

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: January 29, 2013

PROJECT ANALYST: F. Gene DePorter
CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-10050-12/ Carolina Dialysis LLC d/b/a Carolina Dialysis Sanford/ Add seven dialysis stations to its Carolina Dialysis-Sanford facility upon completion of CON Project ID # J-8767-11 [relocation of 13 dialysis stations from Carolina Dialysis-Sanford facility to develop Carolina Dialysis-Lee County] / Lee County.
FID # 955801

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

The applicant, Carolina Dialysis Limited Liability Company-Sanford [**CD-LLC-S**] d/b/a **Carolina Dialysis-Sanford** [**CD-S**] proposes to add seven new dialysis stations to the Carolina Dialysis-Sanford facility upon completion of CON Project # J-8767-11 [relocation of 13 dialysis stations from Carolina Dialysis-Sanford located at 1922 KM Wicker Drive, Sanford to Carolina Dialysis-Lee County, located at Shoppes at Sanford, 3236 NC Hwy 87 South, Sanford]. The number of dialysis stations remaining at the originating facility [1922 KM Wicker Drive, Sanford] will be 33 upon completion of Project # J-8767-11 and this project. No contiguous counties are involved. Both facilities are owned by the University of North Carolina Hospitals, Chapel Hill, NC (67%) and (33%) Renal Research Institute (RRI). Exhibit 4 contains a copy of the RRI management contract. The determination of need is based on application of the facility need methodology as shown in the *2012 State Medical Facilities Plan [2012 SMFP]*. The 2012 SMFP, Policy ESRD-2: Relocation of Dialysis Stations does not apply.

The 2012 State Medical Facilities Plan [2012 SMFP] provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations [Reference 2012 SMFP-Chapter 14, pages 364-366]. According to the July 2012 SDR, the county need methodology shows there is no need for dialysis stations or an additional facility in Lee County. However, the applicant is also eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported

for Carolina Dialysis-Sanford in the July 2012 SDR is 3.69 patients per station and the utilization percentage is 92.31%.

The patients per station and percent utilization exceed the minimum standards of 3.2 and 80% utilization. The utilization rate was calculated based on 144 in-center dialysis patients and 39 certified dialysis stations as of July 30, 2012 [144 patients/39 stations = 3.69 patients per station]. The July 2012 Semiannual Dialysis Report [SDR] indicates a total of 39 certified dialysis stations at Carolina Dialysis-Sanford as of December 31, 2011. Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Carolina Dialysis Sanford
 ESRD Facility Need Methodology
 Semiannual Dialysis Facility Need

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2011		92.31%
Certified Stations		39
Pending Stations		0
Total Existing and Pending Stations		39
In-Center Patients as of 12/31/2011 (SDR2)		144
In-Center Patients as of 6/30/2011 (SDR1)		142
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/2011	.0282
(ii)	Divide the result of step (i) by 12	0.0023
(iii)	Multiply the result of step (ii) by the number of months (12) from 12/31/2010 to 12/31/2011	0.0282
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	148.0563
(v)	Divide the result of step (iv) by 3.2 patients per station	46.2676
	and subtract the number of certified and pending stations as recorded in SDR2 [39] to determine the number of stations needed	7

Step (c) of the facility need methodology, page 366 of the 2012 SMFP, states; “*The facility may apply to expand to meet the need established... up to a maximum of 10 stations.*” As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is seven. The applicant proposes to add seven stations. The

application is consistent with the facility need determination based upon not exceeding 10 dialysis stations.

Policy GEN-3 in the 2012 SMFP is applicable to this review. Policy Gen-3 states:

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

Promote Safety and Quality

On page 24, the applicant’s mission statement reads as follows:

“Through UltraCare, improving the quality of life of every patient, every treatment”

“Carolina Dialysis, LLC is a high quality health care provider. Carolina Dialysis is a member of the Renal Research Institute. Fresenius Medical Care, co-parent to PRI, encourages all Fresenius affiliated facilities to attain the FMC UltraCare certification. This is not a one time test, but rather an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

There are six underlying elements of UltraCare:

- Clinical Leadership
- Continuous Quality Improvement
- Superior Customer Service Team Approach to Care
- Innovative Technology
- Patient-Centered Care

The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Lee County.

