,842	\$875,842
Total Financing	\$875,842	\$875,842

*OE = Owner's Equity

Exhibit F-1 contains a letter dated March 15, 2018 from the Chief Accounting Officer for DaVita, Inc., parent company of TRC, authorizing and committing cash reserves of DaVita for the capital and working capital costs of the project. Exhibit F-2 contains a copy of the balance sheet for DaVita for the year ending December 31, 2016. The report indicates that as of December 31, 2016, DaVita had \$913,187,000 in cash and cash equivalents, \$18.7 billion in total assets and \$5.8 billion in net assets (total assets less total liabilities).

Financial Feasibility

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

	OPERATING YEAR 1 CY 2019	OPERATING YEAR 2 CY 2020
Total Treatments	4,891	5,261
Total Gross Revenues (Charges)	\$1,489,221	\$1,602,337
Total Net Revenue	\$1,419,320	\$1,527,184
Total Operating Expenses (Costs)	\$1,406,225	\$1,493,298
Net Income	\$ 13,095	\$ 33,886

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

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop a new 10-station dialysis facility in Richmond County by relocating four existing dialysis stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis. Both existing facilities and the proposed facility are located in Richmond County. Upon completion of the proposed relocation of stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations and Sandhills Dialysis will be certified for 16 dialysis stations.

On page 365 the 2018 SMFP defines the service area for dialysis stations 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 Richmond County. Facilities may also serve residents of counties not included in their service area.

The applicant is the only provider of dialysis services in Richmond County. The existing and approved Richmond County dialysis facilities are shown in the table below:

Facility	Certified Stations 6/30/17	CON Issued not Certified	% Utilization	# Patients per Station
Dialysis Care of Richmond County	30	0	66.67%	2.67
Sandhills Dialysis	16	+6	93.75%	3.75

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

“As of December 31, 2017 there were two dialysis facilities in Richmond County with a total of 46 certified stations. There is an approved CON for an additional six stations at Sandhills Dialysis. This certificate of need application does not propose to increase the number of stations in Richmond County. Transferring ten stations from DC Richmond County (4) and Sandhills Dialysis (6) will create a new facility at a different location to better serve patients living in the area of the new facility, but it will not result in the duplication of existing services.”

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

- The proposal will not result in an increase in the number of dialysis stations in Richmond County; it will relocate existing dialysis stations to an area of the county not currently served by the applicant.
- The applicant adequately demonstrates that the proposed facility is needed in addition to the existing or approved facilities in Richmond County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 36, the applicant projects staffing for the proposed facility in the second year of operation (CY 2020) as shown in the following table:

PEE DEE DIALYSIS PROJECTED STAFFING CY 2020	
POSITION	TOTAL FTE POSITIONS
Medical Director	NA*
Registered Nurse	2.00
Patient Care Technician	4.00
Dietitian	0.50
Social Worker	0.50
Administrator	1.00
Admin Assistant	1.00
Biomedical Technician	0.30
Total FTEs	9.30

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

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section I.1, page 40, the applicant provides a table, reproduced below, showing the ancillary and support services necessary for the proposed services, and how each will be made available.

PEE DEE DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	To be added
Self-care training (in-center)	To be added
Home training	
HH	Dialysis Care of Moore County
PD	Dialysis Care of Moore County
Accessible follow-up program	Dialysis Care of Moore County
Psychological counseling	To be added
Isolation – hepatitis	To be added
Nutritional counseling	To be added
Social Work services	To be added
Acute dialysis in an acute care setting	FirstHealth of the Carolinas
Emergency care	FirstHealth of the Carolinas
Blood bank services	FirstHealth of the Carolinas
Diagnostic and evaluation services	FirstHealth of the Carolinas
X-ray services	FirstHealth of the Carolinas
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	FirstHealth of the Carolinas
Vascular surgery	FirstHealth of the Carolinas
Transplantation services	UNC Transplant Center
Vocational rehabilitation & counseling	NC DHHS Div. of Vocational Rehab. Services
Transportation	Area of Richmond Transit

In Section I, pages 41 - 42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I, Exhibits I-1 through I-3.

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

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K.2, page 45, the applicant states that the project involves construction and up-fitting of 5,154 square feet in leased space in a building to be constructed at 1305 East Broad Street in Rockingham. A line drawing of the proposed facility is provided in Exhibit K-1.

