

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 27, 2012

PROJECT ANALYST: Lisa Pittman
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-8767-11 / Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County / Establish a new 13-station dialysis facility in Sanford by relocating thirteen stations from Carolina Dialysis-Sanford / Lee 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.

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The applicant, Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County (CD-Lee County) proposes to establish a new 13 station dialysis facility at 3236 NC Hwy 87 South, Sanford, NC by relocating 13 existing stations from its 39 station Carolina Dialysis-Sanford (CD-Sanford) facility located at 1922 KM Wicker Drive, Sanford, NC. The applicant does not propose to establish new dialysis stations. Therefore, neither the county or facility need methodologies in the *2011 State Medical Facilities Plan (SMFP)* are applicable to this review. However, SMFP 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 to contiguous counties shall:

1. demonstrate that the proposal shall not result in a deficit in the number of Dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and

2. demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”

In summary, the applicant proposes to relocate 13 existing, certified dialysis stations within the host county of Lee. Consequently, there is no change in the inventory in Lee County and the application is conforming to Policy ESRD-2 of the 2011 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.

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Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County (CD-Lee County) proposes to establish a new 13 station dialysis facility at 3236 NC Hwy 87 South, in Sanford, NC by relocating 13 existing stations from its 39 station Carolina Dialysis-Sanford (CD-Sanford) located at 1922 KM Wicker Drive, Sanford, NC. The applicant does not propose to establish new dialysis stations.

Population to be served

In Section IV.1, page 46, the applicant states that the number of in-center and home patients served at the CD-Sanford facility as of October 31, 2011 is as follows:

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Harnett	2.0	2.0	4.7%	4.6%
Total	42.6	43.2	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.3(a), page 38, the applicant states:

“The Sanford facility is currently a 39 station dialysis facility and is at physical plant capacity. The facility cannot accommodate further expansion. However, the facility is serving a patient population larger than the entire ESRD patient population of Lee County. Patients from other counties are obviously coming to the Carolina Dialysis – Sanford facility for dialysis care and treatment.

As the patient population of Carolina Dialysis – Sanford increases it is important to develop additional capacity for dialysis patients. Carolina Dialysis has elected to transfer 13 stations to develop the new facility and thereby create space for ‘back-fill’ stations at the Carolina Dialysis – Sanford facility. As the facility demonstrates need for additional stations through Facility Need Methodology, Carolina Dialysis will file appropriate CON applications.”

In Section III.3(b), page 38, the applicant further states that it will serve 3.2 patients per station at the new facility at the end of the first year of operation. The applicant proposes to develop the new facility on the eastern side of Sanford to serve patients residing in that area and in eastern Lee County. Exhibit 22 contains 47 letters of support from CD-Sanford patients.

In Section III.7, pages 41-44, the applicant provides the methodology and assumptions used to project utilization for the first two operating years. The table above, from page 42, identifies the expected county of origin for patients to be served at the proposed facility. As a map from page 42 depicts, the majority of in-center patients live in or close to Sanford.

As of December 31, 2010, there were 112 dialysis patients (9 home dialysis patients and 103 in-center patients) residing in Lee County while the CD-Sanford facility census included 144 in-center patients, per the July 2011 SDR. One hundred five of the CD-Sanford facility patients live in Lee County (73%) and 22 (15%) live in Harnett County. The remaining 17 patients live in Chatham, Durham, Johnston and Moore Counties. See page 39. The applicant assumes that at least 8 Harnett County residents currently receiving services at CD-Sanford will transfer to the proposed new FMC Anderson Creek dialysis facility in Harnett County. These patients signed letters of support for that project (CON Project ID #M-8752-11). Carolina Dialysis also assumes that 44 of the 47 patients who signed letters of support for the CD-Lee County project will transfer their care from

CD-Sanford to the proposed CD-Lee County facility. Of the 44 transferring patients, the applicant projects 40 will be Lee County residents and 2 will be Harnett County residents. The applicant also projects that the census of Lee County will continue to increase at the Lee County Five Year Average Annual Change Rate of 1.5% and that the Harnett County patient population will not grow. Therefore, the applicant begins projections with 42 transferring patients, as shown below.