Promote Equitable Access

On page 25, the applicant provides information about accessibility (economically and for time and distance) to its services. The applicant states:

“Carolina Dialysis has removed economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare/Medicaid; Carolina Dialysis is projecting that 86.7% of In-Center dialysis treatments will be covered by Medicare/Medicaid; an additional 6.0% are expected to be covered by VA. Thus 92.7% of the In-Center revenue is derived from government payors. These projections reflect the current payor mix at Carolina Dialysis-Sanford.

Carolina Dialysis continually strives to develop dialysis stations in close proximity to the patient residence. At this time Lee County has only one operational dialysis facility. As the dialysis patient population the need for dialysis stations will increase. Over the years, Carolina Dialysis has sought to develop new dialysis stations in an effort to make dialysis convenient to the patient. This application to add seven dialysis stations to Carolina Dialysis-Sanford is another example of Carolina Dialysis efforts to meet the needs of the ESRD patient population in counties served by Carolina Dialysis.”

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

Carolina Dialysis is projecting a capital expenditure of \$115,000 for this project. The applicant indicates that it is not seeking State, Federal, or charitable contributions to complete this transfer of stations. The applicant is taking on the financial burden to complete the addition of stations to ensure that an adequate number of stations are available and conveniently located for those choosing to dialyze at either Carolina Dialysis-Sanford or Carolina Dialysis-Lee County.

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The applicant is consistent with the facility need determination in the 2012 SMFP and Policy GEN-3. Therefore, the applicant is conforming to this criteria.

In summary, the applicant proposes to add 7 new dialysis stations to Carolina Dialysis-Sanford based upon the outcome of the facility need methodology described in Section III. Need and Demand. Consequently, the dialysis station inventory in Lee County will increase from 39 to 46 dialysis stations. POLICY GEN-4: Energy Efficiency and Sustainability for Health Service Facilities does not apply because the capital expenditure for this project does not trigger *the > \$2 million capital cost threshold pursuant to G.S. 131E-178*. Therefore, the application is conforming to this criterion.

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

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The July 2012 SDR indicates a total of 26 certified dialysis stations and 7 CON Decision Pending dialysis stations at Carolina Dialysis-Sanford. In this application, CD-S is seeking 7 dialysis stations based on facility need [reference Section III, 2, page 35] to partially replace 13 stations relocated to a new facility on the S.E. side of Sanford referred to as Carolina Dialysis-Lee County. Upon completion of this project and Project I.D. # J-8767-11 the Lee County total dialysis station count will increase from 39 to 46 dialysis stations. All Dialysis stations are scheduled to be operational by July 1, 2013.

Population to be Served

In Section III, the applicant provides very limited historic patient origin. The table on page 38 identifies the Lee and Harnett Counties patient origin as Lee-109 and Harnett-23 as of 6/30/2012.

**CD-Sanford Historic and Interim Patient Origin
 Operating Year 6/30/2012 and 6/30/13**

County	Historic Patient Origin 6/30/ 2012		Interim Patient Origin 6/30/ 2013	
	In Center	Home Dialysis	In Center	Home Dialysis
Lee	109	8	111	8
Harnett	23	3	26	3
Moore	4	2	4	2
Chatham	5	2	6	2
Durham	1	0	1	0
Johnston	1	0	1	0
Total	143	15	149	15

**CD-Sanford Projected Patient Origin
 Operating Years 2014 through 2015
 CSDVA-RDC #1 Projected Patient Origin for
 Operating Years CY 2014 and 2015**

County Of Residence	Operating YR 1 Patients 6/30/2014		Operating YR 2 Patients 6/30/2015		County Patients as a Percent of Total	
	In-Center	Home Patients	In-Center	Home Patients	Year 1	Year 2
Lee	72.60	8.30	74.06	8.50	64.70%	63.70%
Harnett	26.11	3	29.00	3	23.30%	24.70%
Moore	4	2	4	2	4.80%	4.60%
Chatham	5	2	5	2	5.60%	5.40%
Other	2	0	2	0	0.80%	0.80%
Total	109.70	15	114.00	15	100%	100%

