

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 23, 2013
PROJECT ANALYST: Celia C. Inman
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-10106-13 / Total Renal Care of North Carolina d/b/a Reidsville Dialysis Center / Relocate eight dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center for a total of 27 stations upon completion of this project / Rockingham County

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 (TRCNC) d/b/a Reidsville Dialysis Center currently operates a 19-station dialysis facility located at 1307 Freeway Drive, Reidsville, NC. The applicant proposes to relocate eight dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center increasing the total number of stations to 27 upon project completion. Both facilities are located in Rockingham County. The applicant states, "*TRCNC is planning to close the Madison Dialysis Center due to underutilization and fiscal considerations.*"

The applicant is proposing to relocate dialysis stations within Rockingham County; therefore, neither the county need nor facility need methodologies in the 2013 SMFP are applicable to this review. Additionally, Policy GEN-3: BASIC PRINCIPLES is not applicable because neither need methodology is applicable to the review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable because the applicant is not proposing a capital expenditure greater than \$2 million.

However, Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS is applicable to this review. Policy ESRD-2 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 shall:

- (A) 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 Dialysis Report, and*
- (B) 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 Dialysis Report.”*

In summary, the applicant proposes to relocate eight certified dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center. Both facilities are located in Rockingham County. Consequently, there is no change in dialysis station inventory in Rockingham County, thus the application is consistent with Policy ESRD-2 of the 2013 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

TRCNC currently operates three dialysis facilities in Rockingham County: Reidsville Dialysis Center with 19 stations, Dialysis Care of Rockingham County (DC Rockingham) with 23 stations and Madison Dialysis Center with 10 stations. TRCNC has filed two applications proposing to close Madison Dialysis Center after relocating stations and transferring patients to the Reidsville and DC Rockingham facilities as shown in the table below:

TRCNC Proposed Dialysis Station Relocation

	Current # of Stations	Current # of Patients	# of Stations to be Relocated	# of Stations after Relocation	# of Patients to be Relocated	# of Patients after Relocation
Madison Dialysis Center	10	23	-10	0	-23	0
DC Rockingham	23	64	+ 2	25	+ 4	68
Reidsville Dialysis Center	19	63	+ 8	27	+19	82
Totals	52	150	0	52	0	150

Source: # of Stations - January SDR, June 30, 2012 inventory and TRCNC December 31, 2012 internal report
 # of Patients – TRCNC December 31, 2012 internal report

In application, Project I.D. # G-10107-13, the applicant proposes to relocate two dialysis stations from Madison Dialysis Center to DC Rockingham for a total of 25 dialysis stations upon project completion. In this application, the applicant proposes to relocate eight dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center for a total of 27 stations upon project completion. In Section II, page 13, the applicant states,

“We are not applying to add stations to the facility based on facility need methodology. Rather, we are applying to transfer 8 stations from the Madison Dialysis facility in Madison in Rockingham County. The ten-station Madison facility had 28 in-center patients as of June 30, 2012 based on information included on Page 8 of Table A of the January 2013 SDR. This is a utilization rate of 71%. The facility had 23 in-center patients as of December 31, 2012 based on an internal patient census report.

*We have chosen to close the Madison facility once the current lease expires. The justification for the closure is that the facility has never generated a utilization rate of 80% since the facility opened several years ago. The facility opened in 2002. The first report in an SDR indicated that the facility had 14 in-center patients as of December 31, 2002. See the attached document in **Exhibit 7**, which is a chart indicating the in-center patient census and utilization rate from December 31, 2002 through January 31, 2012.”*[Emphasis in original]

The applicant further states:

“Since the Madison Dialysis Center has had a relatively low utilization rate, this has affected the financial viability of the facility. The facility is generating a financial deficit.”

However, Exhibit 7 does not contain the chart described above. The application does not appear to have any accompanying information that provides past years’ patient census and utilization rates for Madison Dialysis Center. The analyst developed the following table to examine the historical utilization of TRCNC’s Rockingham County dialysis centers.