Carolina Dialysis – Lee County	In-Center Patients
Patients projected to transfer to the proposed new facility 7/1/13	40 from Lee County 2 from Harnett County
Lee County patient growth to 6/30/14	$(40 \times 1.015) = 40.6000$
Include Harnett County patients for the total projected census PY1, 6/30/14	$40.6 + 2 = 42.6000$
Lee County patient growth to 6/30/15	$(40.6 \times 1.015) = 41.2090$
Include Harnett County patients for the total projected census PY2, 6/30/15	$41.2090 + 2 = 43.2090$

In Section III.7, page 44, the applicant states:

“Carolina Dialysis['] projected utilization calculation[s] are a function of the projected year end census rounded down to the whole number. Utilization at Carolina Dialysis – Lee County is expected to be:

Operating Year 1

*42 patients dialyzing on 13 stations = 3.23 patients per station
 $42 / (4 \times 13) = 0.808$, or 80.8%*

Operating Year 2

*43 patients dialyzing on 13 stations = 3.31 patients per station
 $43 / (4 \times 13) = 0.827$, or 82.7%”*

As of October 31, 2011, the applicant reports that CD-Sanford’s patient census had decreased to 139 in-center patients and 15 home dialysis patients. As the table below reflects, the decrease is in patients from Moore and Chatham Counties, not in patients from Lee or Harnett Counties. Those patients likely transferred to either the new Carthage facility in Moore County or the expanded Siler City facility in Chatham County. The number of patients from Lee County actually increased from 105 to 107.

County of Residence	12/31/10		10/31/11	
	# In-Center Patients	# Home Patients*	# In-Center Patients	# Home Patients
Chatham	8		5	3
Durham	1		1	-
Harnett	22		22	2
Johnston	1		1	-
Lee	105		107	8
Moore	7		3	2
Total	144	9	139	15

*Applicant did not provide the county of origin of the home patients as of 12/31/10.

The applicant’s projected patient utilization in the first two operating years is reasonable, based on 47 letters from CD-Sanford patients who have expressed an interest in transferring to the proposed facility and the historical growth rate for Lee County in-center hemodialysis patients. Thus, the application conforms to the required minimum of 3.2 patients per station per week as required by rule 10A NCAC 14C .2203(a).

In summary, the applicant adequately identifies the population to be served and demonstrates the need that this population has for a new facility created by relocating 13 existing dialysis stations from CD-Sanford to serve existing patients. 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.

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The applicant proposes to relocate 13 existing dialysis stations from CD-Sanford to a new facility, CD-Lee County, which will be approximately 4.5 miles away. Both facilities will be located in Lee County. In Section III.6, page 41, the applicant states that the stations are being relocated within Sanford and that the same number of stations will remain available. The patients projected to transfer to CD-Lee County have demonstrated their willingness to do so by providing 47 letters of support for the proposed project.

In Section IV.1, page 46, the applicant states that CD-Sanford currently has 139 in-center dialysis patients, 107 of whom are from Lee County. CD-Lee County is proposing that 40 patients from CD-Sanford will transfer to CD-Lee County and 8 will transfer to FMC Anderson Creek. To project future utilization at CD-Sanford, the applicant used the Lee County Five Year Average Annual Change Rate in the July 2011 SDR of 1.5%, through the proposed July 1, 2013 opening of CD-Lee County, as shown below from page 40:

Carolina Dialysis – Sanford	In-Center Patients
CD-Sanford begins with the Lee County In-Center patient population as of 12/31/10	105
Patient growth to 12/31/11	$(105 \times 1.015) = 106.5750$
Patient growth to 12/31/12	$(106.5750 \times 1.015) = 108.1736$
Patient growth to 6/30/13	$(108.1736 \times (.015/2)) + 108.1726 =$ $(108.1736 \times .0075) + 108.1726 =$.8113 + 108.1726 = 108.9839
Add the patients from other counties	$109 + 39 = 148$
Subtract the patients projected to transfer to FMC Anderson Creek	$148 - 8 = 140$
Subtract the patients projected to transfer to CD-Lee County	$140 - 42 = 98$

The applicant projects that CD-Sanford will have 98 in-center dialysis patients as of July 1, 2013 immediately after the transfer of 8 patients to FMC Anderson Creek and 42 patients to CD-Lee County. Thus, the projected utilization at CD-Sanford is projected as follows:

$$98 / (39-13) = 98 / 26 \text{ stations} = 3.7692 \text{ patients/per station}$$
$$98 \text{ patients} / (4 \times 26) = 0.9423 \text{ or } 94.23\% \text{ utilization}$$

The applicant further demonstrates that the needs of the population presently served at CD-Sanford will continue to be adequately met following the relocation of 13 certified dialysis stations to the proposed facility, CD-Lee County. 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.

