

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 28, 2015

Findings Date: August 28, 2015

Project Analyst: Julie Halatek

Assistant Chief: Martha J. Frisone

Project ID #: C-11016-15

Facility: Dialysis Care of Rutherford County

FID #: 955624

County: Rutherford

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

Project: Add three stations to Dialysis Care of Rutherford County by relocating three stations from Asheville Kidney Center in Buncombe County for a total of 33 stations upon completion

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 d/b/a Dialysis Center of Rutherford County (DCRC) proposes to add three dialysis stations to its existing facility for a total of 33 stations upon completion of this project by relocating three existing dialysis stations from Asheville Kidney Center (AKC) located in Buncombe County.

Need Determination

The applicant does not propose to develop new dialysis stations or a new facility. Neither the county nor the facility need methodologies in the 2015 State Medical Facilities Plan (SMFP) are applicable to this review.

Policies

Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS, found in the 2015 SMFP in Chapter 4, page 32, is applicable to this review. The policy states:

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

- 1. Demonstrate that the proposal shall not result in a 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*
- 2. Demonstrate that the proposal shall not result in a 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.”*

Buncombe County is contiguous to Rutherford County. Relocating three dialysis stations from Buncombe County to Rutherford County will decrease the Buncombe County inventory by three stations and increase the Rutherford County inventory by three stations. In the January 2015 Semiannual Dialysis Report (SDR), *Table B: ESRD Dialysis Station Need Determinations by Planning Area* indicates a nine station surplus in Buncombe County and a three station deficit in Rutherford County.

According to publicly available data provided by AKC, as of December 31, 2014, AKC was serving one home hemodialysis patient and one home peritoneal dialysis patient from Rutherford County.

The applicant adequately demonstrates that relocating three existing dialysis stations from Buncombe County to Rutherford County will not cause a deficit of dialysis stations in Buncombe County nor will it cause a surplus of dialysis stations in Rutherford County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The applicant adequately demonstrates that the proposal is consistent with Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS. 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.

NC

Dialysis Center of Rutherford County (DCRC) proposes to add three dialysis stations to its existing facility for a total of 33 stations upon completion of this project by relocating three existing dialysis stations from Asheville Kidney Center (AKC) located in Buncombe County.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located with the exception of any multicounty planning areas. Thus, in this application, the service area is Rutherford County. Dialysis facilities may serve residents of counties not included in their service area.

In Section IV.1, page 24, the applicant identifies the patient population as of June 30, 2014, as illustrated in the table below.

DCRC Patient Population as of June 30, 2014		
County of Residence	# of Patients Dialyzing In-center	# of Home Dialysis Patients
Rutherford	85	17
Polk	1	0
Henderson	0	1
Cleveland	0	1
Burke	0	1
Total	86	20

Note: In the application there is a typographical error identifying the home dialysis patients as in-center dialysis patients. The correct patient categories were confirmed by a review of the June 2014 Data Collection Form for DCRC.

In Section III.7, page 21, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

DCRC Projected Patient Population – Operating Years 1 and 2						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Rutherford	106	19	115	20	96.8%	97.2%
Polk	1	0	1	0	0.8%	0.7%
Henderson	0	1	0	1	0.8%	0.7%
Cleveland	0	1	0	1	0.8%	0.7%
Burke	0	1	0	1	0.8%	0.7%
Total	107	22	116	23	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant states that need for the proposed expansion is based on the following factors:

- Relocating three stations from Buncombe County to Rutherford County will decrease the surplus of stations in Buncombe County and decrease the deficit of stations in Rutherford County. See page 19 of the application and Table B in the January 2015 SDR.
- DCRC is the only dialysis facility located in Rutherford County, which is a rural county. DCRC is located in the population center of Rutherford County. The three additional stations will allow DCRC to better serve patients. See page 19 of the application.
- The applicant projects that DCRC will have 107 in-center patients at the end of Operating Year One (ending December 31, 2016), which is a utilization rate of 81 percent. See page 22 of the application.