Total Renal Care of NC Rockingham County Dialysis Center Percent Utilization

	2013	2012	2011	2010	2009	2008	2007	2006	2005	2004
Madison Dialysis Center	71	70	65	73	63	58	50	60	58	38
DC Rockingham	68	75	74	81	66	82	86	83	81	85
Reidsville Dialysis	75	71	72	65	81	71	65	68		

Rates are from the January SDRs and represent June 30 utilization (in percents) from the prior year.

The above table shows that none of the three TRCNC centers have operated at or above 80% since 2010.

Population to be served

The following table shows the patient origin for Reidsville Dialysis Center at December 31, 2012 as identified by the applicant on pages 12-13.

Historical Dialysis Patient Origin

County	In-Center	Home
Rockingham	55	0
Caswell	8	0
Total	63	0

The applicant states that TRCNC has chosen to close the Madison facility based on its relatively low utilization and its dialysis patients' willingness to transfer to the other TRCNC Rockingham County dialysis facilities. The January 2013 SDR shows that as of June 30, 2012, the Madison Dialysis Center facility was serving 28 dialysis patients with 10 dialysis stations. The applicant states that December 31, 2012 internal data shows the Madison Dialysis Center serving 23 dialysis patients.

In Section II, page 13, the applicant states that 19 of the current 23 patients at Madison have indicated they will consider transferring their care to Reidsville Dialysis Center. After the proposed relocation of stations and transfer of patients, Reidsville Dialysis Center will begin the first year of operation with 82 in-center patients (63 Reidsville patients + 19 patients transferred from Madison).

In Section III.7, page 22, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

Reidsville Dialysis Center Projected Dialysis Patient Origin

COUNTY	PATIENTS AT TIME OF RELOCATION/TRANSFER		OPERATING YEAR 1 2014		OPERATING YEAR 2 2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Rockingham	74	0	80	0	83	0	90.9%	91.2%
Caswell	8	0	8	0	8	0	9.1%	8.8%
Total	82	0	88	0	91	0	100.0%	100.0%

The above patient origin is based on the following methodology and assumptions provided by the applicant in Section II, pages 12-15 and Section III.7, pages 22-23:

“The facility had an in-center patient census of 63 patients as of December 31, 2012 based on an internal report. This is a station utilization rate of 83%. Of the 63 in-center patients as of December 31, 2012, 55 of the patients lived in Rockingham County, 8 patients lived in Caswell County.

...

Nineteen of the current patients at Madison (23 in-center patients) have indicated that they will consider transfer of their care to Reidsville Center.

...

We utilized the 3.6 [%] five-year average annual growth rate for all of the patients. The five-year average annual growth rate for Caswell County as indicated on page one of Table B in the January 2013 SDR is 7.3%

...

Operating Year One is projected to begin January 1, 2014 and end on December 31, 2014[.]

Operating Year Two is projected to begin January 1, 2015 and end on December 31, 2015[.]”

In Section III.7, page 23, the applicant states,

“Based on the patients and stations above, Reidsville Dialysis Center is projected to have at least 88 in-center patients by the end of operating year 1 for a utilization rate of 81.4% or 3.2 patients per station and at least 91 in-center patients by the end of operating year 2 for a utilization rate of 84.3% or 3.3 patients per station.”

