

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 3, 2017

Findings Date: March 3, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: F-11264-16

Facility: Spencer Dialysis

FID #: 160495

County: Rowan

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility in Rowan County by relocating 8 stations from Dialysis Care of Rowan County and 2 stations from Dialysis Care of Kannapolis

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC) proposes to develop a new 10-station dialysis facility, Spencer Dialysis in Spencer by relocating eight dialysis stations from Dialysis Care of Rowan County and two dialysis stations from Dialysis Care of Kannapolis. The two existing facilities and the proposed facility are located in Rowan County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county. Upon completion of this project, the proposed Spencer Dialysis will be certified for 10 dialysis stations. Dialysis Care of Rowan County will be certified for 25 dialysis stations upon completion of this project and Project ID #F-11154-16. Dialysis Care of Kannapolis will be certified for 28 dialysis stations upon completion of this project and Project ID #F-11245-16.

### **Need Determination**

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

### **Policies**

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

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

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

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section 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 are 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, page 12, Section K.1, pages 43 – 44, and Exhibit K-1 (d) the applicant describes how it will assure improved energy efficiency and water conservation. The application is conforming to Policy GEN-4.

*Policy ESRD-2: Relocation of Dialysis Stations*

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

*1. Demonstrate that the facility losing dialysis stations or moving to a contiguous [sic] county is currently serving residents of that contiguous [sic] county; and*

*2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*

*3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.*

The applicant proposes to develop a new 10-station dialysis facility, Spencer Dialysis, to be located in Spencer, by relocating existing dialysis stations from two existing facilities: Dialysis Care of Rowan County and Dialysis Care of Kannapolis. The two existing facilities and the proposed facility are located in Rowan County, therefore there is no change in the total dialysis station inventory in Rowan County. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

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

Therefore, the application is conforming to this criterion.

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

### C

The applicant proposes to develop a new 10-station dialysis facility in Spencer by relocating eight dialysis stations from Dialysis Care of Rowan County and two dialysis stations from Dialysis Care of Kannapolis. The two existing facilities and the proposed facility are located in Rowan County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county. Upon

completion of this project, the proposed Spencer Dialysis will be certified for 10 dialysis stations. Dialysis Care of Rowan County will be certified for 25 dialysis stations upon completion of this project and Project ID #F-11154-16. Dialysis Care of Kannapolis will be certified for 28 dialysis stations upon completion of this project and Project ID #F-11245-16. The applicant proposes to serve both in-center (IC) and peritoneal dialysis (PD) patients at Spencer Dialysis.

**Patient Origin**

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

Spencer Dialysis will be a new facility in Rowan County and therefore has no existing patient origin. TRC is the only provider of dialysis services in Rowan County.

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

**Projected Patient Origin, First Two Operating Years**

COUNTY	OY 1 (CY 2019)		OY 2 (CY 2020)		COUNTY PATIENTS AS % OF TOTAL	
	IC	PD	IC	PD	OY 1	OY 2
Rowan	35	2	39	3	100.0%	100.0%
<b>Total</b>	<b>35</b>	<b>2</b>	<b>39</b>	<b>3</b>	<b>100.0%</b>	<b>100.0%</b>

See pages 13 - 15 for the assumptions and data utilized to project patient origin, including a summary of the patient support letters provided in Exhibit C-1.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 16, the applicant states the need for a new dialysis facility in Rowan County is based on an analysis of patients currently served by TRC in the county. The applicant determined that there are 31 IC patients and two PD patients who live closer to the proposed facility. Each of those patients has signed a letter of support that attests to the proximity of the proposed facility and the patient’s desire to transfer its care to the proposed facility. In Section C.1, page 14, the applicant provides a table, shown below, to illustrate the ZIP code of the residence of each patient who signed a letter of support to illustrate the proximity of those patients to the proposed facility in Spencer.