Projected Utilization

In Section III.7, page 21, the applicant provides projected utilization of the expanded facility for Operating Years One and Two, as shown in the table below:

DCRC Projected Patient Population – Operating Years 1 and 2						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Rutherford	106	19	115	20	96.8%	97.2%
Polk	1	0	1	0	0.8%	0.7%
Henderson	0	1	0	1	0.8%	0.7%
Cleveland	0	1	0	1	0.8%	0.7%
Burke	0	1	0	1	0.8%	0.7%
Total	107	22	116	23	100.0%	100.0%

As shown in the table above, at the end of Operating Year 1, the applicant projects to serve 107 in-center dialysis patients on 33 certified dialysis stations, or 3.24 patients per station per week, which is a utilization rate of 81 percent [$107 / 33 = 3.24$; $3.24 / 4 = 0.81$ or 81%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Assumptions and Methodology Used

In Section III.7, pages 21-22, the applicant states that it used the following assumptions to project utilization.

- There is a need for three additional dialysis stations in Rutherford County because Table B in the January 2015 SDR shows a deficit of three stations for Rutherford County.
- DCRC is not eligible to use the facility need methodology to add stations because it is not at the required 80 percent utilization.
- As of June 30, 2014, DCRC had 86 in-center patients; 85 live in Rutherford County and one lives in Polk County.
- The Average Annual Change Rate (AACR) for Rutherford County, as published in Table B of the January 2015 SDR, is 9.2 percent.
- Operating Year One = Calendar Year 2016.
- Operating Year Two = Calendar Year 2017.
- The applicant projects that the Rutherford County in-center patient population at DCRC will continue to grow at the published 9.2 percent AACR.
- The DCRC Home Training Program population will grow by at least one patient per year in calendar years 2015, 2016, and 2017.

The applicant calculated growth starting on July 1, 2014 with 85 patients from Rutherford County. In Section III.7, page 21, the applicant's calculations appear and are shown below:

“July 1, 2014–December 31, 2014 – 85 patients X 1.046 = 88.91

January 1, 2015–December 31, 2015 – 88.91 patients X 1.092 = 97.08972

January 1, 2016–December 31, 2016 – 97.08972 patients X 1.092 = 106.0219742

January 1, 2017–December 31, 2017 – 106.0219742 patients X 1.092 = 115.7759958”

By the end of Operating Year One, the applicant projects to serve 107 in-center patients (106 from Rutherford County and one from Polk County) dialyzing on 33 stations for a utilization rate of 81 percent or 3.24 patients per station [$107 / 33 = 3.24 / 4.0 = 0.81$ or 81%]. The applicant projects 116 in-center patients (115 from Rutherford County and one from Polk County) at the end of Operating Year Two for a utilization rate of 88 percent or 3.52 patients per station [$116 / 33 = 3.52 / 4.0 = 0.88$ or 88%]. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

However, projected utilization is not based on reasonable and adequately supported assumptions. Therefore, the applicant does not adequately demonstrate it will serve 107 in-center patients by the end of Operating Year One.

Specifically, on page 21, the applicant states one of the assumptions used is that the in-center patient population at DCRC would grow at 9.2 percent per year – the five year AACR for Rutherford County ESRD patients as published in Table B of the January 2015 SDR. However, there has been no net growth in the in-center patient population at DCRC for the last three years.

The Project Analyst reviewed the number of in-center patients listed in the January and July SDRs for the last three years and confirmed that while the total ESRD patient population of Rutherford County has grown, there has been no net growth in the in-center population at DCRC, as shown below.

DCRC Patient Population and Rutherford County ESRD Patient Population				
Data Source	As of Date	In-Center Patients DCRC	In-Center Patients Rutherford County	Total ESRD Patients Rutherford County
July 2012 SDR	12/31/2011	86	91	113
January 2013 SDR	06/30/2012	86	Data missing*	Data missing*
July 2013 SDR	12/31/2012	86	91	117
January 2014 SDR	06/30/2013	84	90	118
July 2014 SDR	12/31/2013	87	98	123
January 2015 SDR	06/30/2014	86	98	121
3 Yr Average Annual Change Rate		0.6%	3.8%	4.3%

*The January 2013 SDR did not contain information about the total in-center patient population in Rutherford County or the total ESRD patient population in Rutherford County as of 6/30/2012.

The applicant does not provide in the application as submitted adequate explanation for how it is going to achieve or sustain a 9.2 percent annual growth rate after reporting no net growth in the in-center patient population during the last three years.