TRCNC begins with the 63 Reidsville Dialysis Center in-center patients as of December 31, 2012 and adds the nineteen Madison patients who have stated interest in transferring to Reidsville Dialysis Center	82
TRCNC projects the 2012 Reidsville Dialysis Center patients forward for 12 months to December 31, 2013	$(82 \times .036) + 82 = 84.95$
TRCNC projects the 2013 Reidsville Dialysis Center patients forward for 12 months to December 31, 2014.	$(84.95 \times .036) + 84.95 = 88.01$
TRCNC projects the 2014 Reidsville Dialysis Center patients forward for 12 months to December 31, 2015.	$(88.01 \times .036) + 88.01 = 91.17$

However this methodology applies the average annual growth rate (AAGR) for Rockingham County to all facility patients, including the eight Caswell County patients to project the total number of projected patients. The applicant then holds the Caswell County patient utilization constant in the projection, which effectively increases the Rockingham County patient utilization above the county AAGR. If the applicant intends to hold the Caswell County patient utilization constant, as stated, the AAGR should only be applied to the Rockingham County patients as in the following table:

TRCNC begins with the 55 Rockingham County Reidsville Dialysis Center hemo-dialysis patients and adds the 19 Madison patients who have signed letters of support for this project.	74
TRCNC projects the Rockingham County Reidsville Dialysis Center patients forward for 12 months to December 31, 2013.	$(74 \times .036) + 74 = 76.66$
Add the 8 Caswell County patients for total patients as of December 31, 2013	$76.66 + 8 = 84.66$
TRCNC projects the Rockingham County Reidsville Dialysis Center patients forward for 12 months to December 31, 2014.	$(76.66 \times .036) + 76.66 = 79.42$
Add the 8 Caswell County patients for total patients as of December 31, 2014	$79.42 + 8 = 87.42$
TRCNC projects the Rockingham County Reidsville Dialysis Center patients forward for 12 months to December 31, 2015.	$(79.42 \times .036) + 79.42 = 82.28$
Add the 8 Caswell County patients for total patients as of December 31, 2015	$82.28 + 8 = 90.28$

Based on the projections in the table above, total Rockingham County patients decrease by one patient each year and the patient origin would be as in the following table:

Analyst Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2014		OPERATING YEAR 2 2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Rockingham	79	0	82	0	90.8%	91.1%
Caswell	8	0	8	0	9.2%	8.9%
Total	87	0	90	0	100.0%	100.0%

Reidsville Dialysis Center is then projected to have 87 in-center patients by the end of operating year one for a utilization rate of 80.9% or 3.2 patients per station and 90 in-center patients by the end of operating year two for a utilization rate of 83.6% or 3.3 patients per station. As shown by the calculations, the difference in the application of the methodology has little to no impact on the utilization percentages or the patients per station.

Thus, the applicant adequately identified the population it proposes to serve.

Demonstration of Need

The applicant proposes to relocate eight certified dialysis stations from an existing Rockingham County facility that is scheduled to be closed at the end of its lease. The applicant projects that its total 27 stations will be utilized at 81.49% by the end of the first year of operation following the relocation of the eight stations [88 patients / 27 stations = 3.26; $88 / (4 \times 27) = .8149$ or 81.49%]. As calculated above, the analyst suggests the facility will be utilized at 80.9% by the end of the first year [87 patients / 27 stations = 3.24; $87 / (4 \times 27) = 80.9\%$], an insignificant difference. The application conforms with Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .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.”

On page 20, the applicant discusses reasons for the closing of the Madison Dialysis Center stating:

“...The current utilization rate of the facility, as of December 31, 2012, is 57.5%. The facility has not been financially viable for a significant period of time. The facility is not receiving enough referrals to keep the facility in operation. The physical facility is in need of a substantial renovation. Remaining in the current facility would only increase the expenses of the facility based on the renovations needed.

...

The Madison Dialysis Center is certified for ten stations and had twenty-three patients as of December 31, 2012. TRC is proposing to transfer eight stations to Reidsville Dialysis Center. Nineteen of the twenty-three patients have indicated that they would consider transferring their care to the Reidsville Dialysis Center. The distance between the Madison Dialysis Center and Reidsville Dialysis Center is 20.3 miles. Most of the current patients live in the Madison and Mayodan area. A few live in Stoneville and Reidsville.

...

Total Renal Care of North Carolina is planning to close the Madison Dialysis Center. The facility has never reached an 80% utilization rate. The facility had an increased utilization from 2009 to 2012, maintaining a utilization rate of between 65% and 75%. The current patient utilization rate is 57.5% as of December 31, 2012.