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In Section II, page 15 and Section III.9, page 45, the applicant states that CD-Sanford cannot be expanded further because the facility is at its physical plant capacity therefore the development of a second facility in Lee County is the only viable option. Carolina Dialysis states it has chosen the most effective and least costly alternative. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. Consequently, the application is conforming to this criterion subject to the following conditions:

- 1. Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County shall materially comply with all representations made in its certificate of need application.**
- 2. Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County shall develop and operate no more than thirteen (13) dialysis stations at Carolina Dialysis – Lee County, which shall include any isolation stations.**
- 3. Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County shall install plumbing and electrical wiring through the walls for no more than thirteen (13) dialysis stations which shall include any isolation stations.**
- 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County shall not offer or develop home hemodialysis training services as part of this project.**
- 5. Upon completion of the project, Carolina Dialysis, LLC shall take the necessary steps to decertify thirteen (13) stations at the Carolina Dialysis-Sanford facility for a total of no more than twenty-six (26) stations at Carolina Dialysis-Sanford.**
- 6. Carolina Dialysis, LLC d/b/a Carolina Dialysis–Lee County 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.

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In Section VIII.1, page 61, the applicant projects that the total capital cost of the project will be \$1,634,298 as shown in the following table:

CD-Lee County	
Construction Contract	\$1,131,751
Dialysis Machines*	\$0
(RO) Water Treatment Equipment	\$132,752
Equipment/Furniture	\$144,577
Architect/Engineering Fees	\$101,858
Contingency	\$123,360
Total	\$1,634,298

*Note: The applicant will transfer dialysis machines from Carolina Dialysis-Sanford.

In Sections IX.1-IX.3, pages 65-67, the applicant projects \$54,760 in start-up expenses and \$1,150,696 in initial operating expenses, for a total working capital expense of \$1,205,456 [\$54,760 + \$1,150,696] for the first eight months of operation. In Section VIII.2, page 63, and Section IX, pages 66-67, the applicant states that it will fund this project from accumulated reserves and with the strong support of its parent company, FMC-NA. Exhibit 24 contains a funding letter, dated November 15, 2011, from Mr. Ronald J. Falk, Chairman of the Board of Managers of Carolina Dialysis, which states:

“This is to inform you that Carolina Dialysis, LLC, is the parent company of Carolina Dialysis-Lee County.

...This project calls for a capital expenditure of \$1,634,298.

As Chairman of the Board of Managers, I am authorized and do hereby authorize the relocation of these stations and development of the new Carolina Dialysis-Lee County facility. I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$1,634,298 for the project. Further, Carolina Dialysis, LLC does commit to all necessary start-up and initial operating costs for the project.”

Exhibit 10 contains the financial statements for Carolina Dialysis Center as of September 30, 2011. Carolina Dialysis Center had \$644,686 in cash, \$31,587,827 in total assets, and \$27,656,942 in Total Net Assets [total assets – total liabilities]. Therefore, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Based on information provided by the applicant in Section X.1, page 68, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

Payor	Charge Per Treatment
Commercial Insurance	\$1,375.00
Medicaid	\$137.29
Medicare	\$234.00
VA	\$146.79
Private Pay	\$1,375.00

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-X.4, pages 68-72, the applicant reported projected revenues and expenses as shown in the following table. On page 69, the applicant states that total number of treatments was reduced by 6.5% to cover missed appointments, however in the table on page 70, column B, the applicant reduces total treatments by only 5% instead of 6.5%. Using a reduction of 6.5% as stated by the applicant, lowers the projected revenue and thus net profit as shown below in brackets.

The applicant projects 42 in-center patients and 6,126 treatments in Year One and in Year Two. At 100% attendance, 42 patients would have 6,552 treatments in Year One and in Year Two [42 x 3 = 126; 126 x 52 = 6,552]. After deducting 6.5% of the treatments as missed treatments, the applicant projects 6,126 treatments for Year One and for Year Two [6,552 x 6.5% = 425.88; 6,552 – 426 = 6,126]. Therefore, the applicant has under-projected its revenue.