Furthermore, in Chapter 14, on page 362 of the 2015 SMFP, Basic Principle 6 states: “No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.” DCRC is an existing facility proposing to expand by relocating three existing dialysis stations from AKC to DCRC. Based on data reported by DCRC and published in the January 2015 SDR, DCRC was operating below 80 percent utilization. Moreover, DCRC has been operating below 80 percent utilization since publication of the January 2012 SDR. The applicant does not adequately demonstrate a need for three additional stations at DCRC.

In Section III.7, page 22, the applicant states:

“It is reasonable to assume that the DC of Rutherford County home-training program will grow at a rate of at least one patient during the current operating year and operating years one and two. DC of Rutherford County had a total of 20 home-

trained patients as of June 30, 2014. It is projected that the census will grow to 21 home-trained patients in 2015, 22 home-trained patients in 2016 and 23 home-trained patients in 2017.”

However, the applicant does not provide any assumptions or supporting data to explain why it expects a growth of at least one home-trained patient per operating year. In Section IV.3, page 24, the applicant states that as of December 31, 2014, DCRC had 15 home-trained patients – a decrease of 5 patients or a 25 percent decrease in patients from six months prior. The projected increase is therefore questionable without something to support it.

Projected utilization is not based on reasonable and adequately supported assumptions. Therefore, the applicant does not adequately demonstrate the need the population to be served has for three additional dialysis stations at the DCRC facility.

Access

In Sections VI.1(b) and VI.1(c), pages 30-31, the applicant provides the current and projected payor mix for the proposed services at DCRC, as shown in the table below. The applicant projects no change from the current payor mix upon project completion:

DCRC Current / Projected Payor Mix		
Payor Source	% Gross Revenue In-Center Patients	% Gross Revenue Home Patients
Medicare	22.22%	13.33%
Medicaid	5.56%	0.00%
Medicare/Medicaid	30.00%	20.00%
Commercial Insurance	8.89%	26.67%
VA	4.44%	6.67%
Medicare/Commercial	28.89%	33.33%
Total	100.00%	100.00%

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately:

- Identifies the population it proposes to serve.
- Demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

However, the applicant does not adequately demonstrate the need this population has for the proposed services. Therefore, the application is not 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

Dialysis Center of Rutherford County (DCRC) proposes to add three dialysis stations to its existing facility for a total of 33 stations upon completion of this project by relocating three existing dialysis stations from Asheville Kidney Center (AKC) located in Buncombe County.

At the time the data for the January 2015 SDR was collected, AKC had 50 certified dialysis stations. In Section III.3(c), page 19, the applicant states that it has a certificate of need to develop two additional stations at AKC and that it anticipates certification of those stations in March 2015. On March 23, 2015, AKC was notified by the Acute and Home Care Licensure and Certification Section, DHSR, that the additional two dialysis stations had been certified, bringing the total number of certified dialysis stations to 52. The proposed project would relocate three existing dialysis stations to DCRC leaving AKC with 49 certified stations. In Section III.3(a), page 19, the applicant states that the proposed project does not involve the transfer of any patients from AKC to DCRC. The January 2015 SDR states that AKC was treating 188 in-center patients as of June 30, 2014. According to Table B: ESRD Dialysis Station Need Determinations by Planning Area in the January 2015 SDR, the AACR for the past five years for Buncombe County is 3.9 percent.

Operating Year One for the proposed project is CY 2016 and Operating Year Two is CY 2017. The applicant does not make any projections as to growth of the patient population at AKC through the end of Operating Year Two. The Project Analyst performed the calculations below:

July 1, 2014 – December 31, 2014: $188 \text{ patients} \times 1.0195 = 191.666$

January 1, 2015 – December 31, 2015: $191.666 \text{ patients} \times 1.039 = 199.141$

January 1, 2016 – December 31, 2016: $199.141 \text{ patients} \times 1.039 = 206.907 \text{ (OY1)}$

January 1, 2017 – December 31, 2017: $206.907 \text{ patients} \times 1.039 = 214.976 \text{ (OY2)}$

At the end of Operating Year One, AKC would operate at 105.5 percent ($207 \text{ patients} / 49 \text{ stations} = 4.22 / 4 = 1.055$ or 105.5%) and at the end of Operating Year Two, AKC would operate at 109.8 percent ($215 \text{ patients} / 49 \text{ stations} = 4.39 / 4 = 1.098$ or 109.8%). In Section III.6, page 20, the applicant states: *“The Asheville Kidney Center will apply for additional dialysis stations as needed.”*

The applicant adequately demonstrates that the needs of the population presently served at AKC will be adequately met following the relocation of three stations to DCRC. 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.