...

Rockingham County had a projected population of 171 in-center patients as of June 30, 2012. Reidsville and Eden are the two communities in Rockingham County with the largest populations. Rockingham County had a total 2011 population estimate of 93,640, according to the US Census Bureau Report. Reidsville had an estimated 2011 population of 14,473 and Eden (DC of Rockingham County) has a population estimate of 15,475. The only data available for any other community in Rockingham County is 2000 census bureau documentation. Based on a chart in that documentation, the Town of Madison had a population of 2,417, the town of Stoneville had a population of 1,002 and the Town of Wentworth had a population of 2,779.

Reidsville is located in the eastern area of Rockingham County and Eden is located in the north central area of the county. That is where the population base of the county is located. The western area of the county, where the Madison Dialysis Center is located, is sparsely populated. The patients who live in Madison, Mayodan and Stoneville can be effectively served by the Reidsville Dialysis Center. No patient will have to travel 30 miles to their treatment site.”

The analyst reviewed the population data presented by the applicant in Exhibit 7 of the application and confirmed the information as presented above. The analyst also determined driving distance and times from Madison to the facilities to which the applicant is proposing to relocate the Madison Dialysis Center dialysis stations. According to MAPQUEST®, Madison is 16.43 miles and 27 minutes from Eden and 20 miles and 31 minutes from Reidsville.

The applicant states that the relocation of the 10 dialysis stations from Madison Dialysis Center to Dialysis Care of Rockingham and Reidsville Dialysis Center is needed because of the Madison facility's low utilization, physical inadequacies of the facility along with the high cost involved in renovating the Madison facility, and Madison Dialysis Center's

historical lack of financial viability. The applicant proposes to close the facility after its stations are relocated and all patients transfer to either DC Rockingham or Reidsville Dialysis Center, as there would be no more patients to be served at the Madison Dialysis Center.

The applicant adequately demonstrates the need the population proposed to be served has for the relocation of eight dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center, assuming the closure of the Madison Dialysis Center.

Access to Services

In Section VI, page 31, the applicant states,

“The Reidsville Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

...

The Reidsville Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. The Reidsville Dialysis Center works with patients who need transportation, when necessary.”

The applicant projects that 65.1% of its patients will be covered by Medicare, Medicaid or VA and another 27.0% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

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

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

C

The applicant states that the relocation of the dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center is needed because of the Madison facility's underutilization, the physical inadequacies of the current facility and the high cost involved in a renovation of the existing building. TRCNC proposes to close the Madison facility and relocate the ten existing dialysis stations; adding two stations to DC Rockingham for a total of 25 and eight to Reidsville Dialysis Center for a total of 27 upon completion of this project and Project ID # G-10107-13.

According to MAPQUEST®, the distance from the current site of Madison Dialysis Center located at 302 Highway St. in Madison to Reidsville Dialysis Center at 1307 Freeway Drive in Reidsville is 20 miles. The applicant states that Reidsville Dialysis Center will be geographically accessible to the same population being served at the Madison facility.

The applicant provided 18 patient letters of support from the Madison Dialysis Center. The following are excerpts from the patient letters of support from the Madison Dialysis Center.

"I am a dialysis patient. I understand that Total Renal Care of North Carolina, LLC, which is the same company that operates Madison Dialysis Center, where I receive treatment now, is proposing to transfer eight dialysis stations to the Reidsville Dialysis Center and two dialysis stations to the Dialysis Care of Rockingham County facility in Eden. I am aware that the Total Renal Care of North Carolina will be closing the Madison Dialysis Center.

I support the transfer of eight stations to the Reidsville Dialysis Center and two stations to the Dialysis Care of Rockingham County facility. I plan to transfer my care to the Reidsville Dialysis Center. I understand that I will continue to be seen by my same Nephrologist."