On pages 44 - 45, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 46 - 48, and Exhibit K-4, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

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

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

Pee Dee Dialysis is not an existing facility; however, in Section L.7, page 54, the applicant reports that 85.3% of the patients who received treatments at Dialysis Care of Richmond County had some or all of their services paid for by Medicare or Medicaid, and that 98.3% of the patients who received treatments at Sandhills Dialysis had some or all of their services paid for by Medicare or Medicaid, in CY

2017. The table below shows the historical (CY 2017) payment source for DC of Richmond County and Sandhills Dialysis:

PAYMENT SOURCES CY 2017	DIALYSIS CARE OF RICHMOND COUNTY IN-CTR. PATIENTS AS PERCENT OF TOTAL	SANDHILLS IN-CTR. PATIENTS AS PERCENT OF TOTAL
Medicare	28.0%	35.0%
Medicaid	9.8%	1.7%
Commercial Insurance	9.8%	1.7%
Medicare/Commercial Insurance	15.8%	26.6%
Medicare / Medicaid	31.7%	35.0%
VA	4.9%	0.0%
Total	100.00%	100.00%

Note: numbers may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Richmond	17%	51%	43%	29%	14%	15%
Anson	17%	47%	55%	25%	15%	14%
Statewide	16%	51%	37%	16%	10%	13%

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

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ 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 27-28². In 2015, over 85% of dialysis

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

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(c), page 53, the applicant states:

“Pee Dee 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. This facility has no obligation under the Hill Burton Act.”

In Section L.6, page 53, the applicant states that during the last five years no patient civil rights access complaints have been filed against any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

- (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(b), page 51, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Pee Dee Dialysis
Projected Payor Mix, Project Year Two (CY 2020)**

PAYMENT SOURCE	PATIENTS AS PERCENT OF TOTAL
Medicare	31.0%
Medicaid	6.3%
Commercial Insurance	7.7%
Medicare/Commercial Insurance	19.0%
Medicare / Medicaid	33.2%
VA	2.8%
Total	100.00%

Note: numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 83.2% of total services will be provided to Medicare patients and 39.5% to Medicaid patients.

On page 51, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for DaVita's other Richmond County dialysis facilities, Dialysis Care of Richmond County and Sandhills Dialysis.

The Agency reviewed the:

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

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

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

C

In Section L.4, page 53, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C

In Section M.1, page 55, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

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

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

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Pee Dee Dialysis (PDD) proposes to develop a new 10-station dialysis facility in Richmond County by relocating four existing dialysis

stations from Dialysis Care of Richmond County and six existing dialysis stations from Sandhills Dialysis. Both existing facilities and the proposed facility are located in Richmond County. Upon completion of the proposed relocation of stations, Dialysis Care of Richmond County will be certified for 26 dialysis stations and Sandhills Dialysis will be certified for 16 dialysis stations.

On page 365 the 2018 SMFP defines the service area for dialysis stations 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 Richmond County. Facilities may also serve residents of counties not included in their service area.

The applicant operates two dialysis centers in Richmond County, and is the only provider of dialysis services in Richmond County. The existing and approved Richmond County dialysis facilities are shown below:

Facility	Certified Stations 6/30/17	CON Issued not Certified	% Utilization	# Patients per Station
Dialysis Care of Richmond County	30	0	66.67%	2.67
Sandhills Dialysis	16	+6	93.75%	3.75

In Section N.1, page 56, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. 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. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.”

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Exhibit O-3, the applicant lists the facilities located in North Carolina owned or operated by DaVita.

In Section O.3, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, Southeastern Dialysis Center-Wilmington. The applicant provided supplemental information to the Agency that demonstrates that Southeastern Dialysis Center-Wilmington is currently back in full compliance with all CMS requirements as of March 21, 2018. The applicant provides additional documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for the facility in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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 13, the applicant projects to serve 34 in-center patients by the end of Operating Year 1, which is 3.4 patients per station per week ($34 / 10 = 3.4$). The discussion regarding projected utilization 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 not proposing to increase the number of dialysis stations in an existing facility or in a facility that was not operational prior to the beginning of the review period.
- .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 the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.