PATIENT'S RESIDENCE		POTENTIAL IC PATIENTS FOR SPENCER DIALYSIS		
ZIP CODE	TOWN	DC ROWAN COUNTY	DC KANNAPOLIS	TOTAL
28159	Spencer	7	1	8
28039	East Spencer	6	0	6
28144	Salisbury	11	0	11
28146	Salisbury	5	0	5
27295	Lexington	1	0	1
<b>Total</b>		<b>30</b>	<b>1</b>	<b>31</b>

According to GoogleMaps<sup>®</sup>, the distance from Salisbury to Spencer is approximately 3.2 miles, and the distance from ZIP code 28159 (Spencer) to ZIP code 28039 (East Spencer) is approximately 2 miles. Lexington, where one patient resides, is approximately 15 miles from Spencer.

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.”*

**Projected Utilization**

*In-Center Patients*

In Section C.1, pages 13 - 15, the applicant provides the assumptions and methodology used to project utilization for the proposed facility, summarized as follows:

- The applicant states that it received 31 letters of support from in-center patients utilizing TRC dialysis facilities in Rowan County, each of which indicates the patient’s willingness to consider transferring their care to the proposed facility.
- The applicant states that it received 2 letters of support from peritoneal dialysis patients utilizing TRC dialysis facilities in Rowan County, each of which indicates the patient’s willingness to consider transferring their care to the proposed facility.
- The applicant assumes that the in-center patients who are residents of Rowan County will increase at a rate commensurate with Rowan County’s Five Year Average Annual Change Rate (AACR) of 13.1%, as published in Table B of the July 2016 Semi-Annual Dialysis Report (SDR), through the second operating year.

- The applicant states that all 31 patients who have expressed an interest in transferring their in-center care to the proposed new facility are residents of Rowan County.
- The applicant assumes that at all of the patients who provided letters of support for the proposed facility will actually transfer to the proposed Spencer Dialysis facility.

In Section C.1, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Years 1 and 2, as follows:

**Spencer Dialysis In-Center Patient Projections**

BEGIN DATE	# PATIENTS BEGIN CENSUS	GROWTH RATE	# PATIENTS END CENSUS	YEAR END DATE	# STATIONS	# PATIENTS / STATION	% UTILIZATION
1/1/19 (OY 1)	31	13.1%	35.06	12/31/19	10	3.5	87.5%
1/1/20 (OY 2)	35	13.1%	39.65	12/31/20	10	3.9	97.5%

At the end of OY 1 (CY 2019) the facility is projected to serve 35 in-center patients and at the end of OY 2 (CY 2020) the facility is projected to serve 39 in-center patients on ten stations.

The projected utilization of 3.5 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

*Peritoneal Patients*

In Section C.1, page 15, the applicant state that two PD patients who currently receive dialysis services at TRC facilities in Rowan County have indicated that they live closer to the proposed facility and would consider transferring their care to the proposed facility. The applicant assumes that at least one of the two patients who signed a letter of support will transfer his or her care to Spencer Dialysis. The applicant states on page 15 that one additional PD patient will seek treatment at Spencer Dialysis each year; therefore, by the end of OY 2 (CY 2020), the applicant projects to serve a total of three PD patients at Spencer Dialysis.

Projected utilization of both IC and PD patients is based on reasonable and adequately supported assumptions regarding continued growth.

**Access to Services**

In Section C.3, page 16, the applicant states,

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

In Section L.1, page 50, the applicant projects that 81.4% of its patients at Spencer Dialysis will be covered by either Medicare or Medicaid. The applicant states that the projected payor mix for the proposed facility is based on sources of payment for its existing facilities in Rowan County for the last full operating year. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

### **Conclusion**

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

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

### C

TRC proposes to develop a new 10-station dialysis facility in Rowan County by relocating eight dialysis stations from Dialysis Care of Rowan County and two dialysis stations from Dialysis Care of Kannapolis. The two existing facilities and the proposed facility are all located in Rowan County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county. Upon completion of this project, the proposed Spencer Dialysis will be certified for 10 dialysis stations. Dialysis Care of Rowan County will be certified for 25 dialysis stations upon completion of this project and Project ID #F-11154-16. Dialysis Care of Kannapolis will be certified for 28 dialysis stations upon completion of this project and Project ID #F-11245-16.

### **Dialysis Care of Rowan County**

In Section D.1, pages 23 - 24, the applicant states that as of December 31, 2015, as reported in the July 2016 SDR, there were 105 in-center dialysis patients at Dialysis Care of Rowan County dialyzing on 29 dialysis stations, for a utilization rate of 90.5% [105 /

29 = 3.62; 3.62 / 4 = 0.905]. Of the 105 patients, the applicant states that 101 were residents of Rowan County, and 4 were from outside of Rowan County.