NC

In Section III.9, page 22, the applicant states the only alternative considered was to maintain the status quo. The applicant states: *"This alternative was dismissed since the facility is rapidly growing."* Thus, the applicant concluded that the project as proposed was the most effective alternative to meet the need.

However, the application is not conforming to all applicable statutory and regulatory review criteria, and thus, the application is not approvable. An application that cannot be approved is not an effective alternative. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

The applicant does not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the need. Consequently, the application is not conforming to this criterion and is denied.

- (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.

NC

In Section VIII.1(b), page 39, the applicant projects a capital cost of \$22,858 for the proposed project, funded through accumulated cash reserves. In Section IX.1(a), page 44, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because it is an existing facility.

In Section VIII.2, page 41, and Section VIII.5, page 42, the applicant states the entire capital cost of the project will be funded with accumulated reserves of DaVita HealthCare Partners, Inc. Exhibit 18 contains a letter dated March 10, 2015, signed by the Vice President of Tax for both DaVita HealthCare Partners, Inc., and Total Renal Care, Inc., which states that DaVita HealthCare Partners, Inc. is authorizing the use of \$22,858 from cash reserves to add three stations to DCRC.

In Exhibit 19, the applicant provides the audited financial statements for DaVita HealthCare Partners, Inc. for the years ending December 31, 2014 and December 31, 2013. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash

equivalents, \$17,942,715,000 in total assets, and \$5,360,311,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 46, the applicant provides the allowable charges per treatment for each payor source for DCRC as follows:

DCRC	
Payor Source	Allowable Charge Per Treatment
Medicare	\$239.43
Medicaid	\$143.00
Medicare/Medicaid	\$239.43
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.43

On page 46, the applicant also provides its assumptions as to how it arrived at the allowable charge per treatment for each payor source.

In Sections X.2, page 47, and X.4, page 51, the applicant projects revenues and expenses for DCRC as follows:

DCRC		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$6,373,435	\$6,866,658
Total Expenses	\$4,860,443	\$5,176,004
Net Profit	\$1,512,992	\$1,690,654

Projected charges, reimbursement rates, and contractual adjustments are based on reasonable assumptions. However, to the extent that the projected revenues and operating costs are based on utilization, including the projected number of patients and treatments, the projected revenues and operating cost are not based on reasonable and adequately supported assumptions. In Section X.3, page 50, the applicant provides its assumptions for each source of revenue used to project revenue in Operating Years One and Two. In Section III.7, page 22, the applicant states:

“NOTE: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses in Section X of this application.” (emphasis in original)

The applicant does not adequately demonstrate how it is going to achieve or sustain a 9.2 percent annual growth rate after reporting no net patient population growth in the last three years and a three year average annual change rate of only 0.6 percent. Therefore, projected in-center revenues and operating costs are not based on reasonable assumptions regarding

projected utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. However, to the extent that the projected revenues and operating costs are based on projected utilization, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable and adequately supported projections of revenue and operating costs. Therefore, the application is not 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.

NC

Dialysis Center of Rutherford County (DCRC) proposes to add three dialysis stations to its existing facility for a total of 33 stations upon completion of this project by relocating three existing dialysis stations from Asheville Kidney Center (AKC) located in Buncombe County. The applicant does not propose to develop new stations or establish a new facility.

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located with the exception of any multicounty planning areas. Thus, in this application, the service area is Rutherford County. Dialysis facilities may serve residents of counties not included in their service area.