The applicant demonstrates that the needs of the population presently served at Madison Dialysis Center will continue to be adequately met following the proposed relocation of eight dialysis stations to Reidsville Dialysis Center. See Discussion in Criterion 13, with regard to access by medically underserved groups which is incorporated hereby as if set forth fully herein.

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 III.9, pages 23-24, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – keep the Madison Dialysis Center open and hope that the patient census increases to a point where the facility is fiscally viable. The facility opened in 2002 and has not reached 80% utilization. The current utilization rate is 57.5%. TRCNC does not foresee an upward turn that would cause the facility to become financially viable, therefore this alternative is unacceptable.
- 2) Close the Madison Dialysis Center and relinquish the stations back to the State of North Carolina. The applicant says the patients being served at the Madison center will need a facility in which to dialyze. The patients know their caregivers (who will transfer with the patients) and their Nephrologist. The applicant states, *“If the stations were relinquished and the patients transferred to another TRC facility in Rockingham County, TRC would have to go through a CON process to add stations to the existing facilities.”* The applicant states that this would require additional time and expense. Therefore, this alternative is unacceptable.
- 3) Chosen alternative - Talk with patients to determine their preference for treatment when the Madison center closes. The patients have a desire to remain with their Nephrologist and with TRCNC as their provider. The applicant states,

“Based on conversations with patients, it was determined that TRC would submit two CON applications, one to transfer eight stations to Reidsville and add on to the existing building in Reidsville and to submit a CON application to transfer the other two stations at Madison to the DC of Rockingham County facility.”

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- Minimal capital will be required to add on to the existing facility to accommodate the relocation of eight stations from Madison to Reidsville Dialysis Center,
- Patient care will continue to be provided by the same caregivers and Nephrologist.
- Patients will not have to travel an unreasonable distance to dialyze.
- The cost of supporting the financially unsuccessful Madison facility will be eliminated.
- DC Rockingham has the capacity to accommodate the four patients expressing willingness to transfer to DC Rockingham in Project I.D. #G-10107-13 without relocating the two dialysis stations as proposed.

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 its 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 Reidsville Dialysis Center shall materially comply with all representations made in its certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Reidsville Dialysis Center shall relocate and operate no more than eight (8) additional dialysis stations for a total of no more than 27 certified stations which shall include any isolation stations.**
 - 3. After the certification of the additional eight dialysis stations at Reidsville Dialysis Center, Total Renal Care of North Carolina, LLC shall decertify all remaining dialysis stations at the Madison Dialysis Center and close the facility.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Reidsville Dialysis Center shall install plumbing and electrical wiring through the walls for eight additional dialysis stations for a total of 27 dialysis stations which shall include any isolation stations.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Reidsville Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 6. Total Renal Care of North Carolina, LLC d/b/a Reidsville Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII, page 38, the applicant states, “*The capital cost for this project is estimated to be \$612,260.*” The capital costs include \$400,000 construction costs to accommodate the eight station addition, \$57,170 for water treatment equipment, 40,500 for televisions and 16,400 for dialysis chairs.

In Section IX.3, page 43, the applicant projects that there will be no start-up expenses associated with the proposed project.

Based on information provided by the applicant in Section X.1, page 45, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

Based on the calculations presented in Section X.3, page 46, the facility reimbursement is as follows:

SOURCE OF PAYMENT	REIMBURSEMENT PER TREATMENT
Medicare	\$192.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.¹ In Sections X.2-X.4, pages 45-48, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$4,006,750	\$4,169,984
Total Operating Costs	\$3,327,972	\$3,449,479
Net Profit	\$678,778	\$720,505

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions on treatments.