TRC proposes to relocate eight stations from Dialysis Care of Rowan County to the proposed Spencer Dialysis. See the following table that illustrates the projects and the resultant number of stations that the facility will have following completion of this and all other projects:

**Dialysis Care of Rowan County Stations**

PROJECT ID #	# STATIONS ADDED	# STATIONS DELETED	# STATIONS END
July 2016 SDR Begin with 29 Stations			
F-10273-14	0	1	28
F-10371-15	0	5	23
F-11023-15	4	0	27
F-11154-16	6	0	33
F-11264-16	0	8	<b>25</b>

The applicant projects that 30 in-center patients currently receiving care/services at Dialysis Care of Rowan County will opt to transfer their care/services to Spencer Dialysis, as evidenced by the letters of support provided in Exhibit C-1.

The applicant assumes that the number of in-center patients who will remain at Dialysis Care of Rowan County who live in Rowan County will increase at 13.1% per year based on the Five Year AACR for Rowan County, as reported in Table B of the July 2016 SDR. The applicant projects the patients will transfer their care at the beginning of CY 2019, the first operating year for Spencer Dialysis. In Section D.1, page 24, the applicant calculates the in-center patient census for Dialysis Care of Rowan County through CY 2020, as follows:

**Dialysis Care of Rowan County Utilization**

YEAR	# SERVICE AREA PTS.	GROWTH RATE	YEAR END CENSUS	# OUT OF S.A. PTS.	TOTAL PATIENTS
CY 2016	101.00	13.1%	114.23	4	118.23
CY 2017	114.23	13.1%	129.19	4	133.19
CY 2018	129.19	13.1%	146.12	4	150.12
OY 1 (CY 2019)	146.12 – 30 = 116.12	13.1%	131.19	4	135.19
OY 2 (CY 2020)	131.19	13.1%	148.38	4	152.38

Numbers may not foot due to rounding

Source: application page 24. The applicant’s calculations for OY 2 include the 30 in-center patients who intend to transfer their care out of DC Rowan County; the calculations in the table above correct that error.

By the end of 2020, the second operating year for Spencer Dialysis, Dialysis Care of Rowan County will have 152 in-center patients dialyzing on 25 stations, which is a utilization rate of 152%, or 6.05 patients per station per week [152 / 25 = 6.08; 6.08 / 4 = 1.52]. The applicant states on page 24 that it will apply for additional stations pursuant to



the facility need methodology for Dialysis Care of Rowan County in order to avoid an overcrowded facility and ensure that the patients' needs continue to be adequately met.

Dialysis Care of Kannapolis

In Section D.1, pages 24 - 25, the applicant states that as of December 31, 2015, as reported in the July 2016 SDR, there were 86 in-center dialysis patients at Dialysis Care of Kannapolis dialyzing on 25 dialysis stations, for a utilization rate of 86.0% [ $86 / 25 = 3.44$ ;  $3.44 / 4 = 0.86$ ]. Of the 86 patients, the applicant states that 51 were residents of Rowan County, and 35 were from outside of Rowan County.

The applicant projects that one in-center patient currently receiving care/services at Dialysis Care of Kannapolis will opt to transfer his care/services to Spencer Dialysis, as evidenced by the letter of support provided in Exhibit C-1.

The applicant assumes that the number of in-center patients who will remain at Dialysis Care of Kannapolis who live in Rowan County will increase at 13.1% per year based on the Five Year AACR for Rowan County, as reported in Table B of the July 2016 SDR. The applicant projects the patient will transfer his care at the beginning of CY 2019, the first operating year for Spencer Dialysis. In Section D.1, page 25, the applicant calculates the in-center patient census for Dialysis Care of Kannapolis through CY 2020, as follows:

<b>Dialysis Care of Kannapolis Utilization</b>					
YEAR	# SERVICE AREA PTS.	GROWTH RATE	YEAR END CENSUS	# OUT OF S.A. PTS.	TOTAL PATIENTS
CY 2016	51.00	13.1%	57.68	35	92.68
CY 2017	57.68	13.1%	65.24	35	100.24
CY 2018	65.24	13.1%	73.78	35	108.38
OY 1 (CY 2019)	$73.78 - 1 = 72.78$	13.1%	82.31	35	117.43
OY 2 (CY 2020)	82.31	13.1%	93.09	35	128.10

Numbers may not foot due to rounding

By the end of 2020, the second operating year for Spencer Dialysis, Dialysis Care of Kannapolis will have 128 in-center patients dialyzing on 23 stations, which is a utilization rate of 139%, or 5.56 patients per station per week [ $128 / 23 = 5.56$ ;  $5.56 / 4 = 1.39$ ]. The applicant states on page 25 that it will apply for additional stations pursuant to the facility need methodology for Dialysis Care of Kannapolis in order to avoid an overcrowded facility and ensure that the patients' needs continue to be adequately met.

In addition, the applicant states on page 25, that it will continue to make dialysis services available to all residents in the service area, stating that the relocation of stations will not affect the ability of underserved groups to obtain needed care at either dialysis facility.

The applicant demonstrates that the needs of the populations presently served at Dialysis Care of Rowan County and Dialysis Care of Kannapolis will continue to be adequately

met following the proposed relocation of dialysis stations to develop Spencer Dialysis, and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

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

#### CA

In Section E.1, page 26, the applicant discusses the alternatives considered prior to submitting this application, summarized as follows:

- Maintain the Status Quo – the applicant states that this alternative was dismissed considering the growth rate in each TRC facility in Rowan County. Additionally, the applicant states that to maintain the status quo would necessitate a third shift at one of the facilities in Rowan County, which is not a convenient alternative for the patients.
- Locate the proposed facility in another location in Rowan County – The applicant states this alternative would ignore the stated needs and desires of the 31 in-center patients and 2 PD patients who signed letters of support for a dialysis station in the Spencer area closest to their homes.

After considering the above alternatives, the applicant states that relocating existing stations in the county to develop Spencer Dialysis is the most effective alternative to meet the identified need for additional stations to serve the existing and projected dialysis patients in Rowan County.

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 Spencer 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 Spencer Dialysis shall develop no more than 10 dialysis stations at Spencer Dialysis by relocating 8 stations from Dialysis Care of Rowan County and 2 stations from Dialysis Care of Kannapolis.**

3. **Total Renal Care of North Carolina, LLC d/b/a Spencer 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.**
  4. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 8 stations at Dialysis Care of Rowan County for a total of no more than 25 dialysis stations at Dialysis Care of Rowan County upon completion of this project and Project ID # F-11154-16.**
  5. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 2 stations at Dialysis Care of Kannapolis for a total of no more than 28 dialysis stations at Dialysis Care of Kannapolis upon completion of this project and Project ID #F-11245-16.**
  6. **Total Renal Care of North Carolina, LLC d/b/a Spencer Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Spencer by relocating eight dialysis stations from Dialysis Care of Rowan County and two dialysis stations from Dialysis Care of Kannapolis.

**Capital Costs and Working Capital Costs**

In Section F.1, page 28, the applicant projects \$2,151,711 in capital costs to develop this project, as itemized below.

**Spencer Dialysis Projected Capital Costs**

Site Costs	\$ 62,540
Construction	\$1,357,700
Dialysis Machines	\$ 165,360
RO Equipment	\$ 139,075
Other Equipment/Furniture	\$ 321,036
Architect/Engineering Fees	\$ 106,000
Total Capital Costs	\$2,151,711

In Sections F.10 - F.12, page 31, the applicant states that start-up expenses and initial operating expenses incurred for this project will be \$203,783 and \$806,833, respectively, for a total estimated working capital of \$1,010,615.