	Operating Year 1 (7/1/13 – 6/30/14)	Operating Year 2 (7/1/14 – 6/30/15)
Total Net Revenue	\$1,848,965 [\$1,817,472]	\$1,858,244 [\$1,826,751]
Total Operating Costs	\$1,726,044	\$1,747,894
Net Profit*	\$122,921 [\$91,428]	\$110,350 [\$78,857]

*Calculated by Project Analyst

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, pages 68-73 for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs, start-up 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.

The applicant proposes to establish a new 13 station dialysis facility at 3236 NC Hwy 87 South, Sanford, NC by relocating 13 existing stations from its 39 station CD-Sanford facility located at 1922 KM Wicker Drive, Sanford, NC. The applicant adequately demonstrated the need to establish a new 13-station dialysis facility by relocating 13 stations from CD-Sanford to CD-Lee County based on the number of in-center patients it currently serves and the number it proposes to serve. See Section III.7, pages 41-44, Section III.9, page 45, and Section V.7, page 52. See Criteria (1) and (3) for discussion. CD-Sanford is currently the only certified dialysis facility in Lee County and cannot expand to serve additional patients. The applicant adequately demonstrates that its proposal will not result in 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.

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In Section VII.10, page 60, the applicant indicates that the facility will operate Monday through Saturday with four direct care staff from 7:00 AM to 12:00 Noon and four direct care staff from 12:00 Noon to 5:00 PM.

The following table illustrates projected staffing during the first two operating years following completion of the project, as reported by the applicant in Section VII.1, page 58:

Position	# of Full Time Equivalent Positions (FTEs)
RN	1.50
Patient Care Tech.	4.00
Clinical Manager	1.00
Medical Director	Contracted Position
Admin.	0.15
Dietitian	0.50
Social Worker	0.50
Medical Records	0.50
Chief Tech.	0.15
Equipment Tech	0.50
In-Service	0.15
Unit Secretary	0.50
Total	9.45

As shown in the above table, the applicant proposes to employ a total of 9.45 FTE positions to staff the proposed dialysis facility during the first two operating years following completion of the project. In Section V.4, page 50, the applicant states that Dr. Roger Lamana will serve as medical director of the facility. Exhibit 21 contains a letter dated November 10, 2011 signed by Dr. Lamana, which states that he has agreed to serve as medical director for the CD-Lee County facility. Exhibit 23 contains a copy of Dr.

Lamana's Curriculum Vitae, which states that he is Board-Certified in Internal Medicine and 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.

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In Section V.1, page 48, the applicant provides a list of providers of the necessary ancillary and support services. Copies of the agreements with some providers are included in the following exhibits: Exhibit 16, a patient transfer agreement between UNC Hospitals and CD-Lee County; Exhibit 17, a transplant services agreement between UNC Hospitals and CD-Lee County; Exhibit 18, a laboratory services agreement between Spectra Laboratories, Inc. and Renal Research Institute-Carolina Dialysis, LLC; Exhibit 19, a letter to Central Carolina Community College offering CD-Lee County as a site for clinical rotation for nursing students; and Exhibit 19, an agreement between CD-Sanford and the applicant for home training in home hemodialysis and peritoneal dialysis. The applicant identifies Central Carolina Community Hospital for acute care services, Vocational Rehabilitation for vocational rehabilitation counseling and services, and the County of Lee Transit System (COLTS) for transportation 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.

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- (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

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- (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.

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- (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.

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In Section XI, pages 74-77, the applicant discusses the primary and secondary sites for the proposed dialysis facility and states it plans to upfit leased space. The primary site has not been developed yet. The applicant states that both the primary and secondary sites will provide easy access from a primary traffic artery, NC Hwy 87, through Sanford. The applicant also proposes that both sites are close to many current CD-Sanford patients and close to the local hospital. The primary site is currently zoned for a dialysis center and the landlord of the second site believes the current zoning will accept a dialysis facility, and has agreed to obtain a Zoning Approval letter prior to finalizing any letter of intent. See Exhibits 29-31. On page 79, the applicant states the facility will be 8,628 square feet with energy saving features as described on page 78. Correspondence in Exhibits 30 and 31 indicates that the applicant is interested in leasing 10,000 square feet. Therefore, the applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing health services if the project were approvable. The application is conforming to this criterion.