In the table above, the applicant projected a Lee County patient volume of 111 in 2013 and then a significant drop in FY 2014 Lee County patient origin to 72.60 patients. The reduction is the number of patients transferring to the new Carolina Dialysis-Lee County facility. The projected growth for FY 2015 shows a total service area growth of 4.3 patients [3.9 %]. In Operating Year One [2014] the applicant projects that the facility utilization will be 3.21 patients per station. In Operating Year Two [2015] the ratio will be 3.50 patients per station.

Therefore, the applicant has adequately identified the population it will serve.

Demonstration of Need

Carolina Dialysis-Sanford proposes to add seven additional dialysis stations to its facility at 1922 KM Wicker Drive, Sanford for a total of 33 dialysis stations upon project completion. The applicant indicates that the following assumptions and methodology are used to project the future patient population of this facility is as follows;

Assumptions

1. Carolina Dialysis assumes that the Carolina Dialysis-Lee County project will be completed and certified as of June 30, 2013.
2. Carolina Dialysis assumes that its projections will remain constant. Thus Carolina Dialysis is expecting 40 Lee County patients and two Harnett County patients to transfer to the new facility upon completion of the project.
3. This project is projected to be completed commensurate with the new facility. No construction is required to add the seven stations back to the facility. Thus this project is schedule for completion at June 30, 2013.
4. Operating Year 1 for this project is July 1, 2013 through June 30, 2014. Operating Year 2 for this project is July 1, 2014 through June 30, 2015.
5. Carolina Dialysis assumes that the ESRD patient population of Lee County will continue to increase at a rate commensurate with the Lee County Five Year Average Annual Change Rate as published within the July 2012 SDR. That rate is 2.0%.
6. A large number of dialysis patients from Harnett County utilize the Carolina Dialysis-Sanford dialysis facility. Only two of these patients are projected to transfer to the new facility upon opening. Because a significant portion of the Carolina Dialysis-Sanford patient population is comprised of Harnett County residents, the applicant will project growth for this segment of the patient population. These patients care projected to increase at a rate commensurate with Harnett County Five Year Average Annual Change Rate as published within the July 2012 SDR. That rate is 11.0%.
7. Carolina Dialysis also notes that there are 11 patients from other counties dialyzing at the facility. Carolina Dialysis assumes that these patients are at the facility as a function of patient choice and that these patients will continue to dialyze at the Sanford Facility. However, due to the small number of patients from these counties, no increase is projected

for this segment of the patient population. These patients are added to the project census at appropriate points in time.

Methodology
In-Center

Carolina Dialysis begins with the Lee County and Harnett County dialysis patient population of Carolina Dialysis-Sanford as of June 30, 2012.	Lee County: 109 Harnett County: 23
This patient population is projected forward for 12 months to June 30, 2013.	$(109 \times .02) + 109 = 111.2$ $(23 \times .11) + 23 = 25.5$
Patients projected to transfer to the new Carolina-Lee County facility are subtracted.	$111.2 - 40 = 71.2$ $25.5 - 2 = 23.2$
The patients from Moore, Chatham, Durham and Johnson Counties are added. This is the beginning census for this project, June 30, 2013.	$71.2 + 23.2 + 11 = 105.7$
The patient population of Lee and Harnett Counties is projected forward for 12 months to June 30, 2014.	$(71.2 \times .02) + 71.2 = 72.6$ $(23.2 \times .11) + 23.2 + 26.1$
The patients from Moore, Chatham, Durham and Johnson Counties are added. This is the ending census for operating Year 1, June 30, 2014.	$72.6 + 26.1 + 11 = 109.7$
The patient population of Lee and Harnett Counties is projected forward for 12 months to June 30, 2015.	$(72.6 \times .02) + 72.6 + 74.1$ $(26.1 \times .11) + 26.1 = 29.0$
The patients from Moore, Chatham, Durham and Johnson Counties are added. This is the ending census for operating Year 2, June 30, 2015.	$74.1 + 29 + 11 + 114.1$