The applicant operates the only existing dialysis facility located in Rutherford County and there are no approved facilities. As of June 30, 2014, DCRC was serving 86 patients weekly on 30 stations, which is 2.8667 patients per station or 71.67 percent of capacity ($86 \text{ patients} / 30 \text{ stations} = 2.8667$; $2.8667 / 4 = 0.7167$ or 71.67%). At the end of Operating Year Two, DCRC projects that it will be serving 116 patients weekly on 33 stations, which is 3.52 in-center patients per station or 88 percent of capacity ($116 \text{ patients} / 33 \text{ stations} = 3.52$; $3.52 / 4 = 0.88$ or 88%).

However, the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The applicant does not provide in the application as submitted an adequate explanation of how it is going to achieve or sustain a 9.2 percent annual growth rate after reporting no net patient population growth in the last three years and a three year average annual change rate of only 0.6 percent. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Furthermore, in Chapter 14, on page 362 of the 2015 SMFP, Basic Principle 6 states: “*No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.*” DCRC is an existing facility proposing to expand by relocating three existing dialysis stations from AKC to DCRC. As of June 30, 2014, DCRC had a utilization rate of 71.67 percent, not 80 percent or greater, and has not operated at or above 80 percent during the last three years as reflected in the SDRs published

since July 2012. The applicant does not adequately demonstrate a need for three additional stations at DCRC.

Therefore, the applicant does not adequately demonstrate that relocating three stations from Buncombe County to Rutherford County will not result in the unnecessary duplication of existing or approved in-center dialysis stations in Rutherford County. Consequently, the application is not conforming to this criterion.

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

C

The following table illustrates current and projected staffing for DCRC, as provided by the applicant in Section VII.1, page 35:

DCRC Current and Projected Staffing			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	5.0	1.0	6.0
HTRN	2.0	0.0	2.0
PCT	12.0	1.0	13.0
Bio-Med Tech	1.0	0.0	1.0
Medical Director*	N/A	N/A	N/A
Admin	1.0	0.0	1.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Unit Secretary	1.0	0.0	1.0
Reuse	1.0	0.5	1.5
Total	25.0	2.5	27.5

*In Section X.5, on page 52, the applicant states the medical director is not an employee of the facility; there is an agreement in place and the annual fee for the medical director is \$75,000.

As shown in the above table, the applicant proposes to employ a total of 27.5 full-time equivalent (FTE) positions to staff DCRC upon completion of the proposed project. In Section V.4(c), page 28, the applicant indicates that Dr. Syed Ahmed will continue to serve as medical director of the facility. Exhibit 13 contains a letter from Dr. Ahmed stating his support for the expansion of DCRC.

In Section VII.10, page 37, the applicant provides the following table showing the projected number of direct care staff for each shift offered at DCRC after the addition of the three dialysis stations.

DCRC Direct Care Staff Per Shift							
	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	9	9	9	9	9	9
Afternoon	11am to 4pm	9	9	9	9	9	9

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 V.1, page 26, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 13 contains a letter from the medical director of the facility expressing his support for the proposed project. In Section V.5(a), page 28, the applicant states: *“Total Renal Care of North Carolina, LLC has had an ongoing working relationship with many of the local healthcare providers for several years through our operation of our existing dialysis facilities in Rutherford County.”* The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
 - (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
 - (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

- (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

In Section VI.1(b), page 30, the applicant reports that 86.67 percent of the in-center patients who received treatments at DCRC and 66.66 percent of the home dialysis patients had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the current payor mix for the facility:

DCRC Current Payor Mix		
Payor Source	% Gross Revenue In-Center Patients	% Gross Revenue Home Patients
Medicare	22.22%	13.33%
Medicaid	5.56%	0.00%
Medicare/Medicaid	30.00%	20.00%
Commercial Insurance	8.89%	26.67%
VA	4.44%	6.67%
Medicare/Commercial	28.89%	33.33%
Total	100.00%	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Rutherford County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population*	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Rutherford County	21.3%	9.7%	18.5%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, is not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race, or gender. But it does not include information on the number of elderly, handicapped, minorities, or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
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%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, incl. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

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 applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service, and access by minorities and handicapped persons. In Section VI.1(f), page 32, the applicant states that DCRC has no obligations under any applicable federal regulation to fulfill.

In Section VI.6(a), page 34, the applicant states there have been no patient civil rights access complaints filed in the last five years. Therefore, 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

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at DCRC, as shown in the table below. The applicant projects no change from the current payor mix upon project completion.