Exhibit 21 contains a letter from DaVita's Interim CFO and Chief Accounting Officer confirming DaVita's commitment of cash reserves in the sum of \$612,260 for the proposed

¹http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Prospective_Payment_System_ICN905143.pdf

project. DaVita's Form 10-K in Exhibit 22 confirms the availability of said cash reserves on the consolidated balance sheet, page F-6.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

C

TRCNC d/b/a Reidsville Dialysis Center proposes to relocate eight in-center dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center for a total of 27 dialysis stations upon project completion. As of December 31, 2012, Reidsville Dialysis Center serves 63 patients weekly at 3.3 patients per station, which is 83% of capacity ($63/(4*19)= 83\%$). Dialysis facilities that operate four shifts per week (2 / day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility or add stations to the county inventory. The applicant discusses projections for the in-center patient population on pages 12-15 of the application. At the end of Operating Year One, with 27 dialysis stations and 87 dialysis patients after the eight-station addition, the Reidsville Dialysis Center utilization will be 3.2 in-center patients per station ($87 \text{ patients} / 27 \text{ dialysis stations} = 3.22$). The growth projections are based on Rockingham County projected five-year average annual growth rate in the number of dialysis patients.

There are currently four dialysis facilities in Rockingham County: TRCNC operates three and BMA operates one. TRCNC is consolidating into two dialysis facilities. As a result, Rockingham County will have one less dialysis facility and two less stations. DC Rockingham has adequate capacity to accommodate the transfer of the four patients without relocating the two dialysis stations as proposed in Project ID # G-10107-13. See Criterion (3) of companion application Project I.D. #G-10107-13 Findings.

The applicant adequately demonstrates the need to relocate eight dialysis stations to the existing facility based on the number of in-center patients it proposes to serve and Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the applicant is conforming to this criterion.

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

C

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

Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	3	1	4
PCT	8	3	11
Bio-Med Tech	0.6	0.2	0.8
MD			
Admin	1	0	1
Dietician	0.6	0.2	0.8
Social Worker	0.6	0.2	0.8
Unit Secretary	1	0	1
Other-Reuse	1	0	1
Total	15.8	4.6	20.4

As shown in the above table, the applicant proposes to employ a total of 20.4 full-time equivalent (FTE) positions to staff Reidsville Dialysis Center upon completion of the proposed project. In Section VII.1, pages 35-36, the applicant states:

“The Regional Operations Director is responsible for the overall operation of the facility and serves as liaison to the governing body. She is also responsible for ensuring compliance with 42 C.F.R. and budgetary compliance.

...

The UA [unit administrator] is responsible for the quality dialysis care for all patients in the facility on a daily basis through planning and teammate scheduling. ... The UA also supervises orientation and training of new teammates and ensures that teammates adhere to facility policies and procedures.”

The following table shows the projected number of direct care staff for each shift offered in the facility after the addition of the eight stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	7	7	7	7	7	7
Afternoon	11am to 4pm	7	7	7	7	7	7
Evening	4pm to 9am	0	0	0	0	0	0

In Section V.4, page 29, the applicant states that Dr. Belayenh Befekadu will serve as Medical Director of the facility. Exhibit 15 contains a letter signed by Dr. Befekadu, as Medical Director for Reidsville Dialysis Center, expressing support for the relocation of the eight stations. In Section VII.2, page 36, the applicant states Dr. Befekadu is Board-Certified in Nephrology.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of 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 27, the applicant provides a list of providers of the necessary ancillary and support services. 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

NA

- (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 31, the applicant reports that 88.9% of the patients who received treatments at Reidsville Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

REIDSVILLE DIALYSIS CENTER	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	33.3%
Medicaid	3.2%
Medicare/Medicaid	25.4%
Commercial Insurance	7.9%
VA	3.2%
Medicare/Commercial	27.0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Rockingham County and statewide.

	2011 Total # of Medicaid Eligibles as % of Total Population *	2011 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Rockingham County	20%	9.3%	19.0%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Reidsville Dialysis Center. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.²

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data are available by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”³

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: “On December 31, 2010, more

² Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16

³<http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

than 376,000 ESRD patients were receiving hemodialysis therapy.” Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”⁴

The report provides 2010 ESRD spending by payor, as follows:

ESRD Spending by Payor⁵		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below:

⁴United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:
http://www.usrds.org/2012/pdf/v2_ch1_12.pdf.