Home Patient Population

Carolina Dialysis begins with the Lee County home dialysis patient population of Carolina Dialysis-Sanford as of June 30, 2012.	8
This patient population is projected forward for 12 months to June 30, 2013.	$(8 \times .02) + 8 = 8.2$
The patients from Moore, Chatham, and Harnett Counties are added. This is the beginning census for this project, June 30, 2013.	$8.2 + 7 = 15.2$
The patient population of Lee County is projected forward for 12 months to June 30, 2014.	$(8.2 \times .02) + 8.2 = 8.3$
The patients from Moore, Chatham, and Harnett Counties are added. This is the ending census for Operating Year 1 June 30, 2014.	$8.3 + 7 = 15.3$
The patient population of Lee County is projected forward for 12 months to June 30, 2015.	$(8.3 \times .02) + 8.3 = 8.5$
The patients from Moore, Chatham, and Harnett Counties are added. This is the ending census for operating Year 1, June 30, 2015.	$8.5 + 7 = 15.5$

In addition, CD-Sanford's projected utilization calculation in project years one [2014] and two [2015] ending census; incorrectly used 34 dialysis stations as a multiplier. The analyst has substituted the correct number of 33 stations in the calculations that follow. The use of 33 stations does not significantly alter the outcome of the calculations. The adjusted calculations still meet the minimal number of patients per station and 80% utilization. Utilization at Carolina Dialysis-Sanford is illustrated in the following formulas:

Operating Year One [2014]

109 patients dialyzing on 33 stations = 3.30 patients per station
 $109 / (4 \times 33) = 0.8257$ or 82.57% by 6/30/2014.

Operating Year Two [2015]

114 patients dialyzing on 33 stations = 3.45 patients per station
 $114 / (4 \times 33) = 0.8636$ or 86.36% by 6/30/2015.

Carolina's Dialysis-Sanford will have 26 certified stations and 7 new stations which will be operational upon completion of this project, for a total of 33 operational stations by July 1, 2013. The applicant shows in Exhibit 28, a floor plan with a total of 33 stations with inclusion of 1 isolation station. The applicant indicates that Home Dialysis training will be provided at Carolina Dialysis Home Training Dialysis Clinics at Sanford RDC. The applicant estimates the number of home patients to be 15 in years 2014 and 2015.

In summary, the application adequately identified the population to be served and demonstrated need for seven additional stations after the relocation of 13 stations to develop a new dialysis facility, Carolina Dialysis-Lee County. 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.

NA

- (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, page 40 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services, stating:

“Carolina Dialysis, LLC has chosen the most effective and least costly alternative to

meet the needs of the patients choosing to receive treatment at the Carolina Dialysis-Sanford facility. Carolina Dialysis could “not apply” for this expansion. This option eventually removes choice from the patient options. Patients choose a dialysis facility for a variety of reasons, such as access to transportation, shift schedules which are compatible with the patient life style, staffing, or even the physical appearance of the facility. If we are to continue to meet the needs of the ESRD population of Lee County, seven additional stations is the only viable option.”

CD-Sanford is proposing to increase its dialysis station count based upon the outcome of applying the 2012 SMFP ESRD facility need methodology which has identified a need for 7 additional dialysis stations at CD-Sanford. Approval of the addition of these stations will rectify issues of access, time and distance, and provide for further growth in the future for both CD-Sanford and CD-Lee County. This positioning on either side of Sanford will serve additional patients from the southeast and northeast portions of the County and will foster the development of dialysis centers that will meet current and near-term care needs of patient growth of the north and south dialysis patient clusters.