DCRC Projected Payor Mix		
Payor Source	% Gross Revenue In-Center Patients	% Gross Revenue Home Patients
Medicare	22.22%	13.33%
Medicaid	5.56%	0.00%
Medicare/Medicaid	30.00%	20.00%
Commercial Insurance	8.89%	26.67%
VA	4.44%	6.67%
Medicare/Commercial	28.89%	33.33%
Total	100.00%	100.00%

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 VI.5(b), page 33, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5(b) is reasonable and credible and supports a finding of conformity with 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 Sections V.3(a) and V.3(c), page 31, the applicant states:

*“DC of Rutherford County has Student Training Agreements with McDowell Technical College and Lenoir-Rhyne University. See **Exhibit 12.**”* (emphasis in original)

Exhibit 12 contains copies of the student training agreements between DCRC and McDowell Technical Community College and between DCRC and Lenoir-Rhyne University. The

information provided in Section V.3(a), V.3(c), and the referenced exhibit is reasonable and credible and supports a finding of conformity 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.

NC

Dialysis Center of Rutherford County (DCRC) proposes to add three dialysis stations to its existing facility for a total of 33 stations upon completion of this project by relocating three existing dialysis stations from Asheville Kidney Center (AKC) located in Buncombe County. The applicant does not propose to develop any new stations or establish a new facility.

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where the stations are located with the exception of any multicounty planning areas. Thus, in this application, the service area is Rutherford County. Dialysis facilities may serve residents of counties not included in their service area.

The applicant operates the only existing dialysis facility located in Rutherford County and there are no approved facilities. As of June 30, 2014, DCRC was serving 86 patients weekly on 30 stations, which is 2.8667 patients per station or 71.67 percent of capacity ($86 \text{ patients} / 30 \text{ stations} = 2.8667$; $2.8667 / 4 = 0.7167$ or 71.67%). By the end of Operating Year One, the applicant projects to serve 107 in-center patients (106 from Rutherford County and one from Polk County) dialyzing on 33 stations for a utilization rate of 81 percent or 3.24 patients per station [$107 / 33 = 3.24 / 4.0 = 0.81$ or 81%]. The applicant projects 116 in-center patients (115 from Rutherford County and one from Polk County) at the end of Operating Year Two for a utilization rate of 88 percent or 3.52 patients per station [$116 / 33 = 3.52 / 4.0 = 0.88$ or 88%]. This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

However, the applicant does not adequately demonstrate the need to add three dialysis stations to DCRC and does not adequately demonstrate that it would not result in an unnecessary duplication. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would be cost-effective.

In Section V.7, page 29, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The proposed expansion of the facility is an effort to provide dialysis services to Forest City and surrounding communities and is not intended to be a competitive venture. The effect of other facilities in surrounding counties would be difficult to determine since most patients from Rutherford County already receive treatment at DC of Rutherford County. There are no other dialysis providers located in Rutherford County.

The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. DC of Rutherford County provides access to all qualified Nephrologists to admit his or her patients.

The bottom line is that patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. DC of Rutherford County provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI, and VII where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The applicant adequately demonstrates that any enhanced competition will have a positive impact on the quality and access to the proposed services based on the information in the application and the following analysis:

- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

However, the applicant does not adequately demonstrate that any enhanced competition will have a positive impact on the cost-effectiveness of the proposed services. This determination is based on the information in the application regarding projected utilization and projected revenues and costs based on the projected utilization. The discussions regarding projected utilization found in Criterion (3) and costs and charges found in Criterion (5) are incorporated herein by reference. Therefore, the application is not 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 I.13 and referenced exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. 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.

NC

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

(1) *Utilization rates;*

-C- In Section II.1, page 10, the applicant states that utilization rates are addressed in the January 2015 SDR and a copy of the January 2015 SDR is included in Exhibit 7. The applicant also states that the question of utilization is addressed in Section IV.1. In Section IV.1, page 24, the applicant provides a table of current patients at DCRC by county and modality of treatment.