⁵United States Renal Data System 2012 USRDS Report, Chapter 11, page 340:
http://www.usrds.org/2012/pdf/v2_ch11_12.pdf.

Number and Percent of Dialysis Patients by Age, Race, and Gender		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.⁶

The applicant demonstrates that it 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

In Section VI.6 (a), page 34, the applicant states, *“There have been no civil rights access complaints filed within 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

⁶ Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

C

In Section VI.1(c), page 32, the applicant provides the projected payor mix for the proposed services at the facility as follows:

REIDSVILLE DIALYSIS CENTER PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	33.3%
Medicaid	3.2%
Medicare/Medicaid	25.4%
Commercial Insurance	7.9%
VA	3.2%
Medicare/Commercial	27.0%
Total	100.0%

The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. 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, page 33, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Reidsville Dialysis Center. These referrals most commonly come from primary care physicians in Rockingham County. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Reidsville Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Reidsville Dialysis Center transfer and transient policies which compromise **Exhibit 17**. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.”* [Emphasis in original.]

The applicant adequately demonstrates that it will provide a wide range of means by which a person can access the 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

Exhibit 14 contains a letter from DaVita Director of Healthcare Planning to the President of Rockingham Community College offering Reidsville Dialysis Center as a clinical learning site for nursing students. The information provided in Section V.3 is reasonable and credible and 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

See Sections II, III, V, VI and VII. In particular, see Section V.7, page 30, in which the applicant discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. On page 30, the applicant states,

“The proposed expansion of the facility is an effort to provide dialysis services to Rockingham County and surrounding communities and is not intended to be a competitive venture.

...

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.”

The information provided by the applicant in the sections above is reasonable and credible and adequately demonstrates that relocating existing dialysis stations from an underutilized facility in Rockingham County will have a positive impact on cost-effectives, quality and access to the proposed service because:

- The applicant adequately demonstrates need based on “Policy ESRD-2”, to relocate eight dialysis stations from Madison Dialysis Center to Reidsville Dialysis Center;
- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide access to patients in Rockingham County;
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, pages 27-30 and 35-37 respectively, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care; and
- The applicant has and will continue to provide adequate access to medically underserved populations (more than 80% are Medicare or Medicaid patients).

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Reidsville Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.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 refers to the utilization rates as reported in the January 2013 SDR (provided in Exhibit 7 of the application). This utilization rate was calculated based on 57 in-center dialysis patients and 19 certified dialysis stations as of June 30, 2012 (57 patients / 19 stations = 3.0 patients per station; 3.0 patients per station / 4.00 patients per station = 75%).

(2) *Mortality rates;*

-C- In Section IV.2, page 25, the applicant reports the 2010, 2011 and 2012 facility mortality rates as 17.7%, 10.4% and 20.0%, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 25, the applicant states, “*Reidsville Dialysis Center is not certified to provide home training services. Dialysis Care of Rockingham County provides the home training services for patients living in Rockingham County and surrounding counties.*”

(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 25, the applicant states, “*Reidsville Dialysis Center referred 18 patients for transplant evaluation in 2012. Reidsville Dialysis Center had 1 patient receive a transplant in 2012.*”

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 26, the applicant states, “*Reidsville Dialysis Center has six patients on the transplant list.*”

- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 26, the applicant states that there were 87 hospital admissions in 2012 for Reidsville Dialysis Center, 4 (4.6%) of which were dialysis related and 83 (95.4%) non-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 26, the applicant states that there was one patient with hepatitis B during 2012. There were no patients treated with infectious disease who converted to infectious status within the last year at Reidsville Dialysis Center.
- (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- Reidsville Dialysis Center is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a 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- Reidsville Dialysis Center is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Reidsville Dialysis Center 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- See Exhibit 8, in which the applicant provides copies 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- Reidsville Dialysis Center 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- In Section XI.6(g), page 54, the applicant states, “*Reidsville Dialysis Center has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health and safety requirements.*”

See Exhibit 1 for Reidsville Dialysis Center Medicare Certification. See Exhibit 26 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 27 for the In-service Calendar with mandatory training classes.