In summary, the applicant adequately demonstrated its proposal is the least costly and most effective for the alternative chosen to meet the need. The application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. Therefore, the application is conforming to the criterion and approved subject to the following conditions:

- 1. Carolina Dialysis LLC d/b/a Carolina Dialysis-Sanford shall materially comply with all representations made in its certificate of need application.**
 - 2. Carolina Dialysis LLC d/b/a Carolina Dialysis-Sanford shall develop and be certified for no more than 33 dialysis stations, which shall include any home hemodialysis or isolation stations.**
 - 3. Carolina Dialysis LLC d/b/a Carolina Dialysis-Sanford prior to issuance of the certificate of need, shall acknowledge in writing to the Certificate of Need Section acceptance of and agreement to comply with all conditions stated herein.**
- (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.1, page 56, the applicant projects that the total capital cost of the project will be \$115,000 for dialysis stations/machines.

In Sections IX., page 61, the applicant indicates that there are no start-up or initial operating expenses. In Section VIII, 3, page 58, the applicant states that Carolina Dialysis-Sanford will

fund this project from cash reserves. Exhibit 24 contains a funding letter, dated September 17, 2012, from the Chairman of the Board of Managers, which states:

“As chairman of the Board of Managers, I am authorized and do hereby authorize the addition of seven dialysis stations. I am authorized and do hereby authorize and commit cash reserves for the capital costs of \$115,000 for the project.”

Exhibit 10 contains the audited financial statements for Carolina Dialysis Center as of June 30, 2012. Carolina Dialysis Center had \$2,236,092 in cash and cash equivalents and \$34,337,290 in total assets. Therefore, the applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project [should such need arise].

Based on information provided by the applicant in Section X.1, page 62, the dialysis facility projected allowable charges per treatment for each payment source as follows:

**Applicant Projected Allowable
 In-Center Charges**

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Private Pay	\$1,375.00
Medicare	\$234.00
Medicaid	\$137.29
Commercial Insurance	\$1,375.00
VA	\$146.79

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Sections X.-2 and X.-4, pages 63-68, the applicant reported projected revenues and expenses as follows:

**CD-Sanford Dialysis Center
 Projected Net Revenues, Operating Expenses and Net Profit
 6/30/2013 to 6/30/2015**

	OPERATING YEAR 1 [7/1/2013 –6/30/2014]	OPERATING YEAR 2 [7/1/2014 –6/30/2015]
Net Revenue	\$5,417,765	\$5,648,474
Total Operating Expenses	\$5,202,863	\$5,401,942
Net Profit	\$214,902	\$230,825

CD-Sanford projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the *pro forma*, including the number of projected treatments, are reasonable [See Section X, pages 63-69 of the application for the applicant’s assumptions].

Assumptions:

Current Operating Year: The facility was providing care for 143 patients as of June 30, 2012. As June 30 is mid year, Carolina Dialysis assumes this is the average number of patients for the year and then multiplies by 156 annual treatments per patient, 3 treatments per week x 52

weeks is the industry standard which equals the number of available treatments for the year. This number is reduced by an allowance for missed treatments of 6.5% to produce expected treatments per year.

Operating Year 1: The Annual number of treatments formula:

$$\begin{array}{rcccccc} \text{Aver. \# 1}^{\text{st}} \text{ Year Pts.} & \times & \text{Annual \# of Treatments} & \times & \text{Missed Treatments} & = \\ 107 & \times & 156 & \times & 6.5\% & = 15,607 \end{array}$$

Operating Year 2: The Annual number of treatments formula:

$$\begin{array}{rcccccc} \text{Aver. \# 1}^{\text{st}} \text{ Year Pts.} & \times & \text{Annual \# of Treatments} & \times & \text{Missed Treatments} & = \\ 112 & \times & 156 & \times & 6.5\% & = 16,336 \end{array}$$

In summary, the applicant adequately demonstrates the financial feasibility of the proposal is based on reasonable projections regarding 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