(2) *Mortality rates;*

- C- In Section IV.2, page 24, the applicant reports 2012, 2013, and 2014 facility mortality rates of 21.0 percent, 21.5 percent, and 27.0 percent, respectively.
 - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
 - C- In Section III.7, page 22, the applicant states that DCRC had 20 patients that were home-trained as of June 30, 2014. In Section IV.3, page 24, the applicant states that DCRC had 15 patients that were home-trained as of December 31, 2014.
 - (4) *The number of transplants performed or referred;*
 - C- In Section IV.4, page 25, the applicant states DCRC referred seven patients for transplant evaluation in 2014. DCRC had one patient who received a transplant in 2014.
 - (5) *The number of patients currently on the transplant waiting list;*
 - C- In Section IV.5, page 25, the applicant states DCRC has two patients on the transplant waiting list.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
 - C- In Section IV.6, page 25, the applicant reports a total of 269 hospital admissions in 2014; 205 (76.3 percent) were non-dialysis related and 64 (23.8 percent) were dialysis related.
 - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
 - C- In Section IV.7, page 25, the applicant reports that as of December 31, 2014, there were no patients with AIDS and one patient with hepatitis B. No patients converted to infectious status in 2014.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will*

provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- DCRC is an existing facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- DCRC is an existing facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- DCRC is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit 8 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- DCRC is an existing facility.

- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section II.1, page 12; Section VII.2, pages 35-36, Section XI.6(g), pages 57-58, and Exhibits 1, 23, and 24 for documentation of conformity with applicable laws and regulations.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 21, DCRC provides projected patient origin based on historical experience for the first two years of operation following completion of the project, as presented in the following table:

Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as Percent of Totals	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Rutherford	106	19	115	20	96.8%	97.2%
Polk	1	0	1	0	0.8%	0.7%
Henderson	0	1	0	1	0.8%	0.7%
Cleveland	0	1	0	1	0.8%	0.7%
Burke	0	1	0	1	0.8%	0.7%
Total	107	22	116	23	100.0%	100.0%

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- DCRC is an existing facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- In Section II.1, page 12, the applicant states:

“Total Renal Care of North Carolina d/b/a Dialysis Care of Rutherford County will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for

dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- DCRC is an existing facility.

(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.*

-NC- In Section III.7, pages 22-23, the applicant projects to serve 107 in-center patients by the end of Operating Year One, which is 3.24 patients per station ($107 / 33 = 3.24$). However, the applicant’s projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 12-14, and Section III.7, pages 21-22. However, see the discussion regarding the reasonableness of the assumptions found in Criterion (3) which is incorporated herein by reference.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) *diagnostic and evaluation services;*

-C- These services are provided by Rutherford Hospital. See Section V.1, page 26.

(2) *maintenance dialysis;*

-C- These services are provided by DCRC. See Section V.1, page 26.

(3) *accessible self-care training;*

-C- These services are provided by DCRC. See Section V.1, page 26.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- These services are provided by DCRC. See Section V.1, page 26.

(5) *x-ray services;*

-C- These services are provided by Rutherford Hospital. See Section V.1, page 26.

(6) *laboratory services;*

-C- These services are provided by Dialysis Laboratories. See Section V.1, page 26.

(7) *blood bank services;*

-C- These services are provided by Rutherford Hospital. See Section V.1, page 26.

(8) *emergency care;*

-C- These services are provided by Rutherford Hospital. See Section V.1, page 26.

(9) *acute dialysis in an acute care setting;*

-C- These services are provided by Rutherford Hospital. See Section V.1, page 26.

(10) *vascular surgery for dialysis treatment patients;*

-C- These services are provided by Shelby Surgical Associates. See Section V.1, page 26.

(11) *transplantation services;*

-C- These services are provided by Duke University Medical Center. See Section V.1, page 26.

(12) *vocational rehabilitation counseling and services; and*

-C- These services are provided by Vocational Rehabilitation. See Section V.1, page 26.

(13) *transportation.*

-C- This service is provided by Rutherford County Transit. See Section V.1, page 26.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

- (a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 [494].*

- C- In Section VII.1, page 35, the applicant provides the proposed staffing. In Section VII.2, pages 35-36, the applicant states that staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

- (b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

- C- See Section VII.5, page 36, and Exhibits 17 and 24 for documentation of ongoing training for staff at DCRC.