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The applicant provides the following projected patient origin on page 22 of the application:

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2014		OPERATING YEAR 2 2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Rockingham	80	0	83	0	90.9%	91.2%
Caswell	8	0	8	0	9.1%	8.8%
Total	88	0	91	0	100.0%	100.0%

See Section III.7, pages 22-23 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- Reidsville Dialysis Center 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.(b)(9), page 12, the applicant states,

“Total Renal Care of North Carolina d/b/a Reidsville Dialysis Center 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.”

.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- Reidsville Dialysis Center 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.*

-C- Reidsville Dialysis Center projects utilization of 3.3 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12-13 and Section III.7, pages 21-23. This utilization was calculated based on 88 in-center dialysis patients and 27 certified dialysis stations as of the end of 2014, the first operating year after relocating the stations (88 patients / 27 stations = 3.26 patients per station).

The applicant has demonstrated a need for 27 stations to serve the population that they identified (88 patients / 3.2 patients per station = 27 stations). As discussed in Criterion (3), the proper application of the applicant's methodology and assumptions results in 87 in-center patients by the end of operating year one for a utilization rate of 80.9% or 3.2 patients per station. The difference in the application of the methodology makes little difference in the utilization percentages and has no impact on meeting the performance standard.

See Criterion (3) for the need analysis discussion which is incorporated hereby as if set forth fully herein. The application is conforming to this rule.

.2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- The table in Section V.1, page 27, shows patients will be referred to Annie Penn Hospital for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 27, shows the facility will provide in-center dialysis.

(3) *accessible self-care training;*

-C- The table in Section V.1, page 27, shows self-care training will be provided by Dialysis Care of Rockingham County.

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

-C- In response to this rule, the applicant states, "*Addressed in Section V, Question 1 of the application.*" However, the applicant instead addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), stating,

"Dialysis Care of Rockingham County provides protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient's blood chemistries are sent to a Medicare certified laboratory where they are

analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”

(5) *x-ray services;*

-C- The table in Section V.1, page 27, shows patients will be referred to Annie Penn Hospital for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 27, shows patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) *blood bank services;*

-C- The table in Section V.1, page 27, shows patients will be referred to Annie Penn Hospital for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 27, shows patients will be referred to Annie Penn Hospital for emergency care.

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

-C- The table in Section V.1, page 27, shows patients will be referred to Annie Penn Hospital for acute dialysis in an acute care setting. See Exhibit 12 for a copy of the hospital transfer agreement.

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

-C- The table in Section V.1, page 27, shows patients will be referred to Annie Penn Hospital for vascular surgery for dialysis patients.

(11) *transplantation services;*

-C- The table in Section V.1, page 27, shows patients will be referred to Duke University Medical Center for transplantation services. See Exhibit 13.

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

-C- The table in Section V.1, page 27, shows patients will be referred to North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 27, shows patients will be referred to Rockingham County on Aging/DSS for transportation.

.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.*

-C- In Section VII.1, page 35, the applicant provides the current and proposed staffing. The applicant states, *“The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.”* Reidsville Dialysis Center plans for two dialysis shifts; additional direct care staffing of 1.0 FTE per shift on Monday through Saturday as noted in response to VII.10.

(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- In Section VII.5, page 36, the applicant refers to Exhibit 20 for a copy of the training program outlines. Exhibit 20 contains a copy of DaVita’s Training Programs for New Patient Care Provider. Exhibits 26 and 27 contain Reidsville Dialysis Center’s Safety Training Outline and In-Service Training Schedule, respectively.