CD-Sanford and CD-Lee County are the only dialysis facilities in Lee County. The facilities are located on the south and north sides of the city of Sanford in Lee County. Carolina Dialysis-Sanford proposes to begin back-filling by adding 7 new stations to replace the 13 stations that were relocated and bring CD-S back to 33 stations upon completion of this project. The North Carolina Semiannual Dialysis Report of July 2012 illustrate that Carolina Dialysis-Sanford was providing dialysis services to 144 patients with a 12/31/11 utilization of 92.31% and a patients per station ratio of 3.69. The establishment of CD-Lee County improves access for the two clusters of dialysis patients that live in and around the city of Sanford. The applicant adequately demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 53, the applicant provides the current and projected staffing for CD-Sanford as shown in the following table:

Title	# of Current (FTE) Positions	# of Projected (FTE) Positions	Current Annual Salary Per FTE	Projected Annual Salary Year 1	Projected Annual Salary Year 2
RN	5.00	6.00	\$ 59,280	\$61,058	\$62,890
LPN	2.50	2.50	\$40,560	\$41,777	\$43,030
Tech.	14.00	15.00	\$33,280	\$34,278	\$35,307
Clinical Manager	1.00	1.00	\$58,240	\$59,987	\$61,787
MD *	Contract	Contract	Contract	Contract	Contract
Administrator	0.25	0.25	\$79,040	\$81,411	\$83,854
Dietitian	1.50	1.50	\$59,592	\$61,380	\$63,221
Social Worker	1.50	1.50	\$57,200	\$58,916	\$60,683
Home Training Nurse	1.00	1.00	\$61,360	\$63,201	\$65,097
Medical Records	1.00	1.00	\$31,200	\$32,136	\$33,100
Chief Tech.	0.30	0.30	\$57,200	\$58,916	\$60,683
Equipment Tech.	1.00	1.00	\$40,560	\$41,777	\$43,030
In-Service	0.30	0.30	\$61,880	\$63,736	\$65,648
Clerical	1.00	1.00	\$34,320	\$35,350	\$36,410
Total	30.35	32.35	-	-	-

*Note: the Medical Director is a contract Employee.

The applicant indicates that currently there are 30.35 FTE positions and future staffing, by the end of the first full year [FY 2014] of operation, of 32.35 FTEs. The applicant indicates in Section VII.4, page 54; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in Section VII.1, page 53 and the estimated annual salaries and revenues are reasonable and credible. The Medical Director is a member of a nephrology physicians group associated with the University of North Carolina Hospitals-Division of Nephrology and Hypertension. The information regarding staffing provided in Section VII is reasonable and credible. 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 application Section V.1, page 43, Carolina Dialysis provides a listing of those who provide necessary ancillary and support services. Exhibit 16 contains copies of “*Affiliation Agreements*” with Duke University Medical Center for “*Evaluation Services and Kidney Transplant Agreements*”; UNC Medical Center, Central Carolina Hospital, and The North Carolina Memorial Hospital. In Section V.4 (b), page 45 contains a listing of physicians who have expressed support for the addition of 7 dialysis stations at CD-Sanford and who have expressed a willingness to provide medical coverage for ESRD patients. 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 (a), page 48, the applicant states that Carolina Dialysis-Sanford provides services to all residents “*without qualifications.*” Furthermore, on page 29, the applicant states:

“Carolina Dialysis has historically provided substantial care and service to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an under served person. For example, Medicare patients represented 79.7% of North Carolina dialysis patients in Fresenius Medical Care (co-parent to RRI) facilities in FY 2011. Medicaid patients represented an additional 4.8% of North Carolina patients in Carolina Dialysis facilities for FY 2011. Carolina Dialysis experiences similar levels of Medicaid patients. Low income and medically underserved persons will continue to have access to all services provided.”

In Section VI.1 (d), page 49, the applicant states the following:

“The Admission Policy included in Exhibit8 indicates that patients are required to have some type of insurance prior to admission for treatment. Clearly, it is in the best interest of the patient to have some ability to pay for services. However, in the interest of providing services where needed, the Director of Operations does have the authority to override the policy. Social worker and business office staff will assist the patient by identifying available sources of funding and completing the required information necessary to obtain assistance.

Carolina Dialysis LLC-Sanford will 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.”

In Section VI.1. (c), page 49 the applicant reports the current and projected payer mix for CD-Sanford, as shown in the following table. The applicant is not projecting any change in reimbursement.