The applicant proposes to lease 10,000 square feet for total capital costs of \$1,634,298, including construction upfit cost of \$1,131,751. See Section VIII.1, pages 61-62 and XI.6(h), page 79. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 79:

Facility Area	Estimated Total Square Feet
Support Areas:	
Administration	1,724
Public Lobby	428
Mechanical Equipment	131
Housekeeping	39
General Storage	1,010
Exam/Treatment	100
Staff Lounge	200
RO	361
Other (Toilets, Circulation /Med. Waste)	1,871
Sub-Total Support	5,864
Treatment Areas:	
Dialysis Stations	2,582
Isolation Room(s)	134
Other (Toilets/Circulation)	48
Sub-Total Treatment	2,764
Total Square Feet	8,628

The applicant adequately demonstrates that the cost, design and means of construction are reasonable and that the construction costs will not unduly increase the costs and charges of providing the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section VI.1(b), page 54, the applicant reports that 86.7% of the patients who received treatment at CD-Sanford had some or all of their services paid for by Medicare or Medicaid. The table below illustrates the historical payment source of the facility:

Payor	Percentage
Commercial Insurance	7.9%
Medicare	79.6%
Medicaid	7.1%
VA	5.2%
Other-Self/Indigent	0.1%
Total	100.0%

As illustrated in the table above, CD-Sanford provides services for medically underserved populations. The applicant further states the following in Section VI.1(d), pages 54-55:

“The admission policy included at Exhibit 8 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, Heather Ansele, does have the authority to override the policy. The 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.”

[Emphasis in original.]

In Section VI.1(a), page 53, the applicant states:

“The Carolina Dialysis [sic] facilities have a long history of providing dialysis services to the underserved populations of North Carolina. ...Each of our facilities has a homogenous patient population, including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The expected patient population of the Carolina Dialysis – Lee County facility is a reflection of the current experience at Carolina Dialysis-Sanford and is comprised of the following:

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>Carolina Dialysis – Lee County</i>	54.5%	44.2%	81.2%	51.9%	61.7%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 81.2% of the facility treatment reimbursement is from Medicare.”

The applicant demonstrates that it provides adequate access to the 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;

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CD-Sanford is a new facility and thus has no history regarding uncompensated care, community service, or civil rights access. However, in Section VI.6(a), page 56, the applicant states: *“There have been no Civil Rights complaints lodged against any Carolina Dialysis, LLC facilities in the past five years.”*

In Section VI.1(f), page 55, 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 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 [f]acilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

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

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Exhibit 8 contains FMCNA’s business and admission policies. In Section VI.1(c), page 54, the applicant projects that 86.7% of patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table:

Payor	Percentage
Commercial Insurance	7.9%
Medicare	79.6%
Medicaid	7.1%
VA	5.2%
Other-Self/Indigent	0.1%
Total	100.0%

The applicant demonstrates that it will provide adequate access to the elderly and medically underserved populations. 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.

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In Section VI.5(a), page 56, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Carolina Dialysis-Sanford [Lee County] 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 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.

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In Section V.3(a), pages 49-50, the applicant states:

“Exhibit 19 contains a letter from Heather Ansele, Carolina Dialysis Area Manager inviting the Nursing Program of Central Carolina Community College to have nursing students utilize the Carolina Dialysis-Lee County 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 welcomed [sic] to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”

In Section V.3(b), page 50, the applicant states:

“The Carolina Dialysis-Lee County facility Center Manager or In-Service Coordinator of the facility will provide discussion of ESRD and dialysis for students, after which time the students may observe, tour the facility and talk with patients.”

In Section V.3(c), page 50, the applicant states:

“Carolina Dialysis has communicated with the local student nursing programs encouraging those programs to utilize the resources of the Carolina Dialysis-Lee County facility to enhance the educational opportunities for the nursing student.”

Exhibit 19 contains a letter to Central Carolina Community College.

The information provided in Sections V.3(a)-(c), pages 49-50, and Exhibit 19 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-

Carolina Dialysis, LLC adequately demonstrates that its proposal to establish CD-Lee County, a new 13 station dialysis facility by relocating 13 existing stations from its 39 station CD-Sanford facility would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The establishment of a 13 station dialysis facility by relocating 13 existing stations is needed and the proposal is a cost-effective alternative to meet the need of current patients [see Criteria (1), (3), (4) (5), and (12) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

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 currently provides dialysis services as CD-Sanford at 1922 KM Wicker Drive, Sanford, NC. According to 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 promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

10A NCAC 14C .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 IV.1, page 46, and Exhibit 2 (copy of the January 2011 SDR).