**Financial Feasibility**

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

	OPERATING YEAR 1	OPERATING YEAR 2
Total Treatments	4,891	5,483
Total Gross Revenues (Charges)	\$1,723,075	\$1,980,817
Total Net Revenue	\$1,648,383	\$1,895,572
Total Operating Expenses (Costs)	\$1,613,665	\$1,770,961
Net Income	\$ 34,718	\$ 124,611

Source: Pro Formas, Section R of the application

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 that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC (TRC) proposes to develop a new 10-station dialysis facility, Spencer Dialysis in Spencer by relocating eight dialysis stations from Dialysis Care of Rowan County and two dialysis stations from Dialysis Care of Kannapolis. The two existing facilities and the proposed facility are located in Rowan County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county. Upon completion of this project, the proposed Spencer Dialysis will be certified for 10 dialysis stations. Dialysis Care of

Rowan County will be certified for 25 dialysis stations upon completion of this project and Project ID #F-11154-16. Dialysis Care of Kannapolis will be certified for 28 dialysis stations upon completion of this project and Project ID #F-11245-16.

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

The July 2016 SDR indicates there are currently two dialysis facilities in Rowan County, each of which is owned and operated by Total Renal Care of North Carolina, LLC.

Dialysis Care of Rowan County was operating at 90.52% of capacity as of December 31, 2015. Similarly, Dialysis Care of Kannapolis was operating at 86.0% of capacity as of December 31, 2015.

The applicant is not increasing the total number of dialysis stations in Rowan County; rather, it is transferring existing stations to create a new facility in which to serve existing patients.

In Section C.1, pages 13 - 15, the applicant provides reasonable projections for the in-center patient population it proposes to serve. The applicant's growth projections are based on the Rowan County Five Year AACR as published in the July 2016 SDR.

The applicant adequately demonstrates the need to develop a new ten-station dialysis facility in Rowan County by transferring existing stations from existing facilities. The discussion on analysis of need found in Criterion (3) 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 Rowan County. Consequently, the application is conforming to this criterion.

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

## C

In Section H.1, page 35, the applicant provides projected staffing following the development of the project, as illustrated in the following table:

**Spencer Dialysis Projected Staffing**

POSITION	TOTAL FTE POSITIONS
Registered Nurse	2.0
Patient Care Technician	4.0
Administrator	1.0
Dietician	0.5
Social Worker	0.5
Home Training RN	0.5
Administrative Assistant	1.0
Biomedical Technician	0.3
Total	9.8

In Section H.2, page 36, the applicant states that the Medical Director for Spencer Dialysis will be Dr. John Gerig, who is board certified in nephrology. In Exhibit I-3, the applicant provides a letter signed by Dr. Gerig, dated October 13, 2016, confirming his commitment to serve as Medical Director.

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

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

C

In Section I, pages 39 - 41, the applicant includes a list of providers of the necessary ancillary and support services to be provided for the patients who dialyze at the facility. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-3, including letters from DaVita Laboratory Services, Inc. and several nephrologists. The information in Section I and Exhibits I-1 and I-3 is reasonable and adequately supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated

new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

In Section K.2, page 44, the applicant states it will develop 3,485 square feet of treatment area, which includes space for an isolation room. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). The drawing depicts a facility with office space, nine dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 10 dialysis stations. In Section F.1, page 28, the applicant lists its project costs, including \$62,540 for site costs, \$1,357,700 for construction and \$731,471 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,151,711. In Section B.5, pages 11 - 12, the applicant describes its plans to assure improved energy-efficiency and water conservation, including the following:

- The use of full LED lighting packages with occupancy and vacancy sensors, dimmers, and a full lighting control system that will provide 28% energy reduction.
- Adopt water optimization protocols to reduce the volume of water required to provide patient care, including adjusting the recovery rate for reverse osmosis devices and utilizing water-conserving plumbing fixtures.
- Interior finishes and materials will be used based on sustainable design and *“Indoor Environmental Quality criteria...defined in the US Green Building Council’s LEED Rating system.”*

- The HVAC system will be selected for its high performance and energy efficiency.
- All appliances, when possible, and most information technology equipment will be Energy Star rated.