**CD-Sanford Payor Mix
Historic and Projected**

Payor Source	Percent of Total
Private	0.0%
Commercial Insurance	6.1%
Medicare	77.8%
Medicaid	8.9%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	6.0%
Other: Self Pay/Indigent	1.2%
Total	100.0%

The applicant demonstrates that medically underserved populations currently have adequate access to services available at CD-Sanford. Based on historic facility utilization data and

information from CMS, and based on projections from the applicant, the applicant demonstrates, in the following table, that it provides adequate access to medically underserved populations.

Facility	Medicaid Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Sanford	53.2%	43.0%	77.9%	50.6%	60.1%

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 as of CY 2010 and June 2010, respectively. The data in the table were obtained on December 5, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

Percent of Medicaid Eligible and Percent Uninsured by County

County	CY 2010 Total # of Medicaid Eligible as % of Total Population	CY 2010 Total # of Medicaid Eligible Age 21 and older as % of Total Population	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Lee	19.5	7.2	21.5
Statewide	16.5	6.7	19.7

Source: www.ncdhhs.gov/dema-Medicaid-Eligible, June 2010.

The majority of the Medicaid eligible population is 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 the DVA-RDC.

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 is available by age, race or gender. However, a direct comparison to the

applicants' current payer mix would be of little value. The population data by age, race or gender does 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 Centers for Medicare and Medicaid Services (CMS) website, in 2008, about 95% of dialysis patients were covered by Medicare. About 2.5% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as a secondary payer. Also, the CMS website states:

“Although the ESRD population in 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.”

Additionally, the United States Renal Data System, in its 2011 USRDS Annual Data Report shows the following statistics for FY 2009 in Network 6, which includes North Carolina, South Carolina, and Georgia:

Percent of Dialysis Patients by Race/Ethnicity

RACIAL GROUP	% OF DIALYSIS POPULATION
White/Caucasian	30.5%
African American	67.2%
Native American	0.6%
Asian	1.1%
Hispanic	2.6%

Percent of Dialysis Patients by Age

AGE GROUP	% OF DIALYSIS POPULATION
0 – 19	0.35%
20 – 44	13.4%
45 – 64	41.6%
65 – 74	22.8%
75 +	21.8%

Further data from that report also provides national statistics:

On December 31, 2009, more than 362,000 ESRD patients were receiving hemodialysis therapy. On December 31, 2010, the number receiving hemodialysis therapy had increased to 594,374 (a 4.0% increase over 2009). The report corroborates the statistical constancy reported by the CMS.

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 application Section VI.1 (f), page 29, the applicant states:

“Carolina Dialysis, LLC facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care or community service under any federal

regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will continue to treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, Carolina Dialysis Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act. In Section VI.6 (a), page 51, the applicant states, There have been no Civil Rights equal access complaints filed within the last five years.”

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In application Section VI.1 (c), page 49, the applicant provides projected Payor mix for the services to be provided. The applicant projects no change from the current Payor mix for dialysis visits as stated in Criterion (13a) above. The applicant reports approximately 92.7% of patients [77.8% Medicare, 8.9% Medicaid, and 6.0% VA = 92.7%] that receive treatments at CD-Sanford and CD-Lee County have some or all of their services paid for by Medicare, Medicaid or other government sources. In Section VI.1 (d), the applicant demonstrates that medically underserved patients will have adequate access to proposed services.

Therefore, the application is conforming with 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 (a), page 50, the applicant states the following;

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Carolina Dialysis-Sanford will have an open policy which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access the CD-Sanford services. Therefore, the application is conforming 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 application Section V.3 (a), page 44-45, the applicant states:

“Exhibit 19 contains an agreement with Carolina Community College to have students utilize the Carolina Dialysis-Sanford facility for student rotations. Students will be provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations. All health related education and training programs are welcome to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment.

The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The applicant is conforming to this criterion.