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 46, the applicant reports the following facility mortality rates for CD-Sanford: 2008 – 13.9%, 2009 – 11.3%, 2010 – 6.2%.

.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;

-C- In Section IV.3, page 46, the applicant states that there are seven home-trained patients and 15 home patients at CD-Sanford.

.2202(a)(4) The number of transplants performed or referred;

-C- In Section IV.4, page 46, the applicant reports 4 transplants performed and 21 patients referred in 2009; 7 transplants performed and 34 referred in 2010.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- In Section IV.5, page 46, the applicant reports 22 patients on the transplant waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

-C- In 2010 the applicant reported 289 hospital admissions. 48 admissions were dialysis related and 241 admissions were non-dialysis related. See Section IV.6, pages 46-47.

.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- During 2009 and 2010 the applicant reported no conversions and no patients with infectious disease. See Section IV.7, page 47.

(b) An applicant that proposes to develop a new facility, increase the number of 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.

-C- Exhibit 16 contains a copy of a transfer agreement between UNC Hospitals and CD-Lee County.

.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.*

-C- Exhibit 17 contains a copy of a transplant services agreement between UNC Hospitals and CD-Lee County:

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-C- Documentation of utilities is included in site specific information in Exhibits 30 and 31.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit 12 contains a copy of backup procedures in the event of a power outage.

.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.*

-C- Site specific information is included in Exhibits 30 and 31. Exhibit 31 contains information that Site 1 may not be possible after all.

In Section XI.2(j), the applicant states: “*Carolina Dialysis will diligently pursue a lease for the space subsequent to issuance of the Certificate of Need.*”

- .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, water supply, and other relevant health and safety requirements.*
- C- See Sections II, page 14; VII.2, page 59; and, XI.6(g), pages 78-79. See also Exhibits 1, 8, 9, 11, 12, and 20.
- .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 41-44, 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.*
- C- In Section III.8, page 44, the applicant states “*The Carolina Dialysis-Lee County facility does not expect any patient to travel more than 30 miles.*”
- .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 for such services.*
- C- In Section II.1, page 18, Carolina Dialysis states:
“*Carolina Dialysis-Lee County will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payments for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section III.7, page 44, the applicant states that it projects to serve 42 in-center patients by the end of the first operating year, for a utilization of 3.23 patients per station. See discussion in Criterion (3).
- .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 not been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant does not propose to increase the number of dialysis stations in an existing facility.
- .2203(c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*
- C- In Section III.7, pages 41-44, the applicant provides the assumptions and

methodology used to project utilization of the proposed facility.

10 NCAC 14C .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 48, and Exhibit 16.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1(c), page 48.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1(d), page 48, and Exhibit 20.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.2(d), page 49, and Exhibit 20.
- .2204(5) *X-ray services;*
 - C- See Section V.1(g), page 48, and Exhibit 16.
- .2204(6) *Laboratory services;*
 - C- See Section V.1(h), page 48, and Exhibit 18.
- .2204(7) *Blood bank services;*
 - C- See Section V.1(i), page 48. The applicant identifies Central Carolina Community Hospital as the provider of blood bank services.
- .2204(8) *Emergency care;*
 - C- See Section V.1(b), page 48.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1(a), page 48, and Exhibit 16.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1(p), page 48 and Exhibit 16.
- .2204(11) *Transplantation services;*
 - C- See Section V.1(f), page 48, and Exhibit 17.
- .2204(12) *Vocational rehabilitation counseling and services;*
 - C- See Section V.1(o), page 48. The applicant identifies the local Vocational Rehabilitation department as the provider.
- .2204(13) *Transportation*
 - C- See Section V.1(q), page 48. The applicant identifies the County of Lee Transit System (COLTS) as the provider of transportation services.

10 NCAC 14C .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 405.2100.*

-C- In Section VII.1, page 58, the applicant provides the proposed staffing. The applicant states on page 59 that the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.

.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 59, and Exhibits 14 and 15.