Costs and charges are described by the applicant in Section F, pages 29-33, 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

Spencer Dialysis is a proposed facility and thus has no current patient origin to report. However, the applicant provided current payor mix for its two Rowan County facilities, Dialysis Care of Rowan County and Dialysis Care of Kannapolis CY 2015, as shown in the following tables:

**DC Rowan County  
 Payor Mix CY 2015**

PAYOR TYPE	% OF TOTAL PATIENTS
Medicare	35.0%
Medicaid	2.9%
Commercial Insurance	10.2%
Medicare/Commercial	27.0%
Medicare/Medicaid	16.8%
VA	8.0%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding



**DC Kannapolis  
IC Payor Mix CY 2015**

PAYOR TYPE	% OF TOTAL PATIENTS	% OF TOTAL HHD PATIENTS	% OF TOTAL PD PATIENTS	% OF TOTAL IC PATIENTS
Medicare	28.3%	58.3%	17.2%	27.9%
Medicaid	6.3%	0.0%	3.4%	8.1%
Commercial Insurance	14.2%	8.3%	27.6%	10.5%
Medicare/Commercial	20.5%	25.0%	24.1%	18.6%
Medicare/Medicaid	26.0%	0.0%	24.1%	30.2%
VA	4.7%	8.3%	3.4%	4.7%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not foot due to rounding

The applicant describes its admission and financial policies in Section L.3, pages 50 - 52, and provides a copy of its admission policy which states that patients will be admitted *“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.

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

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

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

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

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

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

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

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

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

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

C

In Section L.3(e) page 52, the applicant states:

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

In Section L.6, page 52, the applicant states, in reference to any facilities owned by DVA 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 50, the applicant states that the projected payor mix for Spencer Dialysis is based on sources of payment for its existing facilities in Rowan County for the last full operating year, as follows:

**Spencer Dialysis Payor Mix OY 2**

PAYOR TYPE	% OF TOTAL IC PATIENTS	% OF TOTAL PD PATIENTS	% OF TOTAL PATIENTS
Medicare	31.9%	26.2%	30.6%
Medicaid	5.2%	3.3%	4.8%
Commercial Insurance	10.5%	18.0%	12.3%
Medicare/Commercial	22.0%	29.5%	23.8%
Medicare/Medicaid	24.1%	16.4%	22.2%
VA	6.3%	6.6%	6.3%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not foot due to rounding

The applicant projects that 81.4% of its total patients will be covered by Medicare or Medicaid. In Section L, page 50, the applicant states projected payor mix is based on the historical payor mix of its other Rowan County facilities.

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 52, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients who contact the facility directly or indirectly

will be referred to “*a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary....*” In Exhibit I-3, the applicant provides letters of support from area Nephrologists, including a letter of support from the medical director of the proposed facility.

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

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

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

C

Total Renal Care of North Carolina, LLC (TRC) proposes to develop a new 10-station dialysis facility, Spencer Dialysis in Spencer by relocating eight dialysis stations from Dialysis Care of Rowan County and two dialysis stations from Dialysis Care of Kannapolis. The two existing facilities and the proposed facility are located in Rowan County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county. Upon completion of this project, the proposed Spencer Dialysis will be certified for 10 dialysis stations. Dialysis Care of Rowan County will be certified for 25 dialysis stations upon completion of this project

and Project ID #F-11154-16. Dialysis Care of Kannapolis will be certified for 28 dialysis stations upon completion of this project and Project ID #F-11245-16.

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

The July 2016 SDR indicates there are currently two dialysis facilities in Rowan County, each of which is owned and operated by Total Renal Care of North Carolina, LLC.

Dialysis Care of Rowan County was operating at 90.52% of capacity as of December 31, 2015. Similarly, Dialysis Care of Kannapolis was operating at 86.0% of capacity as of December 31, 2015.

The applicant is not increasing the total number of dialysis stations in Rowan County; rather, it is transferring existing stations to create a new facility in which to serve existing patients.

In Section N.1, page 55, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

*“The development of Spencer Dialysis will have no effect on any dialysis facilities located in Rowan County or in counties contiguous to it. DaVita operates the other two facilities in the county.*

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

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

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

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

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section B, pages 8 - 9, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. However, in Section O.3, page 56, the applicant states that each facility is back in compliance as of the date of this decision.

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

(21) Repealed effective July 1, 1987.

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

being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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

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

-C- In Section C.1, pages 14 - 15, the applicant adequately demonstrates that Spencer Dialysis will serve at least 35 in-center patients on 10 stations at the end of the first operating year, which is 3.5 patients per station per week, or a utilization rate of 87.5% ( $35 / 10 = 3.5$ ;  $3.5 / 4 = 0.875$ ). 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 the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.