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

C

The applicant is a sole source provider of dialysis services in Lee County. As the only dialysis service in the county the applicant states that the addition of seven dialysis stations at CD-Sanford will have no competitive effect in the traditional sense of different providers competing against one another.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access of the proposed services based on the information in the application and the following analysis:

- 1) Projected utilization of CD-Sanford Dialysis Center is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding historical and projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Pro Forms and Criterion (5) for discussion regarding financial feasibility which is incorporated hereby as if fully set forth herein. Therefore, the applicant adequately demonstrates the cost effectiveness of its proposal.

- 2) The applicant projects to provide adequate access to medically underserved groups, including self pay/charity care patients, Medicare beneficiaries and Medicaid recipients. The operation of CD-Sanford and CD-Lee County demonstrate a commitment by the applicant to keep dialysis services accessible. See Section VI of the application and Criterion (13c) for discussion regarding projected access by these groups which is incorporated hereby as if fully set forth herein.
- 3) The applicant adequately documents that it will provide quality care. See Sections II and VII of the application.

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

The applicant has been providing dialysis services at CD-Sanford since July 2002. According to files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen 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 as required by 10A NCAC 14C .2200. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANT

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

- .2202(a)(1) Utilization rates;*
-C- See Section II, 1 (1), page 12, Exhibit 7 and Section IV 1. page 41 and Section III 7, page 36-37.
- .2202(a)(2) Mortality rates;*
-C- See Section IV.2, page 41, Column 5
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*
-C- See Section IV.3, page 41.
- .2202(a)(4) The number of transplants performed or referred;*
-C- See Section IV.4, page 41.
- .2202(a)(5) The number of patients currently on the transplant waiting list;*
-C- See Section IV.5, page 41.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- See Section IV.6, page 42.
- .2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-C- See Section IV.7, page 42.

(b) An applicant that proposed develop a new facility, to 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:

- .2202(b)(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- CD-Sanford County is an existing facility.
- .2202(b)(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- CD-Sanford County is an existing facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-C- Reference Section XI, 6, (d), (e) and (f) and Exhibits 8 & 11.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- See Section XI.6 (f), page 72 and Exhibit 11 regarding back-up capabilities.
- .2202(b)(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- Existing facility adding 7 new stations.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
-C- See Section IV.1 through 7, pages 41 and 42.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
-C- See Section III.7, pages 36-37, and Criterion (3).
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
-NA- CD-Sanford is not a new facility. The proposal is to back fill 7 of 13 transferred stations.
- .2202(b)(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- See Section II.3, pages 31-34.

.2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per 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- CD-Sanford is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-NA- This is an existing facility of 26 dialysis stations inclusive of an isolation station and the addition of 7 new dialysis stations upon completion of this project for a total of 33 stations.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- Reference Section III, pages 35-40.

.2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*
-C- See Section V.1 (e), page 43.

.2204(2) *Maintenance dialysis;*
-C- See Section V.1 (c), page 43.

.2204(3) *Accessible self-care training;*
-C- See Section V. 2 (d), page 44.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
-C- See Section V.2 (d), page 44.

.2204(5) *X-ray services;*
-C- See Section V.1, (g) page 43.

.2204(6) *Laboratory services;*
-C- See Section V.1 (h) page 43.

.2204(7) *Blood bank services;*
-C- See Section V.1, (i) page 43.

.2204(8) *Emergency care;*
-C- See Section V.1, (b) page 43

.2204(9) *Acute dialysis in an acute care setting;*
-C- See Section V.1, (a) page 43.

.2204(10) *Vascular surgery for dialysis treatment patients;*
-C- See Section V.1 (p), page 43.

.2204(11) *Transplantation services;*
-C- See Section V.1, (f) page 43.

.2204(12) *Vocational rehabilitation counseling and services; and*
-C- See Section V.1, (o) page 43.

.2204(13) *Transportation*
-C- See Section V.1, (q) page 43.

.2205 STAFFING AND STAFF TRAINING

.2205(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 494 (formerly 405.2100)

-C- See Section VII.1 and VII.2, pages 53-54.

.2205(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 54 and Exhibit 12.